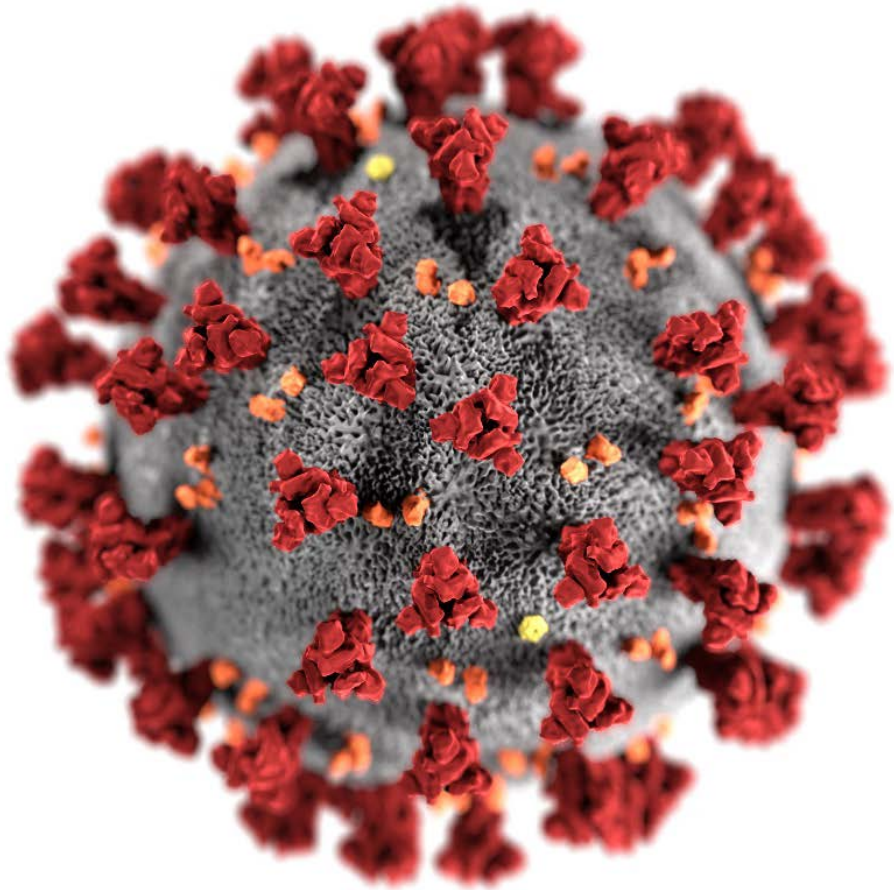
Clinical Considerations for Use of COVID-19 Vaccines



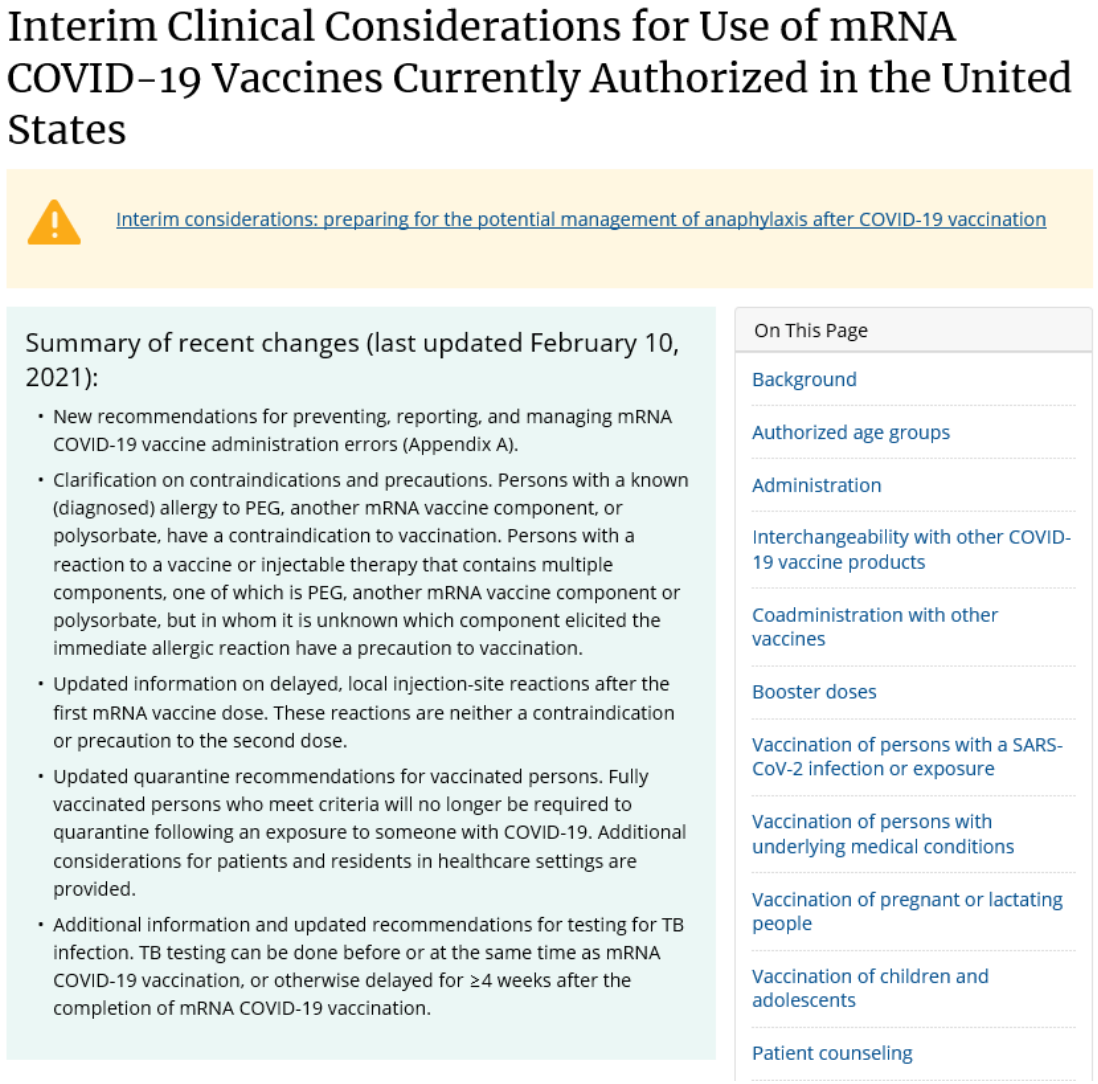
Jessica MacNeil, MPH

March 1, 2021

Clinical considerations for use of mRNA COVID-19 vaccines

- CDC clinical considerations for mRNA COVID-19 vaccines published previously:
  - https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- Clinical considerations are being updated to include Janssen COVID-19 vaccine
  - Viral vector COVID-19 vaccine



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

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

Summary of recent changes (last updated February 10, 2021):

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

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Sign up to receive email updates when clinical considerations are updated: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Vaccine administration

Administration of COVID-19 vaccines

- COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose
- One valid vaccination series should be completed

Vaccine	Authorized age group	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	≥16 years	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	≥18 years	100 µg	0.5 ml	2	1 month (28 days)
Janssen	≥18 years	5×10^{10} virus particles	0.5 ml	1	N/A

Interchangeability of COVID-19 vaccine products

- Any COVID-19 vaccine can be used when indicated; no product preference

- COVID-19 vaccines are **not** interchangeable
  - Safety and efficacy of a mixed series has not been evaluated

- If first dose of mRNA COVID-19 vaccine was received but patient unable to compete series with same or different mRNA vaccine (e.g., contraindication)
  - Single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose*
  - Considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series (mRNA/viral vector)

*Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine. In these patients, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

Coadministration of COVID-19 vaccines with other vaccines

- Currently authorized COVID-19 vaccines are all inactivated vaccines
- COVID-19 vaccine should be administered alone with minimum interval of 14 days before or after administration of other vaccines
- A shorter interval may be used in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks (e.g., tetanus toxoid vaccine for wound management, etc.) or to avoid barriers or delays to vaccination

COVID-19 vaccination and SARS-CoV-2 infection

Persons with prior SARS-CoV-2 infection

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Data from clinical trials indicate vaccination safe in these persons

- Viral testing for current infection, or serologic testing for prior infection, is **not** recommended for the purpose of vaccine decision-making

Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation

- No minimal interval between infection and vaccination

- Current evidence suggests reinfection uncommon in the months after initial infection, thus while vaccine supply remains limited, persons with recent documented infection may choose to temporarily delay vaccination
  - Risk of reinfection, and need for vaccination, might increase with time following initial infection

https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Persons who previously received passive antibody therapy for COVID-19

- Currently no data on safety and efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment

- Vaccination should be deferred for at least 90 days to avoid interference of the passive antibody therapy with vaccine-induced immune responses

- Recommendation does not apply to persons receiving antibody therapies not specific to COVID-19 treatment

https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

COVID-19 vaccination of special populations

COVID-19 vaccination of persons with underlying medical conditions

- Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including:
  - Immunocompromised persons
  - People with autoimmune conditions
  - People with history of Guillain-Barré syndrome, Bell's palsy, dermal filler use

- Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

COVID-19 vaccination of immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19

- Immunocompromised persons may receive COVID-19 vaccine unless otherwise contraindicated
  - All currently authorized vaccines are inactivated vaccines

- Individuals should be counseled about:
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow current guidance to protect themselves against COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#phrecs

COVID-19 vaccination of pregnant people

- COVID-19 and pregnancy
  - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
  - Might be an increased risk of adverse pregnancy outcomes

- Currently limited data on safety of COVID-19 vaccines in pregnant people
  - No concerns demonstrated in animal developmental and reproductive toxicity (DART) studies
  - Janssen adenovirus vector platform previously used for other clinical development programs that included pregnant people, including a large-scale Ebola vaccine trial

- Currently authorized COVID-19 vaccines are all inactivated vaccines

- Clinical trials to evaluate safety and efficacy of COVID-19 vaccines in pregnant people planned or underway

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html

COVID-19 vaccination of pregnant people

- Pregnant people may choose to receive COVID-19 vaccine when eligible
  - A conversation between the patient and their clinical team may assist with decision, but is not required
  - Conversation should consider:
    - Level of COVID-19 community transmission
    - Personal risk of contracting COVID-19
    - Risks of COVID-19 to patient and fetus
    - Efficacy and side effects of vaccine
    - Limited data about vaccine during pregnancy

Contraindications and precautions

Contraindications and precautions for COVID-19 vaccines

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine[†] • Immediate allergic reaction[*] of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine[†] Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.[†]	Among persons without a contraindication, a history of: • Any immediate allergic reaction[*] to other vaccines or injectable therapies[‡] Note: persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa[#] Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Among persons without a contraindication or precaution, a history of: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies Actions: • 30-minute observation period: persons with history of anaphylaxis (due to any cause) • 15-minute observation period: all other persons

[†] See Appendix C for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

[*] Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

[‡]Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

[#]Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

Information by vaccine type

mRNA COVID-19 vaccines	Janssen COVID-19 vaccine
• Persons with contraindication to one mRNA vaccine should not receive doses of either vaccine (Pfizer-BioNTech or Moderna) • Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine.* • In persons who received one mRNA COVID-19 dose but are contraindicated to receive the 2nd dose, consideration may be given to vaccination with Janssen COVID-19 vaccine (at least 28 days after mRNA dose).*	• Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines.*

*In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

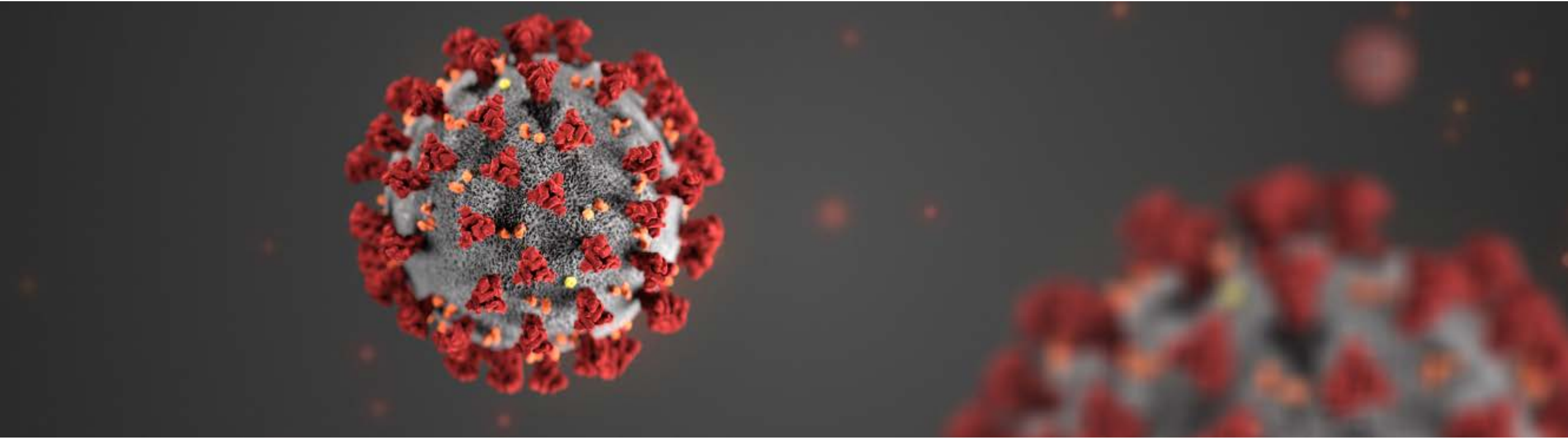
Note: Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur.

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?



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

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.