Pharmacovigilance Drug Safety Alert



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)

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

- H1 antihistamine (e.g., diphenhydramine)
- Stethoscope

Contraindications & Precautions²

CDC considers a history of the following to be a contraindication 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)*
- *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** History of allergies that are unrelated to History of any immediate allergic reaction History of the following are contraindications to receiving either of the components of an mRNA COVID-19 to vaccines or injectable therapies (except vaccine, other vaccines, injectable those related to component of mRNA mRNA COVID-19 vaccines: therapies, or polysorbate, such as: COVID-19 vaccines or polysorbate, as Severe allergic reaction (e.g., Allergy to oral medications (including the these are contraindicated) anaphylaxis) after a previous dose of an oral equivalent of an injectable mRNA COVID-19 vaccine or any of its **ACTIONS:** medication) components Risk assessment History of food, pet, insect, venom, Immediate allergic reaction of any severity environmental, latex, etc., allergies Consider deferral of vaccination and/or to a previous dose of an mRNA COVID-19 referral to allergist-immunologist Family history of allergies vaccine or any of its components 30-minute observation period if vaccinated (including polyethylene glycol) **ACTIONS** Immediate allergic reaction of any severity 30-minute observation period: Persons to polysorbate with a history of anaphylaxis (due to any **ACTIONS** cause) Do not vaccinate 15-minute observation period: All other persons Consider referral to allergist-immunologist

References:

- CDC MMWR. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine United States, December 14–23, 2020. January 6, 2021.
- CDC ACIP. Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. December 30, 2020.
- CDC ACIP. <u>Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination.</u> Accessed January 3, 2021.
- 4. CDC Clinical Outreach and Communication Activity Webinar. Update on Allergic Reactions, Contraindications, and Precautions. December 30, 2020.