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

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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)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
Administration
### Pfizer-BioNTech dosing and administration

<table>
<thead>
<tr>
<th>Authorized age groups</th>
<th>≥ 12 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses in series</td>
<td>2 doses</td>
</tr>
<tr>
<td>Interval between 1(\text{st}) and 2(\text{nd}) doses*</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Dose volume</td>
<td>0.3 ml</td>
</tr>
<tr>
<td>Route</td>
<td>Intramuscular</td>
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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) 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.

Contraindications and Precautions
Anaphylaxis

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

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

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 vaccine communication resources

- Engaging in Effective COVID-19 Vaccine Conversations
  - [https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.htm](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](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