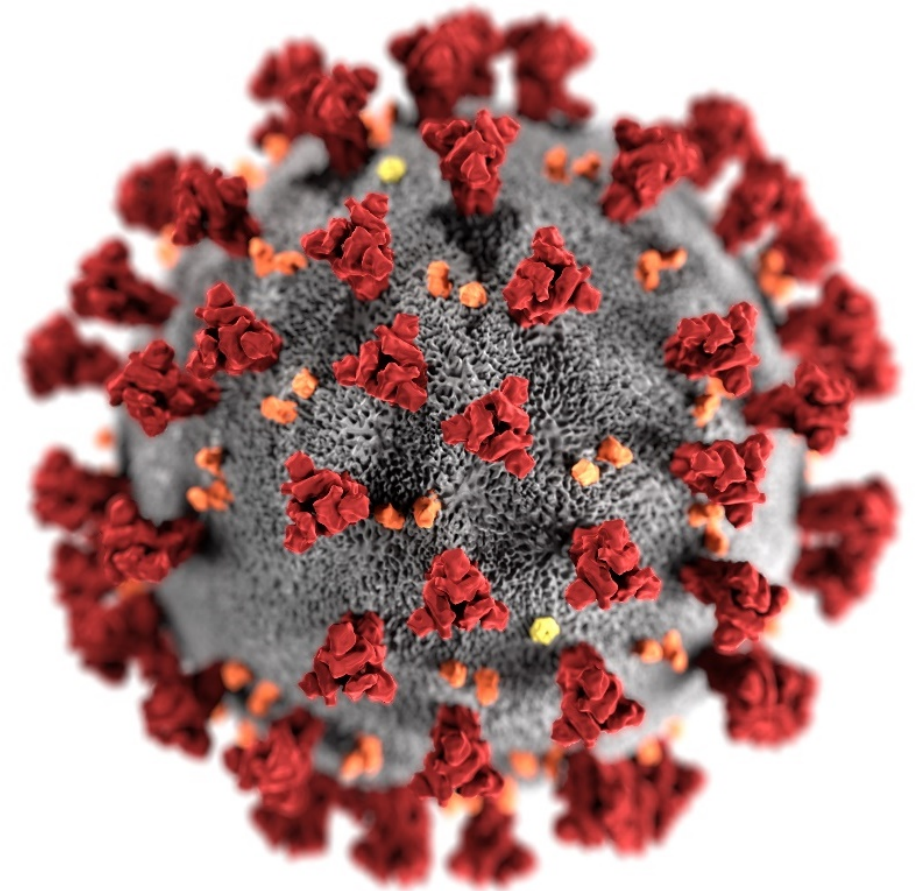


# Clinical Considerations for Pfizer-BioNTech COVID-19 Vaccination in Adolescents


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May 12, 2021



# Interim clinical considerations for COVID-19 vaccines

- Recommendations apply to the use of the Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA)
- Clinical considerations are being updated to include guidance for adolescents and recommendations regarding vaccine coadministration and vaccination after Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)

## 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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[What's this?](#)

The Advisory Committee on Immunization Practices' (ACIP) updated recommendations on the use of the Janssen (Johnson & Johnson) COVID-19 vaccine

On April 23, 2021, ACIP [reaffirmed its interim recommendation](#) for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA). CDC and FDA had recommended a pause in the use of the Janssen COVID-19 vaccine on April 13, 2021 after reports of U.S. cases of thrombosis with thrombocytopenia syndrome (TTS) among Janssen COVID-19 recipients. TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. The FDA's EUA now includes a warning that rare clotting events might occur after vaccination, primarily among women aged 18–49 years.

# Administration



# Pfizer-BioNTech dosing and administration

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<b>Authorized age groups</b>	<b>≥ 12 years</b>
Number of doses in series	2 doses
Interval between 1 <sup>st</sup> and 2 <sup>nd</sup> doses*	3 weeks
Dose volume	0.3 ml
Route	Intramuscular

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\*If it is not feasible to adhere to the recommended interval, the second dose may be administered up to 6 weeks (42 days) after the first dose.

# Syncope (fainting)

- Syncope (fainting) may occur in association with any injectable vaccine.
- Procedures should be in place to prevent falling injuries and manage syncopal reactions following COVID-19 vaccination.
- All people are recommended to be observed following COVID-19 vaccination for at least 15 minutes; patients should be seated or lying down during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

# Consent



# Consent

- The federal government does not have specific requirements for medical consent for vaccination.
- States/jurisdictions have medical consent laws that address the circumstances requiring and the processes for obtaining consent.
  - These laws vary across jurisdictions.
  - Providers may also be subject to policy requirements for consent within their own organizations.
- Sites administering vaccines should follow current state/jurisdictional policies and practices for other routine immunizations in this age group.

# Coadministration





# Coadministration

- Due to the novelty of the COVID-19 vaccines, the previous recommendation was to administer COVID-19 vaccines alone, with a minimum interval of 14 days before or after administration of any other vaccine to better understand any adverse reactions.
- However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by FDA for use under EUA.
- Extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

# Coadministration

- COVID-19 and other vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 and other vaccines on the same day, as well as co-administration within 14 days.

# Routine adolescent vaccines

- Updated coadministration recommendations may facilitate catch up vaccination of adolescents.
- As of May 2, 2021, overall VFC provider orders (other than influenza) are down by **11.7 million doses** compared with 2019.
- This gap is largest in vaccines primarily given to adolescents.
  - Tdap – down **18.9%**
  - HPV – down **19.3%**
  - Meningococcal conjugate vaccine – down **15.1%**

# Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)



# Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)

- MIS-C and MIS-A are severe hyperinflammatory syndromes occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications.
- The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2.

# Clinical considerations for people with a history of MIS-C or MIS-A

- Children with MIS-C have high antibody titers to SARS-CoV-2; however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist.
- It is unclear if people with a history of MIS-C or MIS-A are at risk for recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to a COVID-19 vaccine.

# Clinical considerations for people with a history of MIS-C or MIS-A

- People with a history of MIS-C or MIS-A may choose to be vaccinated.
- Considerations for vaccination may include:
  - Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
  - Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
  - Level of COVID-19 community transmission and personal risk of reinfection
  - Lack of safety data of COVID-19 vaccines following these illnesses
  - Timing of any immunomodulatory therapies

# Clinical considerations for people with a history of MIS-C or MIS-A

- Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from illness and **for 90 days after the date of diagnosis of MIS-C or MIS-A**, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.



# Clinical considerations for people with a history of MIS-C or MIS-A

Healthcare personnel or health departments can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project if they have complex COVID-19 vaccine safety questions not readily addressed by CDC guidance.

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

# Contraindications and Precautions



# Anaphylaxis

- Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines.

- <https://www.cdc.gov/vaccines/covid-19/downloads/Interim-Considerations-for-Anaphylaxis-in-Covid-19-Vaccine-Sites.pdf>

## How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system**.



### Respiratory:

- sensation of throat closing
- stridor (high-pitched sound while breathing)
- shortness of breath
- wheeze, cough



### Gastrointestinal:

- nausea
- vomiting
- diarrhea
- abdominal pain



### Cardiovascular:

- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)



### Skin/mucosal:

- generalized hives
- itching
- swelling of lips, face, or throat



### Neurological:

- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

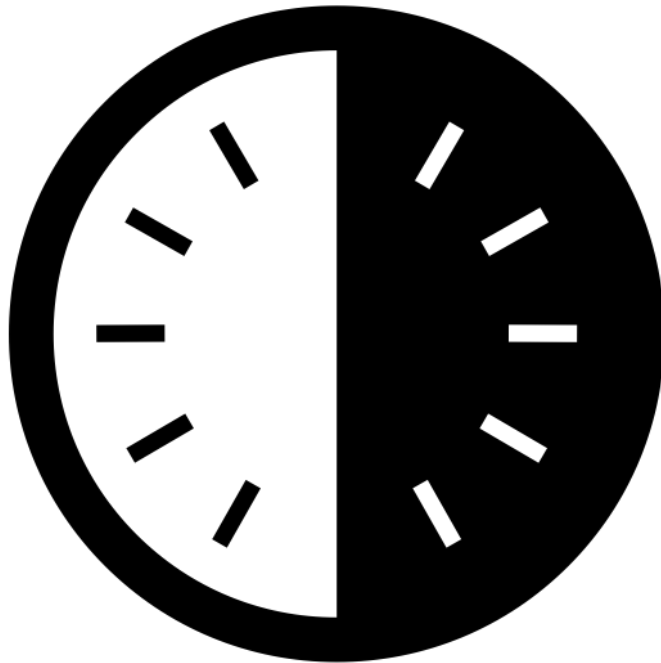
# Contraindications

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
- Known polysorbate allergy is no longer a contraindication to mRNA vaccination but is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

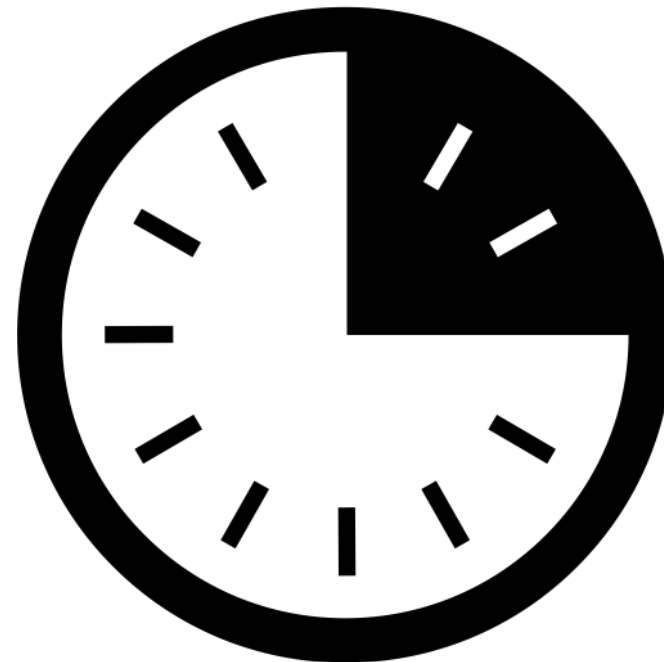
# Observation period following vaccination

- History of immediate allergic reaction (any severity) to a vaccine or injectable therapy
- Contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis (due to any cause)

All other persons



30 minutes



15 minutes

# Additional resources



# CDC Resources

Learn more with **CDC's COVID-19 vaccine tools and resources**. Find information for COVID-19 vaccination administration, storage, reporting, patient education, and more.

- COVID-19 Vaccination: <https://www.cdc.gov/vaccines/covid-19/index.html>
- For Healthcare Professionals: <https://www.cdc.gov/vaccines/covid-19/hcp/index.html>

**YOU CALL THE SHOTS**  
Vaccinating Adolescents

Vaccination can be a stressful experience. Adolescents may experience fear and anxiety, which if not addressed, can have long-term effects such as avoidance of needed health care throughout their lifetime. Your practices can positively impact adolescents' experiences and perceptions of vaccination. Consider strategies to manage pain and potential acute reactions.

COVID-19 Vaccination

- Product Info by US Vaccine
  - Pfizer-BioNTech Vaccine**
  - Moderna Vaccine
  - Janssen/J&J Vaccine
  - EUA
  - FAQs for Healthcare Professionals
- Clinical Care +
- Provider Requirements and Support +
- Training and Education +
- Vaccine Recipient Education +
- Health Departments +
- Planning & Partnerships +
- Vaccine Effectiveness Research +
- Vaccination Toolkits +
- COVID-19 Vaccine Data Systems +
- Content Syndication +
- Vaccinate with Confidence +

## Pfizer-BioNTech COVID-19 Vaccine

### Summary of Recent Changes and Updates

Webpage content and individual PDFs are updated when there's new guidance concerning the Pfizer-BioNTech COVID-19 vaccine. Expand each section below to see a summary of new and updated items.

- General Information Updates +
- Preparation and Administration Information Updates +
- Storage and Handling Information Updates +

### General Pfizer-BioNTech Vaccine Information

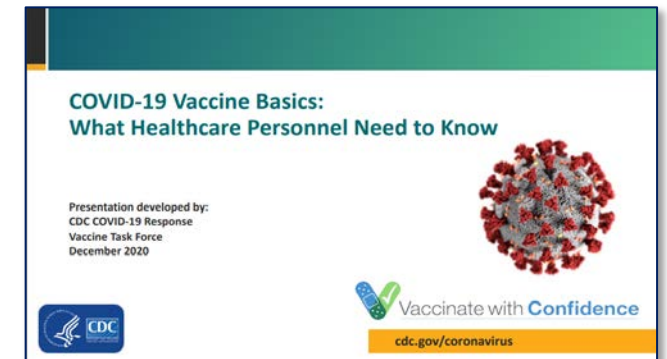
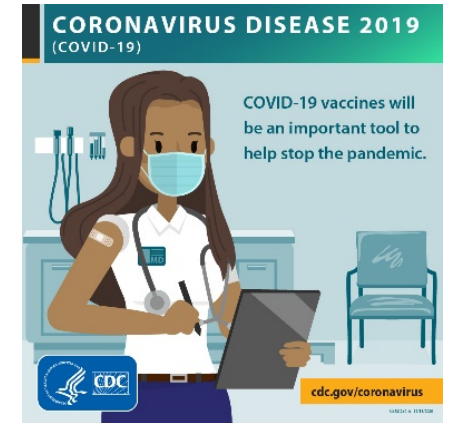
Vaccine: Pfizer-BioNTech COVID-19 Vaccine  
 Diluent: 0.9% sodium chloride (normal saline, preservative-free)  
 Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

- Dosing Information +
- Age Indications +
- Schedule +
- Administration +

EUA	Interim Clinical Considerations
Pfizer BioNTech Covid-19 Vaccine FAQs	ACIP Recommendations

# COVID-19 vaccine communication resources

- Engaging in Effective COVID-19 Vaccine Conversations
  - <https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.htm>
- Toolkit for Medical Centers, Clinics, and Clinicians
  - <https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>





# Discussion



# Discussion

- Does ACIP agree with the proposed clinical considerations related to vaccination?
- Are there any sections of the clinical considerations that ACIP would like to discuss?

# Thank you



The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)