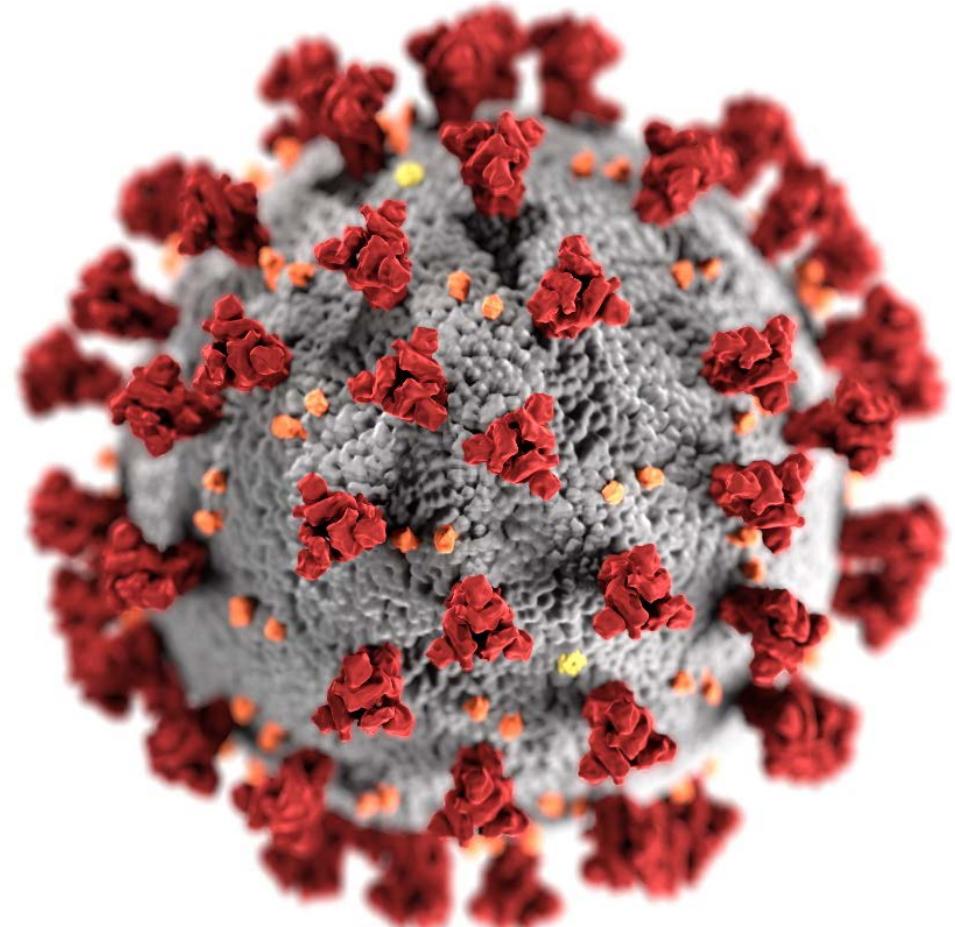




Benefits and Risks of COVID-19 Vaccines: Work Group Interpretation

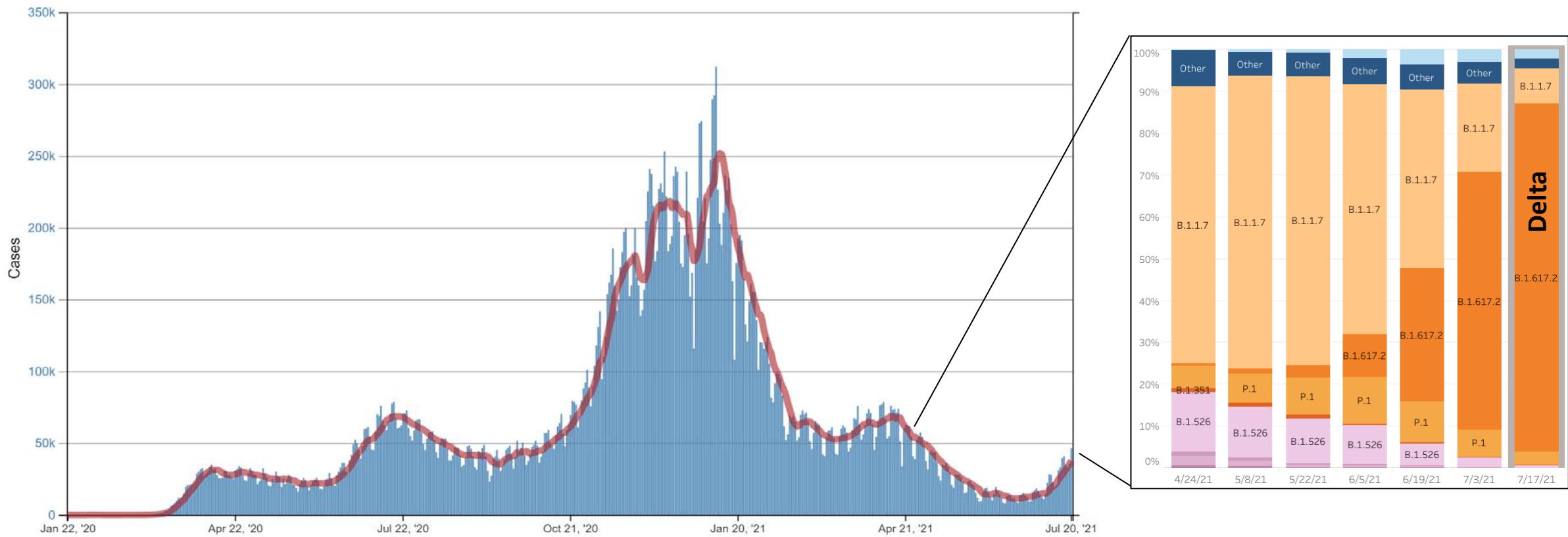
Sarah Mbaeyi, MD MPH
Centers for Disease Control and Prevention
July 22, 2021



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

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

Majority of cases due to Delta variant

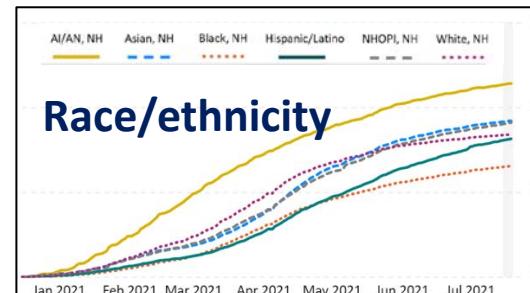
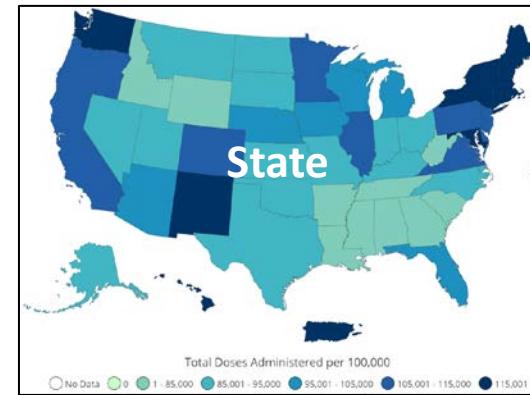
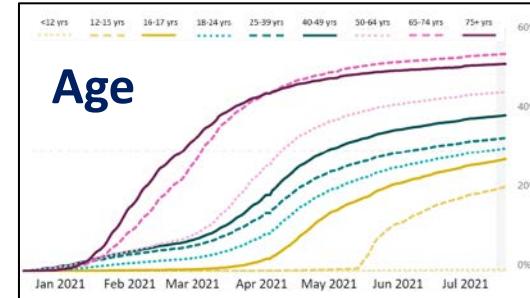
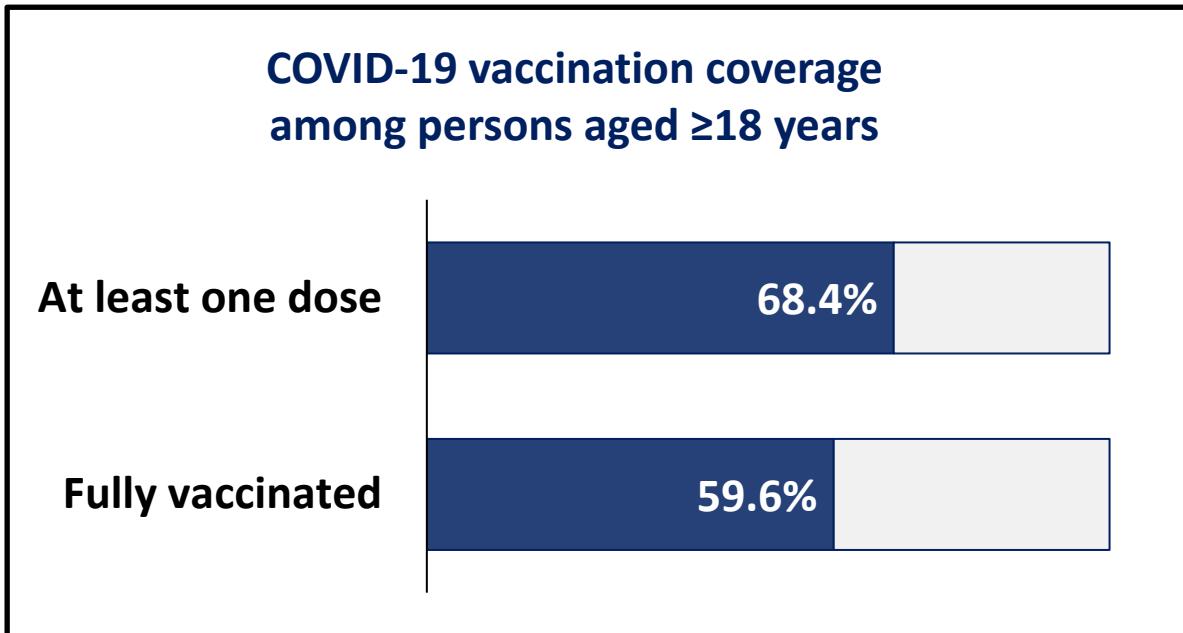


As of July 21, 2021

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

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

Coverage varies by



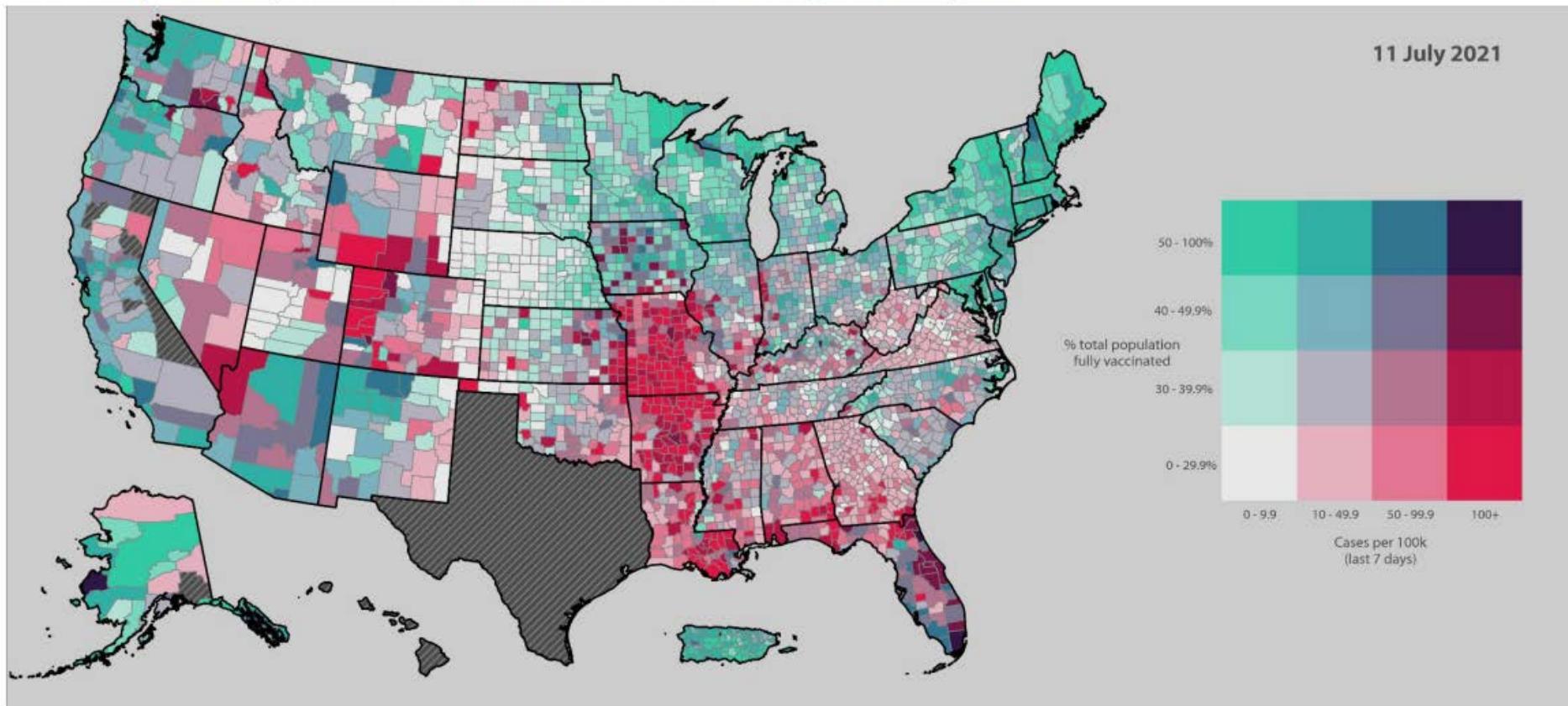
As of July 21, 2021

<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)



CDC
ATSDR

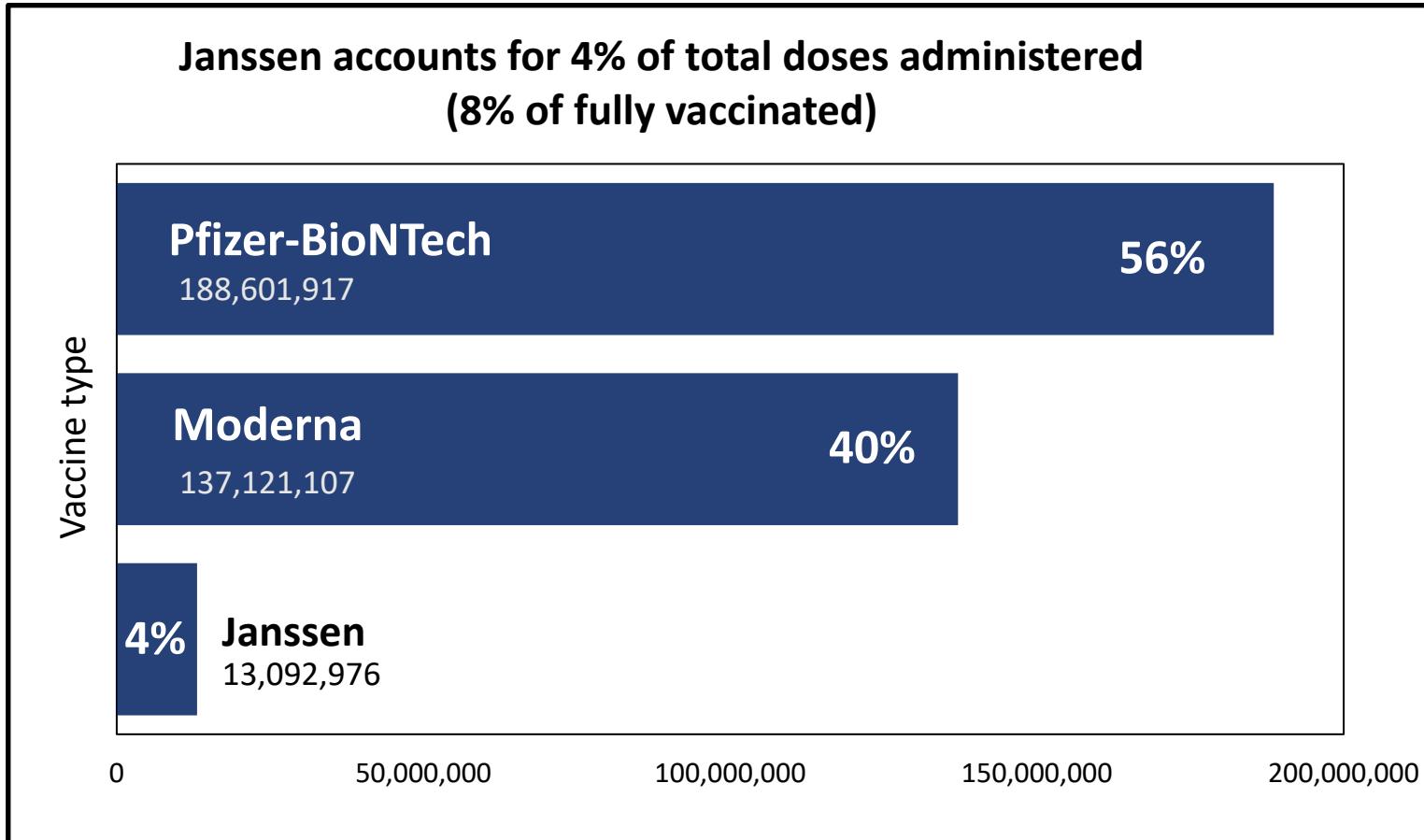
Centers for Disease Control and Prevention
Agency for Toxic Substances
and Disease Registry

GRASP

Geospatial Research, Analysis and
Services Program

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

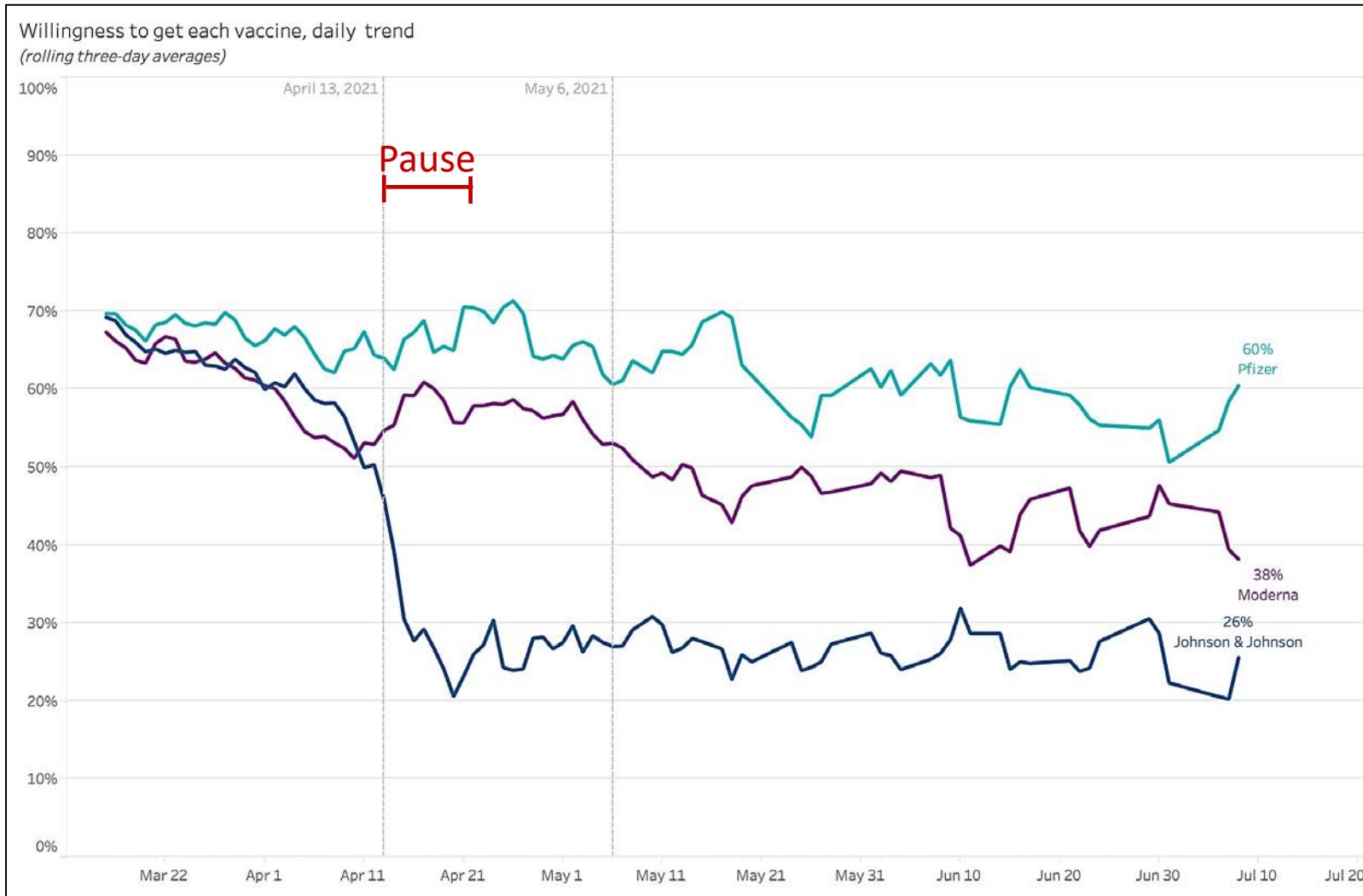
mRNA vaccines account for majority of doses administered in the United States



As of July 21, 2021.

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

Willingness to receive Janssen vaccine remains lower since the April pause



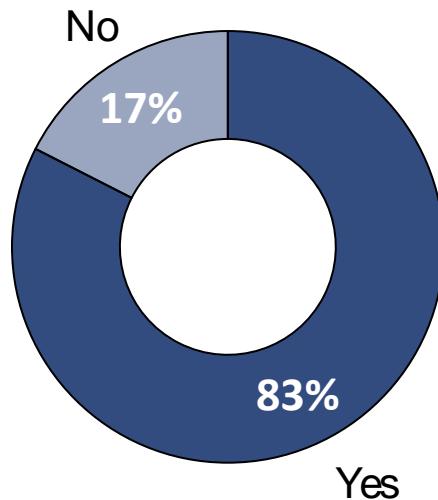
Results shown are among those who haven't received a vaccine but plan to get one



Janssen vaccine: Patient choice, access, and vaccine equity

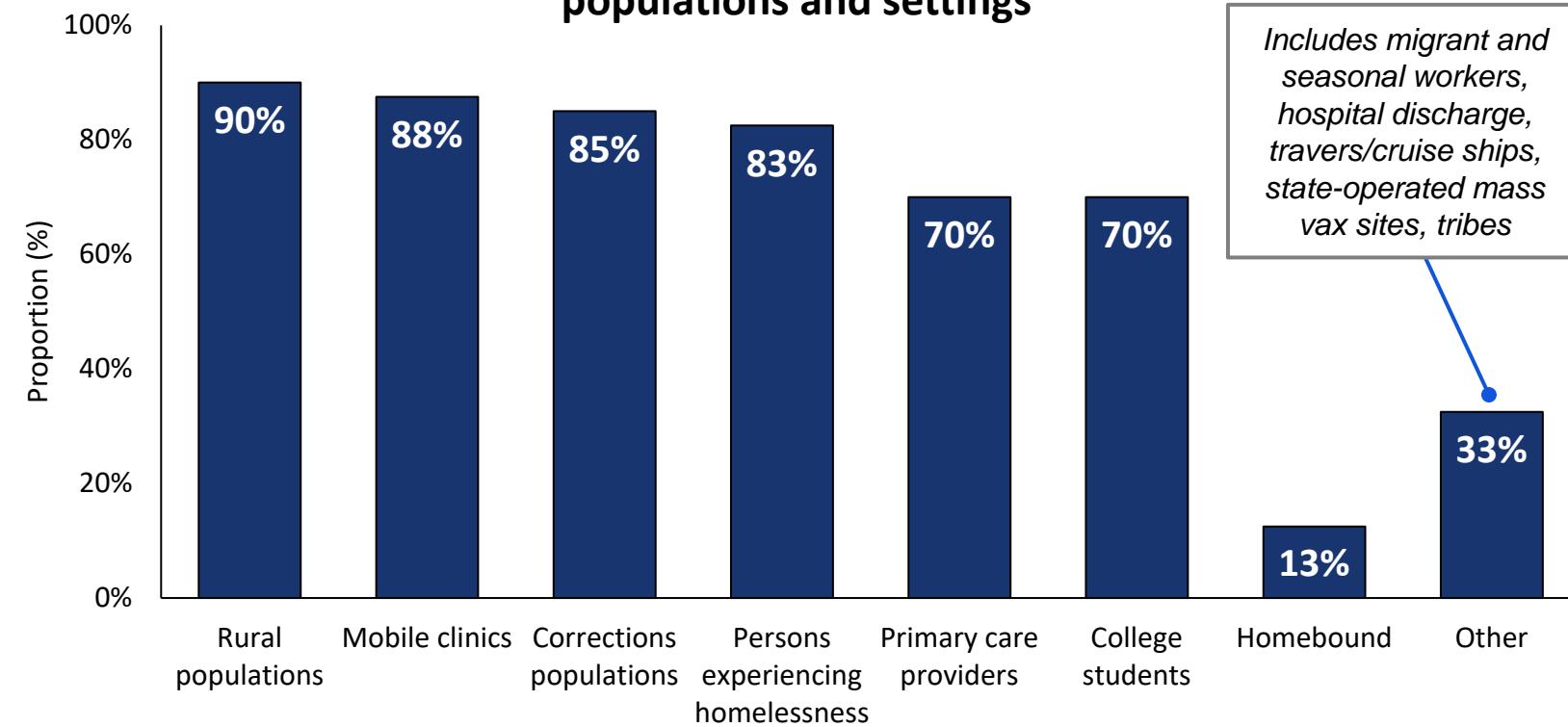
Findings from survey of jurisdictions – July 16, 2021

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 <u>hospitalizations/</u> ICU admissions/deaths | GBS Cases | TTS Cases | Prevented COVID-19 <u>hospitalizations/</u> ICU admissions/deaths | | Myocarditis Cases | | | | |
| FEMALES | | | | | | | | | | |
| 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 |
| MALES | | | | | | | | | | |
| 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

Updates will be posted at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

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

Updates to additional clinical resources

Updates will be posted at: <https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html>



Prevaccination Checklist for COVID-19 Vaccines

For vaccine recipients:

Janssen COVID-19 Vaccine (Johnson & Johnson)
Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

CDC

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

- Assess persons 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:
 - Women aged 18–49 years: Inform women of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group and about the availability of other authorized vaccines (i.e., mRNA vaccines).⁴
 - Offer another FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) to persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., heparin-induced thrombocytopenia) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine.⁴
 - Note:** Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.
 - Has not completed a COVID-19 vaccination series, regardless of brand.
 - The Janssen COVID-19 Vaccine requires 1 dose. No additional doses are needed.
 - If the recipient has received 1 previous dose of an mRNA vaccine, the same brand should be administered for the second dose.
 - In situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. However, vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. See footnote for further information on administering Janssen COVID-19 Vaccine to persons with a contraindication to mRNA COVID-19 vaccines.⁴

Contraindications

- Severe allergic reaction (e.g., anaphylaxis) to a component of Janssen COVID-19 Vaccine
- Immediate allergic reaction⁵ of any severity or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of ingredients in COVID-19 vaccines)

Note: Persons who have a contraindication to Janssen COVID-19 Vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).⁵

Precautions

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of an immediate allergic reaction⁵ of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
 - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polysorbate or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- People with a contraindication to an mRNA COVID-19 vaccine have a precaution to the Janssen COVID-19 Vaccine (see footnote).⁵
- Moderate to severe acute illness

*Educational materials are available at: <https://www.cdc.gov/coronavirus/2019-nCoV/vaccines/safety/1update.html>

¹Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation with the Clinical Immunization Safety Assessment COVID-19 Project. Vaccination of these individuals should be performed under the close supervision of a healthcare provider experienced in the management of severe allergic reactions.

⁴ People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.

⁵ When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccine.

⁶ For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

Name _____
Age _____
Yes **No** **Don't know**

Another Product

Presentation? (yes/no)

Reaction to treatment with epinephrine or EpiPen® or that caused swelling, or respiratory distress, including wheezing.)

Medications following:
laxatives and
steroids and
other than COVID-19 vaccine
treatment with epinephrine or EpiPen® or that caused hives, swelling, or respiratory distress,

Date _____
the Immunization Action Coalition (IAC) screening checklists

1

Planned CDC communication materials

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

The screenshot shows the CDC COVID-19 Vaccination website. The top navigation bar includes links for "COVID-19 Vaccination", "Product Info by U.S. Vaccine" (selected), "Pfizer-BioNTech Vaccine", "Moderna Vaccine", and "Janssen/J&J Vaccine". Below this, a sidebar lists "Questions about Janssen COVID-19 Vaccine". The main content area has a teal header "Talking to Patients about Safety of the Janssen COVID-19 Vaccine". It states: "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." To the right is a cartoon illustration of a person wearing a mask. The page also features a sidebar with sections like "Storage and Handling", "Administration", "Safety and Efficacy", and "Thrombocytopenia Syndrome". At the bottom, there's a call to action: "If they have questions, you can send them to: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html>". The footer includes the CDC logo and the URL "cdc.gov/coronavirus".

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?