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Interim Considerations – Preparing for the potential management of anaphylaxis at COVID-19 Vaccination Sites

The Centers for Disease Control and Prevention (CDC) has released guidance on preparing for the potential management of anaphylaxis at COVID-19 vaccination sites, summarized below.

Anaphylaxis is an acute and potentially life-threatening serious allergic reaction. Severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine listed in the prescribing information is a contraindication to vaccination.

Anaphylactic reactions in persons receiving the Pfizer-BioNTech COVID-19 vaccine outside of clinical trials have been reported. While these reports are further investigated, CDC considers a history of severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution, but not contraindication, to vaccination. Detailed information on CDC recommendations can be found in the Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine.

These clinical considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination. Institutional practices and site-specific factors may also be considered. In all cases, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a Pfizer-BioNTech COVID-19 vaccine.

Observation period following COVID-19 vaccination

CDC currently recommends that persons who receive a Pfizer-BioNTech COVID-19 vaccine be observed after vaccination for the following time periods:

- Persons with a history of anaphylaxis (due to any cause): 30 minutes
- All other persons: 15 minutes

Early recognition of anaphylaxis

Because anaphylaxis requires immediate treatment, diagnosis is primarily made based on recognition of clinical signs and symptoms, including:

- Respiratory: sensation of throat closing, stridor (high-pitched sound while breathing), shortness of breath, wheeze, cough
- Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain
- Cardiovascular: dizziness, fainting, tachycardia (abnormally fast heart rate), hypotension (abnormally low blood pressure)
- Skin/mucosal: generalized hives, itching, or swelling of lips, face, throat

- Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. In addition, not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions. Symptoms are considered generalized if there are generalized hives and/or more than one body system is involved. If a patient develops itching and swelling confined to the injection site, the patient should be observed closely for the development of generalized symptoms (beyond the recommended observation periods noted above, if necessary). If symptoms are generalized, epinephrine should be administered as soon as possible and emergency medical services should be sought.

Medications and supplies for assessing and managing anaphylaxis

COVID-19 vaccines will likely be administered in a wide variety of clinical settings, including hospitals, long-term care facilities, outpatient medical offices, pharmacies, mass vaccination sites, and curbside or drive-through sites. These settings differ in terms of usual on-hand human and material resources to manage anaphylaxis. The following medications and supplies are important for evaluating and managing of anaphylaxis and are recommended for COVID-19 vaccination sites.

A clinical provider with access to the emergency equipment should be immediately available to assess and manage anaphylaxis.

Should be available at all sites	**If feasible, include at sites (not required)**
Epinephrine prefilled syringe or autoinjector*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine) †	Oxygen
Blood pressure cuff	Bronchodilator (e.g., albuterol)
Stethoscope	H2 antihistamine (e.g., famotidine, cimetidine)
Timing device to assess pulse	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

*COVID-19 vaccination sites should have at least 3 doses of epinephrine on hand at any given time.

†Antihistamines may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.

Management of anaphylaxis at a COVID-19 vaccination site

If anaphylaxis is suspected, take the following steps:

- Rapidly assess airway, breathing, circulation, and mentation (mental activity).
- Call for emergency medical services.

- Place the patient in a supine position (face up), with feet elevated, unless upper airway obstruction is present or the patient is vomiting.
- Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately.
- In adults, administer a 0.3 mg intramuscular dose using a premeasured or prefilled syringe, or an autoinjector in the mid-outer thigh.
- The maximum adult dose is 0.5 mg per dose.
- Epinephrine dose may be repeated every 5-15 minutes (or earlier) as needed to control symptoms while waiting for emergency medical services.
- Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.
- Antihistamines (e.g., H1 or H2 antihistamines) and bronchodilators do not treat airway obstruction or hypotension, and thus are not first-line treatments for anaphylaxis. However, they can help provide relief for hives and itching (antihistamines) or symptoms of respiratory distress (bronchodilators) but should only be administered after epinephrine in a patient with anaphylaxis. Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for several hours is advised, even after complete resolution of symptoms and signs.

Patient counseling

Patients who experience anaphylaxis after the first dose of COVID-19 vaccination should be instructed not to receive additional doses. In addition, patients should be referred to an allergist-immunologist for appropriate work-up and additional counseling.

Reporting of anaphylaxis

Any adverse events that occur in a recipient following COVID-19 vaccination, including anaphylaxis, should be reported to the Vaccine Adverse Event Reporting System (VAERS). Vaccination providers administering a COVID-19 vaccine that is under Emergency Use Authorization are required by the Food and Drug Administration to report vaccine administration errors, serious adverse events, cases of Multisystem Inflammatory Syndrome, and cases of COVID-19 that result in hospitalization or death. . Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967. In addition, CDC has developed a new, voluntary, smartphone-based tool, called v-safe, that uses text messaging and web surveys to provide patients with near real-time health check-ins after they receive a COVID-19 vaccination. CDC/v-safe call center representatives will follow up on reports of medically significant health impacts to collect additional information to complete a VAERS report. Information on v-safe is available here: https://www.cdc.gov/vsafe

Additional resources

ACIP Rapid overview: Emergent management of anaphylaxis in infants and children

ACIP Rapid overview: Emergent management of anaphylaxis in adults

Immunization Action Coalition: Medical Management of Vaccine Reactions in Adults

Pfizer-BioNTech COVID-19 vaccine prescribing information

Lieberman P, et al. “Anaphylaxis: A practice parameter update.” Annals of Allergy, Asthma & Immunology 2015; 115(5): 341-384. doi: 10.1016/j.anai.2015.07.019.

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