Clinical considerations for use of an additional mRNA COVID-19 vaccine dose after a primary mRNA COVID-19 vaccine series for immunocompromised people

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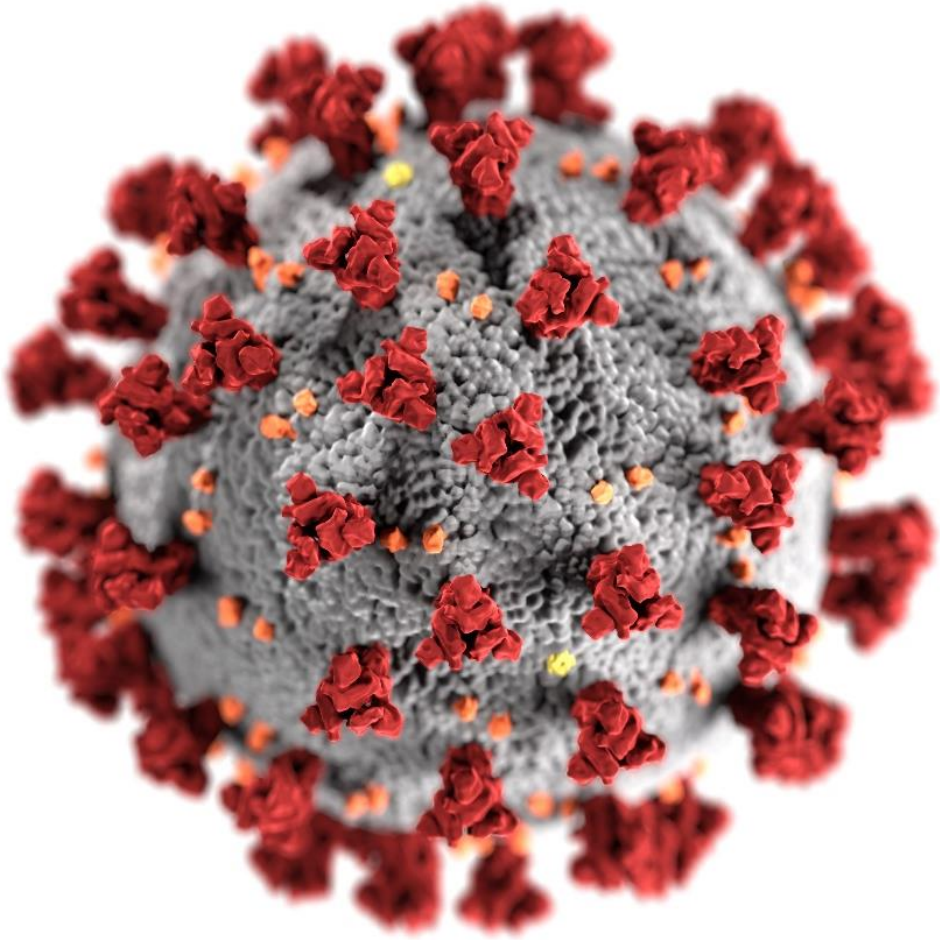
ACIP Meeting

August 13, 2021



cdc.gov/coronavirus

Recent CDC Update on Pregnancy Language

COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future

- COVID-19 vaccine safety in pregnancy
  - COVID-19 vaccines do not cause infection in the pregnant person or the fetus
  - No safety signals in animal studies
  - Reassuring early safety data on mRNA COVID-19 vaccines during pregnancy
  - Early data suggest mRNA COVID-19 vaccines during pregnancy are effective

- There is no evidence that any of the COVID-19 vaccines affect current or future fertility

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

https://www.idsociety.org/covid-19-real-time-learning-network/CDC-IDSA-COVID-19-Clinician-Calls/

Additional doses in immunocompromised people

Review data:
Assess safety, immunogenicity, and implementation

FDA

Regulatory allowance:
EUA amendment would allow recommendations under EUA

BLA would allow for 'off label' recommendations

CDC/ACIP

Clinical update:
Clinical considerations/ recommendations for use

EUA= Emergency Use Authorization; BLA= Biologics License Application

Roles of an Additional Dose

There are two distinct potential uses for an additional vaccine dose:

- **Additional dose after an initial primary vaccine series**: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.

- **Booster dose:** a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established

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Focus of Clinical Considerations

For people with moderate to severe immune compromise due to a medical condition or immunosuppressive treatment, the potential to increase immune response coupled with an acceptable safety profile support consideration for an additional dose of mRNA COVID-19 vaccine following an initial 2-dose primary mRNA COVID-19 vaccine series in this population

Moderately and severely immunocompromised people*

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

*ACIP General Best Practice Guidelines for Immunization; CDC Yellow Book; 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

Additional considerations

- Chronic medical conditions may be associated with varying degrees of immune deficit
- Patient's clinical team is best able to assess the degree of altered immunocompetence and optimal timing of vaccination, with specific attention paid to current or planned immunosuppressive therapies
- Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be given at least two weeks before initiation of immunosuppressive therapies.
- Factors to consider in assessing the general level of immune competence of patients with chronic diseases include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment
- Utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., need for an additional dose) has not been established and is not recommended at this time

Implementation Considerations

- The additional dose should be the same mRNA vaccine as the primary series
- Alternate mRNA product can be used if primary series product not available
- Until more data are available, the additional dose should be administered at least 28 days after completion of the initial primary series
- Currently there are not data to support the use of an additional mRNA COVID-19 vaccine dose after a primary Janssen COVID-19 vaccine in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue.

Importance of infection prevention measures

- Immunocompromised people (including those who receive an additional mRNA dose) should be counseled about the potential for reduced immune response to COVID-19 vaccination and need to follow prevention measures*
  - Wear a mask
  - Stay 6 feet apart from others they don't live with
  - Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider

- Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19

* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

Updates to additional clinical resources

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 12 Years of Age and Older

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 examination or direct order from th time of the interaction.

Procedure

- Assess persons 12 years of age and Pfizer-BioNTech COVID-19 Vaccine
  - History of myocarditis or pericar dose of an mRNA COVID-19 vacc
    - Defer the second dose of an m Administration of the second vaccine series can be consider after the episode of myocardit completely resolved. Consider www.cdc.gov/vaccines/covid- covid-19-vaccines-us.html#un
  - History of myocarditis or pericar vaccination
    - May receive any FDA-authorize episode of myocarditis or perica
  - Has not completed a COVID-19 v brand. If 2 doses of an mRNA vac or a single dose of Janssen vacci additional doses are recommenc
  - If the recipient has received 1 pre COVID-19 Vaccine, administer th least 21 days (but preferably befo
  - If the vaccine product given as th determined or is no longer availa vaccine product may be adminis first dose.
- Inform recipients, especially males and their parents/legal representat possibility of myocarditis or pericar COVID-19 vaccines and the need to myocarditis or pericarditis develop
- For people who received a COVID-
- Defer vaccination with Pfizer-BioNTech COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - Immediate allergic reaction[§] of any severity to a previous dose or

Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

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 Moderna COVID-19 Vaccine based on the following criteria:
  - History of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine
    - Defer the second dose of an mRNA COVID-19 vaccine. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
  - History of myocarditis or pericarditis prior to COVID-19 vaccination
    - May receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - Has not completed a COVID-19 vaccination series, regardless of brand. If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen vaccine has been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at an interval of least 28 days (but preferably before 42 days).*
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
- Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination.†
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Moderna COVID-19 vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.‡
- Defer vaccination with Moderna COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - Immediate allergic reaction[§] of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of vaccine components)

Note: Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).¶ Prior to administration of Janssen COVID-19 Vaccine, inform women 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group.# Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.

- 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 reaction[§] 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 polyethylene glycol (PEG) or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
    - People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote).¶
  - Moderate to severe acute illness

*Administer the second dose as close as possible to the recommended interval (28 days). If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Doses inadvertently administered less than 28 days apart do not need to be repeated.

†Educational materials are available at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

‡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 vaccines.

§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.

¶Consider consultation with an allergist-immunologist to help determine if a patient with a contraindication to an mRNA vaccine can safely receive the Janssen COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- 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.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

#Educational materials are available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/AEfi-update.html

Prevaccination Checklist for COVID-19 Vaccines

vaccine recipients:

llowing questions will help us determine if there is any reason ould not get the COVID-19 vaccine today. **If you answer "yes" question, it does not necessarily mean you should not be ated.** It just means additional questions may be asked. If a on is not clear, please ask your healthcare provider to explain it.

Name _____

Age _____

	Yes	No	Don't know
e you feeling sick today?	☐	☐	☐
ve you ever received a dose of COVID-19 vaccine?	☐	☐	☐
f yes, which vaccine product did you receive? Pfizer ☐ Moderna ☐ Janssen (Johnson & Johnson) ☐ Another Product _____			
cination record card or other documentation? *(yes/no)*	☐	☐	
ergic reaction to: *gic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)*			
ID-19 vaccine, including either of the following:			
PEG), which is found in some medications, such as laxatives and noscopy procedures	☐	☐	☐
found in some vaccines, film coated tablets, and intravenous steroids	☐	☐	☐
/ID-19 vaccine	☐	☐	☐
ergic reaction to another vaccine *(other than COVID-19 vaccine)* on? *gic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that It would also include an allergic reaction that caused hives, swelling, or respiratory distress,*	☐	☐	☐
u:			
ages 18 and 49 years old			
ges 12 and 29 years old			
carditis or pericarditis			
eaction to something other than a vaccine or injectable therapy such as food, pet, venom, medication allergies			
s treated with monoclonal antibodies or convalescent serum			
system Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection			
nune system (i.e., HIV infection, cancer)			
sive drugs or therapies			
der			
arin-induced thrombocytopenia (HIT)			
t or breastfeeding			
fillers			

Date _____

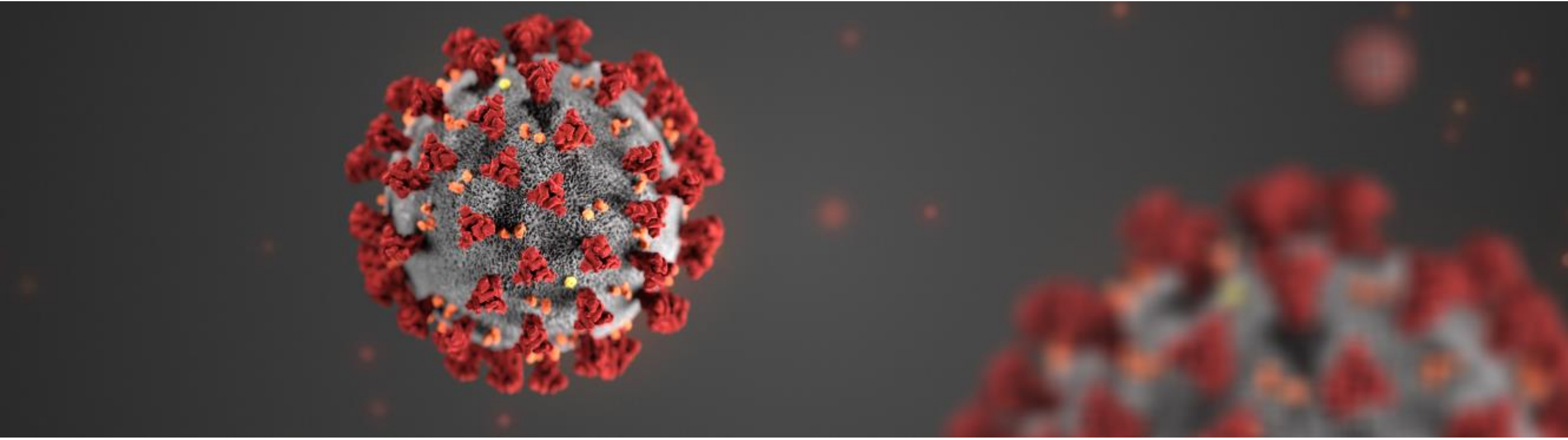
Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists

1

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

Acknowledgements

- Kristine Schmit
- Mary Chamberland
- Kathleen Dooling
- Sara Oliver
- Kevin Chatham-Stephens
- John Omura
- Amanda Cohn
- CDC COVID-19 Response Vaccine Task Force



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

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