

Vaccine Safety: Anaphylaxis and COVID-19 vaccinations^{1,2}

The CDC Advisory Committee on Immunization Practices has issued <u>interim recommendations</u> for the <u>Pfizer-BioNTech</u> and <u>Moderna</u> COVID-19 vaccines for prevention of COVID-19 in the US. Anaphylaxis is a severe, life-threatening allergic reaction which occurs rarely after vaccination and has been reported with the Pfizer-BioNTech COVID-19 vaccine.

During December 14–23, 2020, monitoring by the Vaccine Adverse Event Reporting System (VAERS) detected 21 cases of anaphylaxis after administration of a reported 1,893,360 first doses of the Pfizer-BioNTech COVID-19 vaccine (11.1 cases per million doses); 71% of these occurred within 15 minutes of vaccination. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine.

Medications and Supplies for Assessing and Managing Anaphylaxis³

(should be available at all sites, at minimum)

H1 antihistamine (e.g., diphenhydramine)

Stethoscope

- Epinephrine prefilled syringe or autoinjector (> 3 doses)
- Blood pressure cuff
- Timing device to assess pulse

Contraindications & Precautions²

CDC considers a history of the following to be <u>a contraindication</u> to vaccination with both COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or its components (including polyethylene glycol [PEG])*
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*
- ^t These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and determined that the person can safely receive the vaccine.

CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy <u>as a precaution</u> but not a contraindication to vaccination for both COVID-19 vaccines.

Triage of persons presenting for mRNA COVID-19 vaccination⁴

| MAY PROCEED WITH VACCINATION | PRECAUTION TO VACCINATION | CONTRAINDICATION TO VACCINATION |
|---|--|---|
| ALLERGIES | ALLERGIES | ALLERGIES |
| History of allergies that are unrelated to components of an mRNA COVID-19 vaccine, other vaccines, injectable therapies, or polysorbate, such as: 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 | History of any immediate allergic reaction to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines or polysorbate, as these are contraindicated) ACTIONS: Risk assessment Consider deferral of vaccination and/or referral to allergist-immunologist 30-minute observation period if vaccinated | History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines: Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol) |
| ACTIONS | | Immediate allergic reaction of any severity |
| 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) | | to polysorbate ACTIONS |
| 15-minute observation period: All other persons | | Do not vaccinate Consider referral to allergist-immunologist |

References:

 CDC MMWR. <u>Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020.</u> January 6, 2021.

- 2. CDC ACIP. Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. December 30, 2020.
- 3. CDC ACIP. Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination. Accessed January 3, 2021.
- 4. CDC Clinical Outreach and Communication Activity Webinar. Update on Allergic Reactions, Contraindications, and Precautions, December 30, 2020.