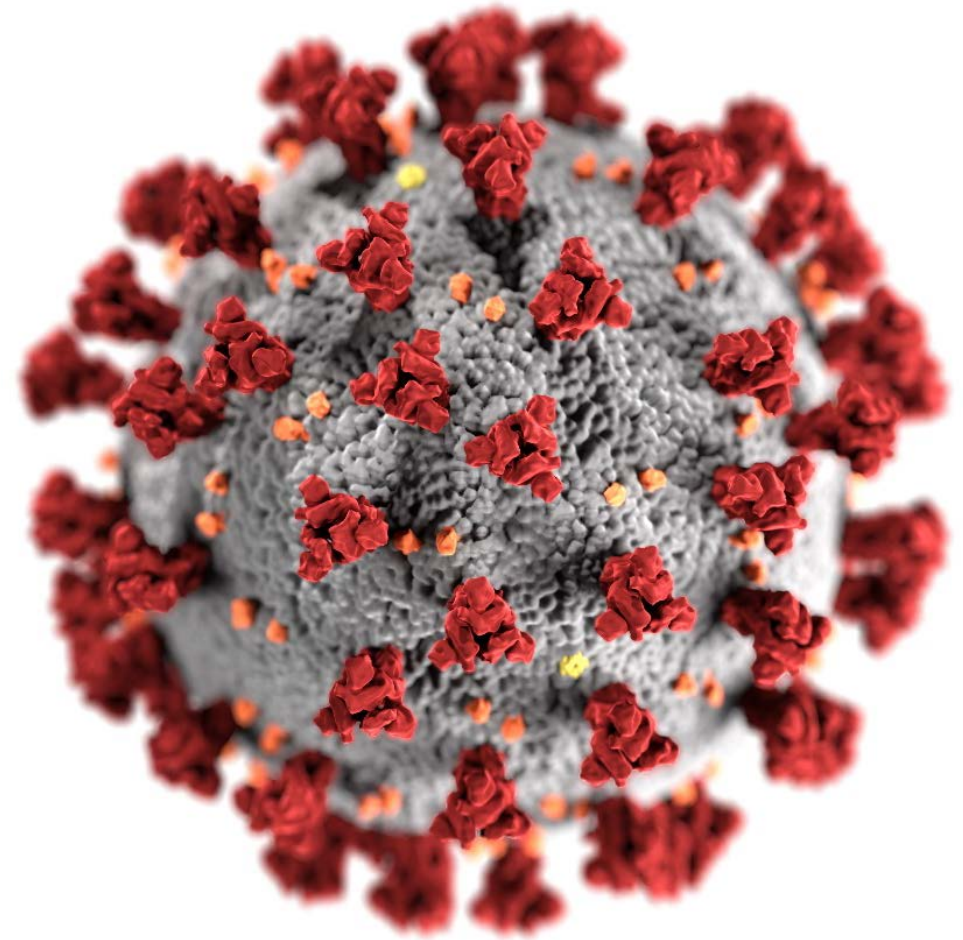


# Benefits and Risks of COVID-19 Vaccines: Work Group Interpretation

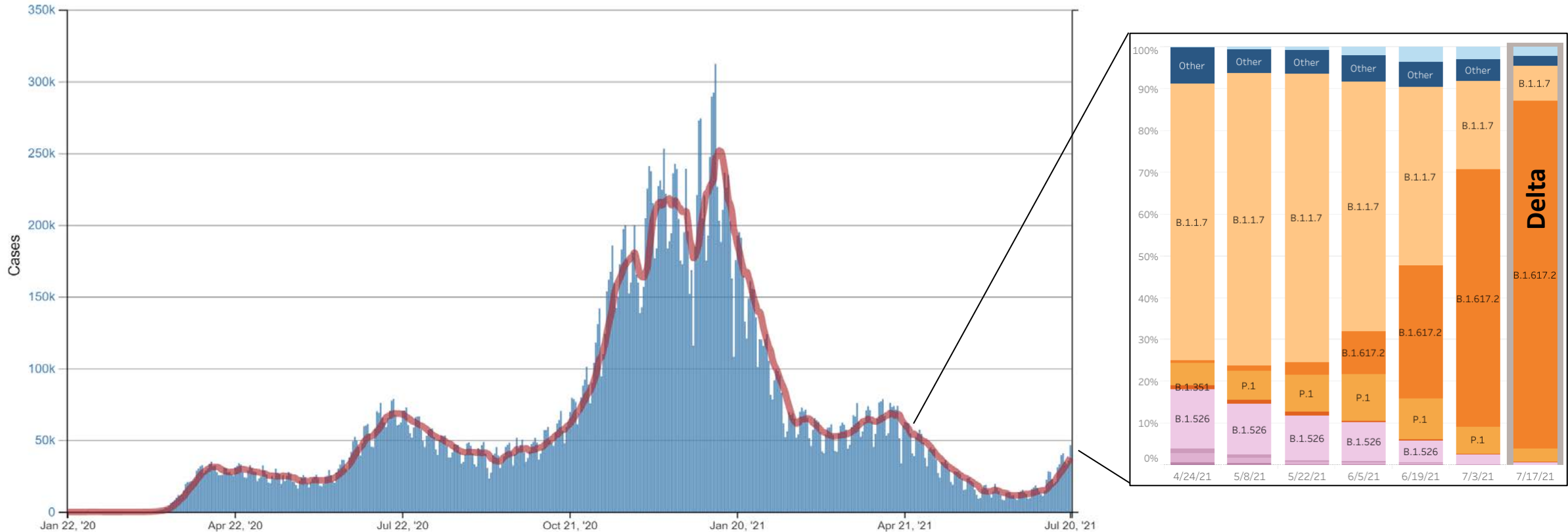
Sarah Mbaeyi, MD MPH  
Centers for Disease Control and Prevention  
July 22, 2021



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

# After a period of decline, COVID-19 cases rising again

## Majority of cases due to Delta variant



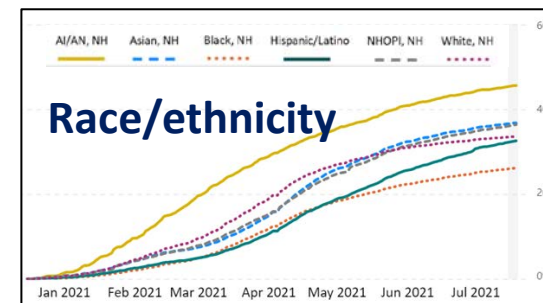
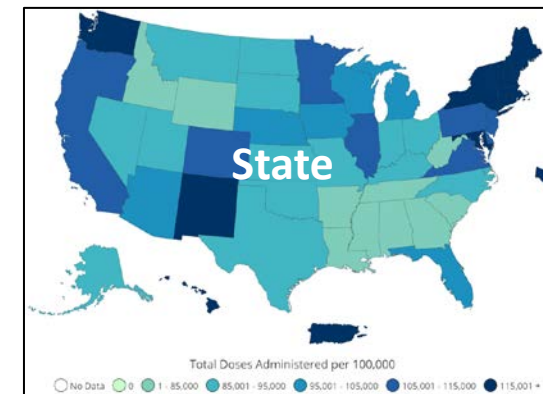
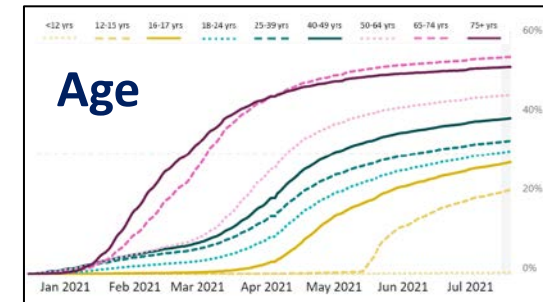
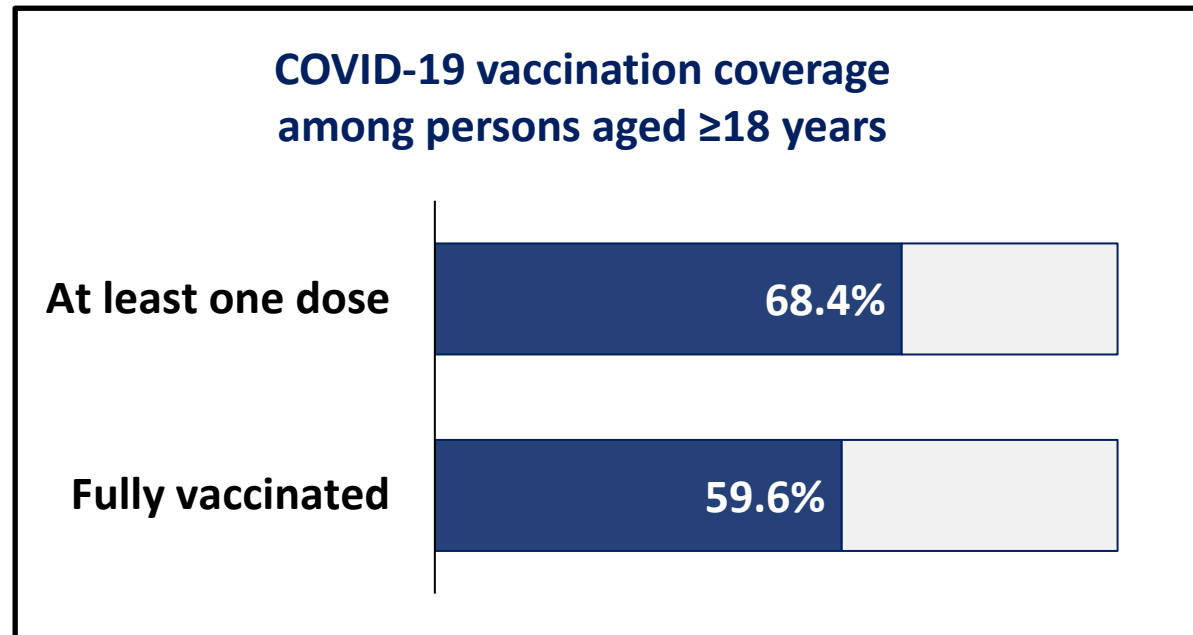
As of July 21, 2021

[https://covid.cdc.gov/covid-data-tracker/#trends\\_dailytrendscases](https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases)

<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

# Over two-thirds of U.S. adults have received at least one COVID-19 vaccine dose

Coverage varies by



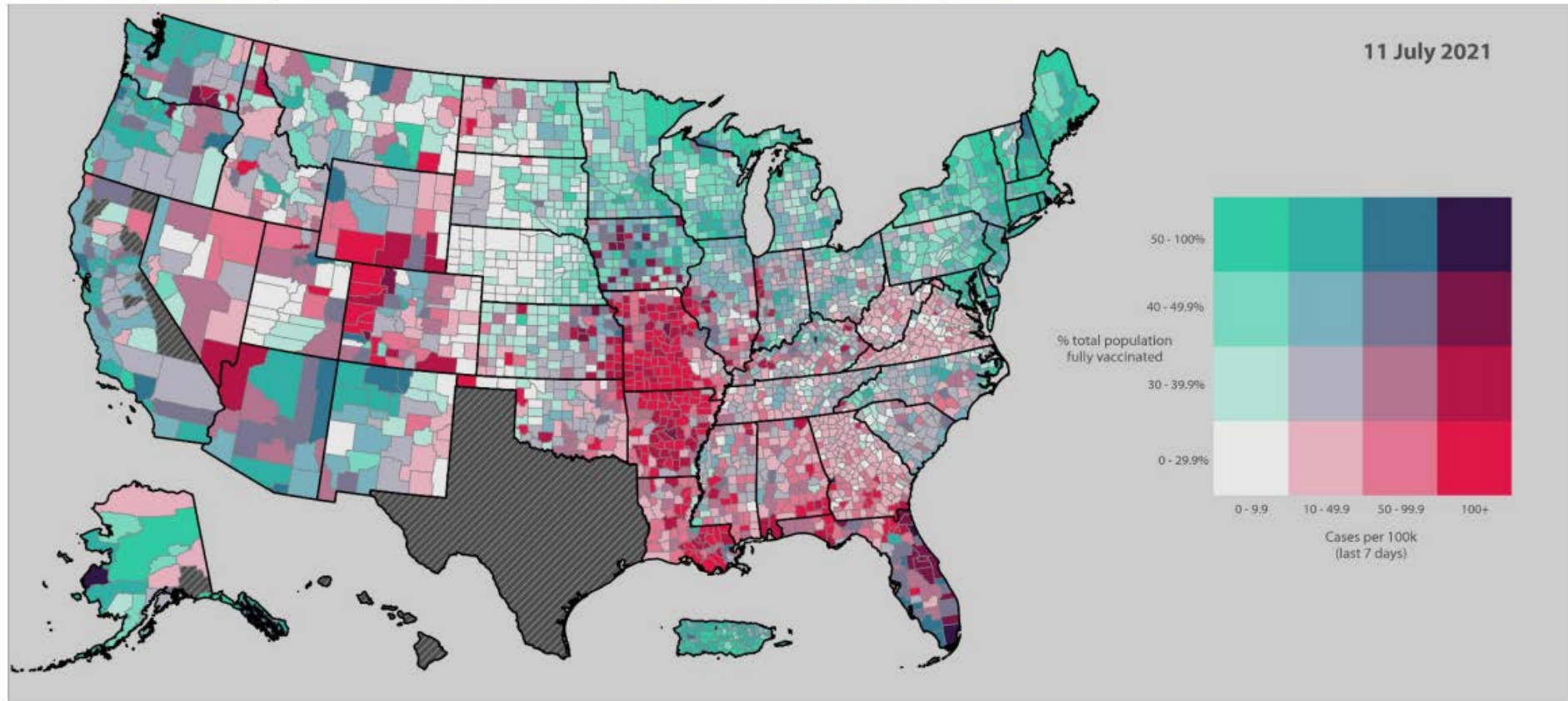
As of July 21, 2021

<https://covid.cdc.gov/covid-data-tracker/#vaccinations>

# Low COVID-19 vaccination coverage puts individuals and communities at risk

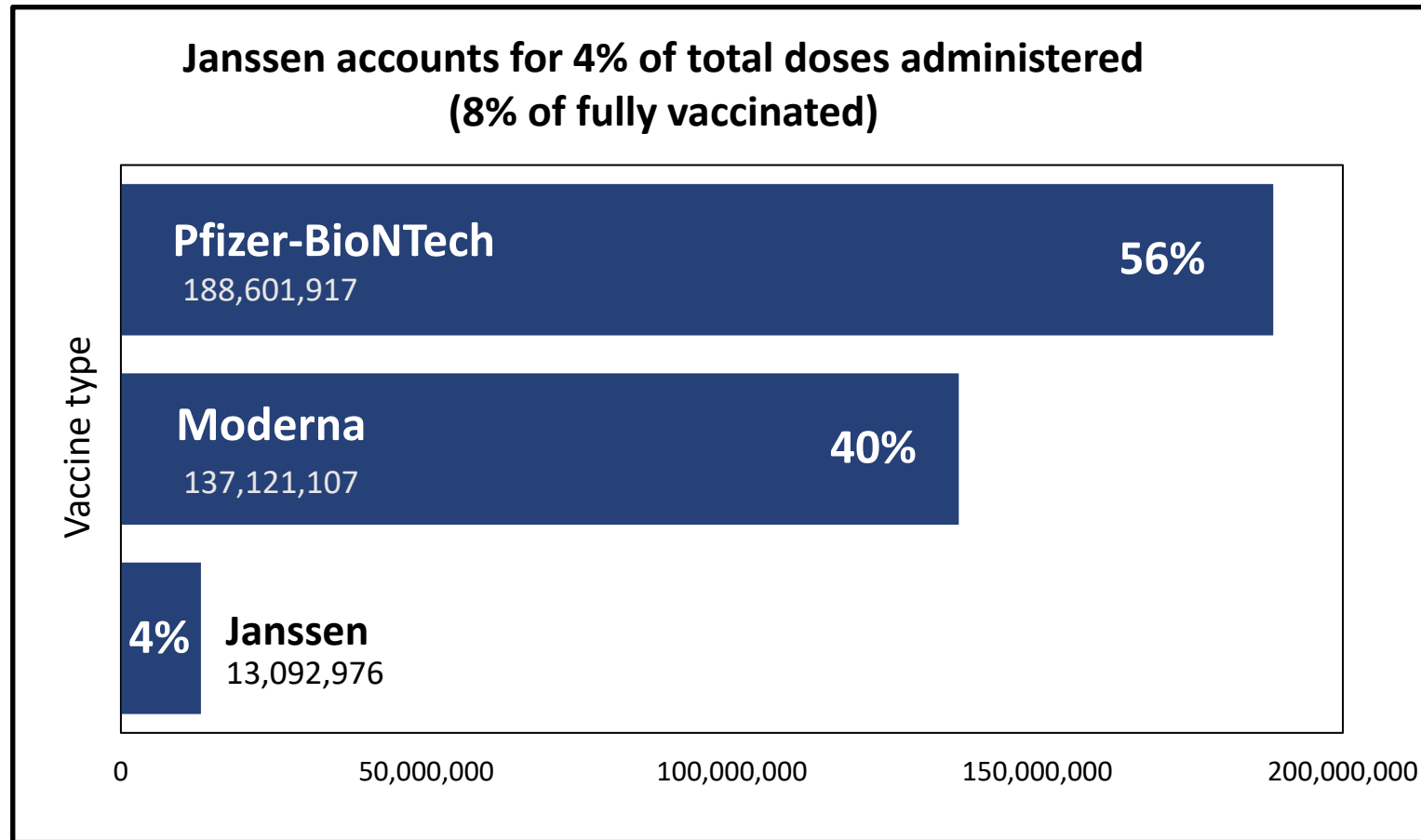
## COVID-19 Reported Cases per 100,000 Population (last 7 days) and % of Total Population Fully Vaccinated

Source: Data reported to CDC by State/Territorial Jurisdictions/Select Federal Entities (Data for 11 July 2021 as of 13 July 2021)



Note: Counties with no data/missing data are indicated in gray diagonal stripes (n=274 counties).

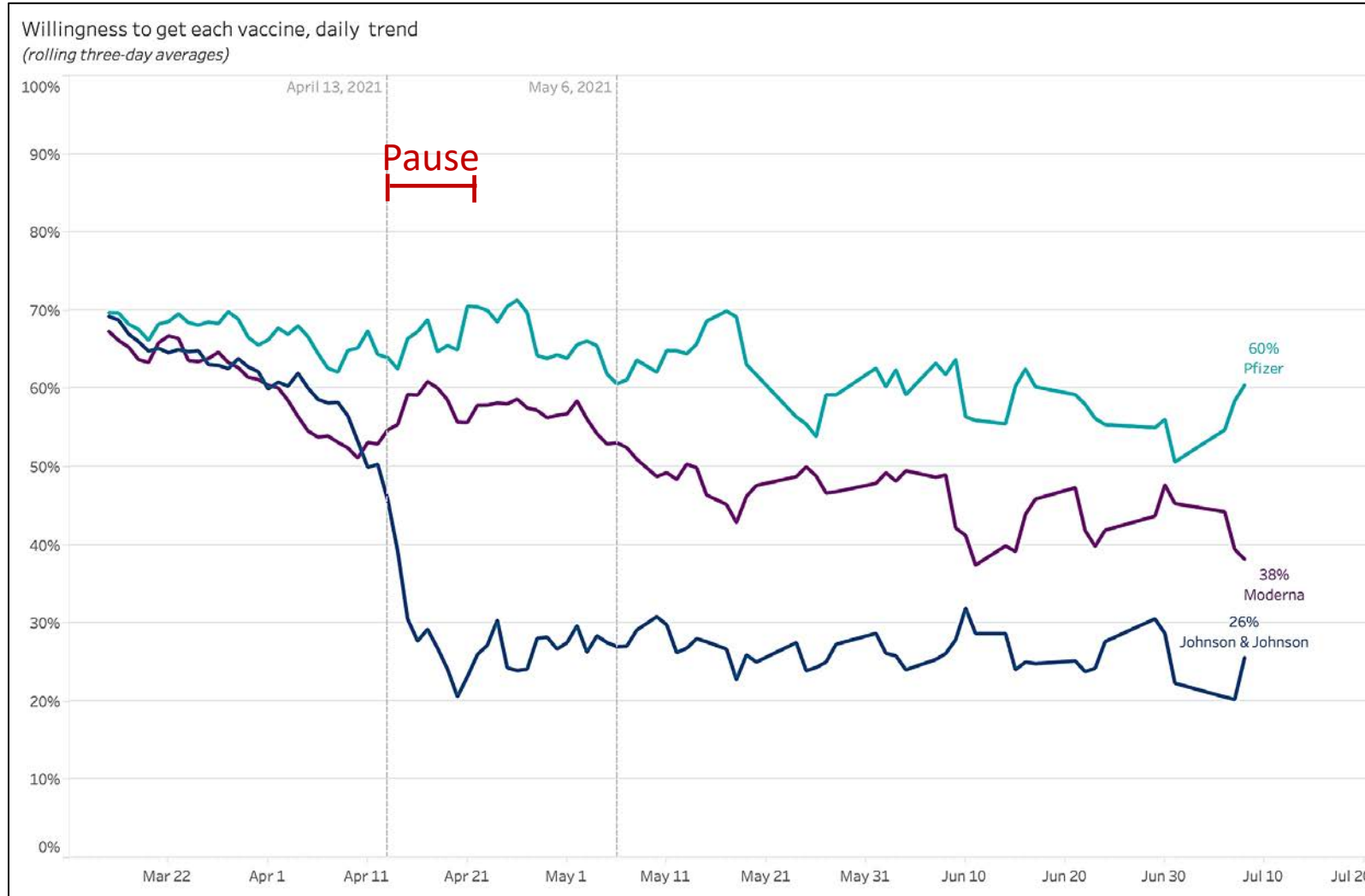
# mRNA vaccines account for majority of doses administered in the United States



As of July 21, 2021.

<https://covid.cdc.gov/covid-data-tracker/#vaccinations>

# Willingness to receive Janssen vaccine remains lower since the April pause

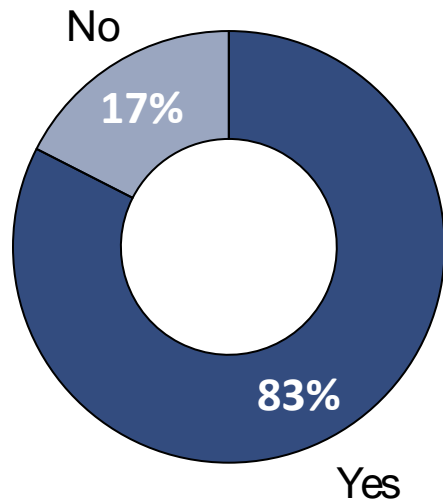


Results shown are among those who haven't received a vaccine but plan to get one

# Janssen vaccine: Patient choice, access, and vaccine equity

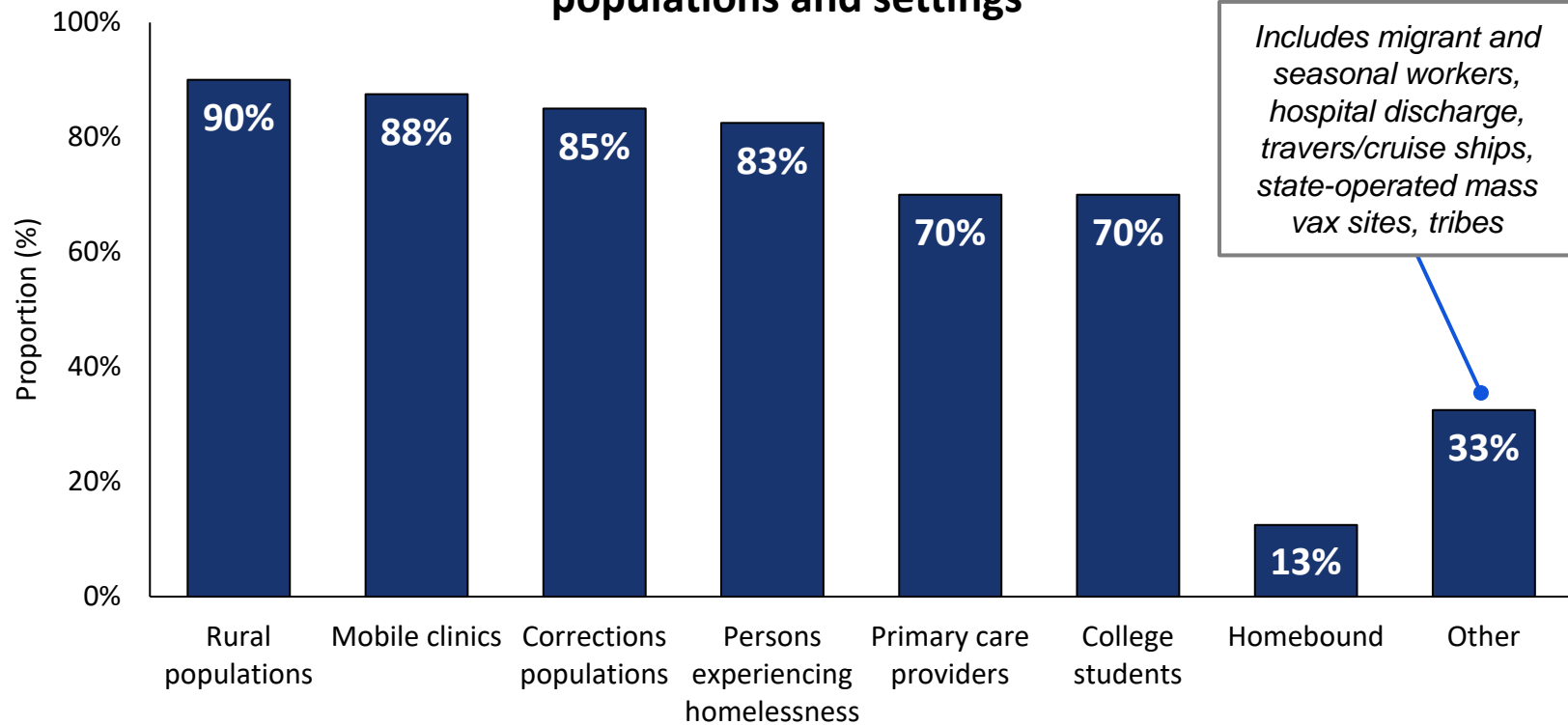
## Findings from survey of jurisdictions – July 16, 2021

**Most vaccination sites offer more than one type of vaccine**



Responding to question: Do most of the vaccinations sites in your jurisdiction offer more than one type (Pfizer, Moderna, Janssen) of COVID vaccine?

**Most jurisdictions report Janssen vaccine used in a variety of populations and settings**



Responding to question: Which populations or settings in your jurisdiction are utilizing the Janssen vaccine?

# Benefits of COVID-19 vaccines are unequivocal

- All COVID-19 vaccines currently authorized in the United States are effective against COVID-19, including serious outcomes like severe disease, hospitalization, and death
- Available evidence suggests that currently authorized vaccines offer protection against known circulating variants, including the Delta variant
- A growing body of evidence indicates that people fully vaccinated with an mRNA vaccine are less likely to have asymptomatic infection or to transmit SARS-CoV-2 to others

<https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

Nasreen S, et al. "Effectiveness of COVID-19 vaccines against variants of concern, Canada." *medRxiv* (2021).

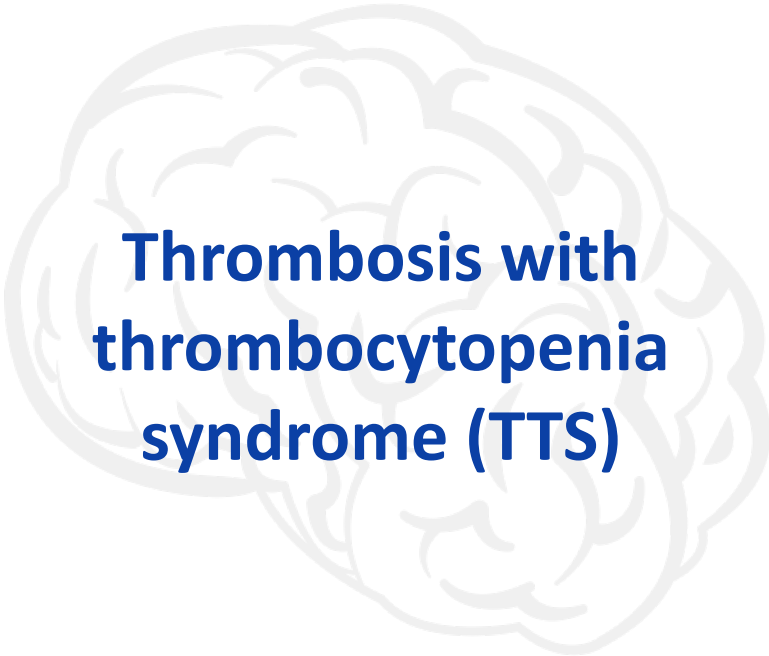
Stowe J, et al. "Effectiveness of COVID-19 vaccines against hospital admission with the Delta (B.1.617.2) variant." Public Health England. 2021.

Sheikh A, et al. "SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness." *The Lancet* (2021).



# Rare serious adverse events have been reported after COVID-19 vaccination

## Janssen



**Thrombosis with  
thrombocytopenia  
syndrome (TTS)**



**Guillain-Barré  
syndrome (GBS)**

## mRNA



**Myocarditis**

# Benefits of COVID-19 vaccination continue to outweigh risks

For every million doses of vaccine given with U.S. exposure risk and hospitalization rates from June 19, 2021

Age	Janssen COVID-19 vaccine				mRNA COVID-19 vaccine				
	Prevented COVID-19 hospitalizations/ ICU admissions/deaths	GBS Cases	TTS Cases		Prevented COVID-19 hospitalizations/ ICU admissions/deaths	Myocarditis Cases			
<b>FEMALES</b>									
18-29 years	700	50	5	1	4-5	750	50	5	3-4
30-49 years	900	140	20	6-7	8-10	950	140	20	1-2
50-64 years	1600	350	120	7-8	3-4	1,700	375	125	1
65+ years	5,900	1250	840	8-10	0	6,200	1300	900	<1
<b>MALES</b>									
18-29 years	300	60	3	2	2-3	300	60	3	22-27
30-49 years	650	150	25	7-8	1-2	700	160	25	5-6
50-64 years	1,800	480	140	14-17	1-2	1,900	500	150	1
65+ years	11,800	3300	2300	7-8	0	12,500	3500	2400	<1

# Work Group interpretation

## Benefits and risks of COVID-19 vaccination

- Vaccination continues to be critical during this period of rapidly increasing cases and spread of variants of concern
- The reported adverse events (TTS, GBS, and myocarditis) are potentially serious and should be transparently communicated with the public
- Even with new GBS safety signal, benefits of Janssen vaccination continue to outweigh risks

# Work Group interpretation

## Additional considerations for use of Janssen COVID-19 Vaccine

- In addition to benefit-risk profile, the Work Group discussed:
  - Importance of patient choice in vaccine product
  - Access to vaccines for disproportionately affected populations
  - Confidence in patients and providers to understand benefits and risks of vaccines and make informed decisions
  - Need for communication and educational materials
  - Implications of any change in vaccine recommendations on global vaccine confidence and use

# Work Group interpretation

## Use of Janssen COVID-19 Vaccine after reports of GBS in vaccine recipients

- Work Group reaffirms that all eligible persons should receive a COVID-19 vaccine
- Patients and providers should be aware of both the benefits and risks of COVID-19 vaccination when choosing a vaccine product
- **Work Group members expressed strong support for continued use of Janssen vaccine according to the current recommendations**

# Updates to CDC Clinical Considerations

- Persons with a prior history of GBS:
  - Can receive any of the authorized vaccines
  - Given possible association between Janssen vaccine and GBS, **patients with a history of GBS and their clinical team should discuss the availability of mRNA vaccines to offer protection against COVID-19**
- Information on signs and symptoms of GBS

## Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States



Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

### Reference Materials

[Summary Document for Interim Clinical Considerations](#)

[Summary Document for Interim Clinical Considerations poster](#)

[COVID-19 Vaccine Administration Errors and Deviations](#)

[COVID-19 Vaccine Administration Errors and Deviations Poster](#)

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### Summary of recent changes (last updated July 16, 2021):

- Updated considerations regarding mRNA vaccine dosing intervals
- Updated considerations for immunocompromised people.

#### Key points

COVID-19 vaccination is recommended for everyone 12 years and older for the prevention of coronavirus disease 2019 (COVID-19) in the United States. The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of:

- Pfizer-BioNTech COVID-19 vaccine (in persons [ages 12–15 years](#) and [ages ≥16 years](#))
- [Moderna](#) COVID-19 vaccine (in persons ages ≥18 years)
- [Janssen \(Johnson & Johnson\)](#) COVID-19 vaccine (in persons ages ≥18 years)

These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

The Advisory Committee on Immunization Practices' (ACIP) update on the use of mRNA COVID-19 vaccines after reports of myocarditis or pericarditis in vaccine recipients

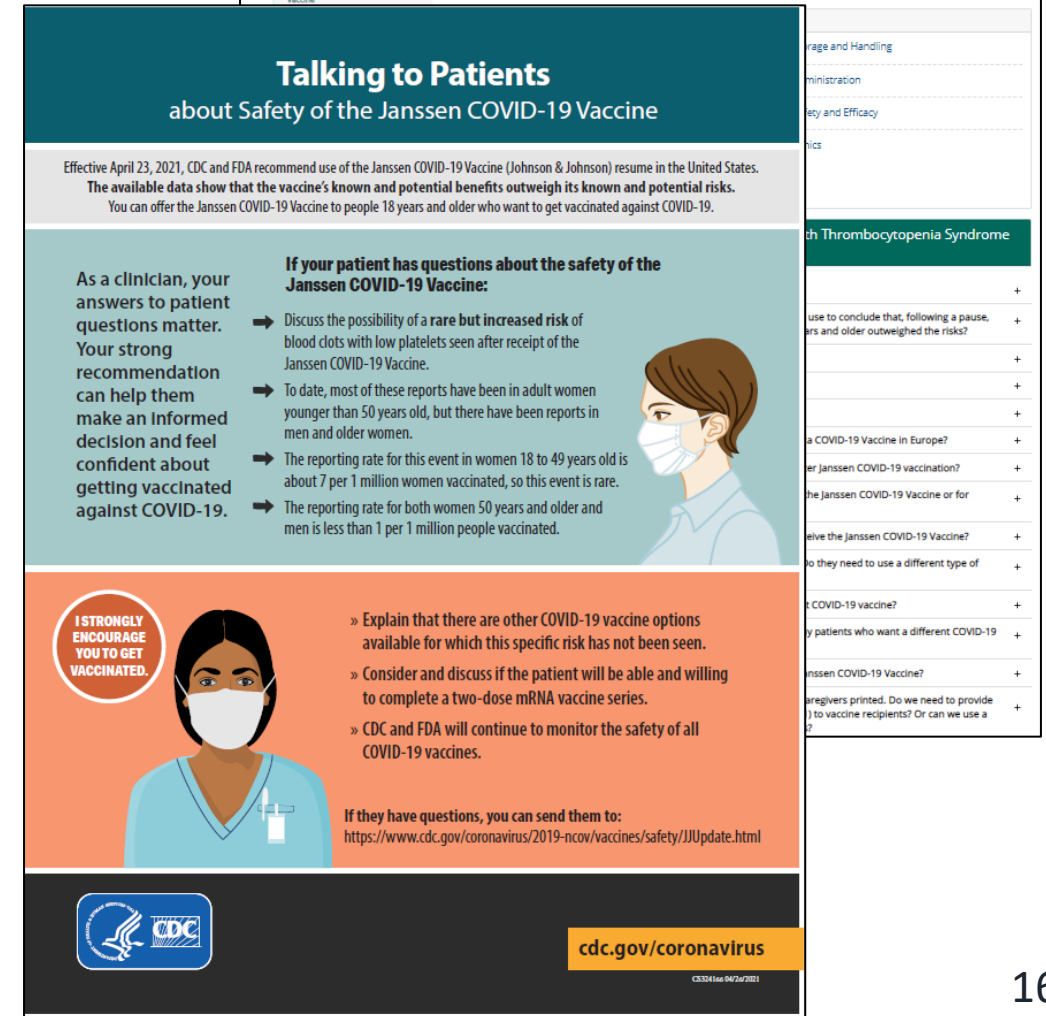
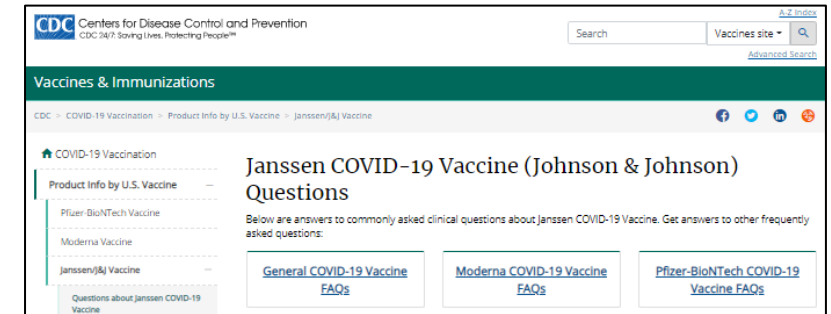
On June 23, 2021, [ACIP met to review reported cases of myocarditis or pericarditis in mRNA COVID-19 vaccine](#) (Pfizer-BioNTech and Moderna) recipients. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12–29 years, with symptoms typically developing within a few days after receipt of the second dose of vaccine.

ACIP reviewed the benefits and risks of mRNA COVID-19 vaccines in the United States and determined that the benefits of using mRNA COVID-19 vaccines under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) clearly outweigh the risks of myocarditis and pericarditis in all people aged 12 years or older. The FDA updated the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers for [Pfizer-BioNTech COVID-19 vaccine](#) and [Moderna COVID-19 vaccine](#) to include information about the occurrence of myocarditis or pericarditis in some people following use of the vaccine. Based on the benefit-risk assessment, COVID-19 vaccination continues to be recommended for everyone aged 12 years and older under the



# Planned CDC communication materials

- Updated materials for providers on talking to patients about Janssen vaccine safety
- Updated frequently asked questions



## Talking to Patients about Safety of the Janssen COVID-19 Vaccine

Effective April 23, 2021, CDC and FDA recommend use of the Janssen COVID-19 Vaccine (Johnson & Johnson) resume in the United States. **The available data show that the vaccine's known and potential benefits outweigh its known and potential risks.** You can offer the Janssen COVID-19 Vaccine to people 18 years and older who want to get vaccinated against COVID-19.

**As a clinician, your answers to patient questions matter. Your strong recommendation can help them make an informed decision and feel confident about getting vaccinated against COVID-19.**


**If your patient has questions about the safety of the Janssen COVID-19 Vaccine:**

- ➔ Discuss the possibility of a rare but increased risk of blood clots with low platelets seen after receipt of the Janssen COVID-19 Vaccine.
- ➔ To date, most of these reports have been in adult women younger than 50 years old, but there have been reports in men and older women.
- ➔ The reporting rate for this event in women 18 to 49 years old is about 7 per 1 million women vaccinated, so this event is rare.
- ➔ The reporting rate for both women 50 years and older and men is less than 1 per 1 million people vaccinated.

**I STRONGLY ENCOURAGE YOU TO GET VACCINATED.**

- » Explain that there are other COVID-19 vaccine options available for which this specific risk has not been seen.
- » Consider and discuss if the patient will be able and willing to complete a two-dose mRNA vaccine series.
- » CDC and FDA will continue to monitor the safety of all COVID-19 vaccines.

If they have questions, you can send them to:  
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html>

 [cdc.gov/coronavirus](https://cdc.gov/coronavirus)

CS23166 04/23/2021



# Discussion

- What is the ACIP's interpretation of the benefits and risks of COVID-19 vaccines?
- Does ACIP agree with the Work Group's interpretation that Janssen COVID-19 Vaccine should continue to be used according to the current recommendations?