Interim Considerations:

Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccine Sites



A serious allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine or an immediate allergic reaction of any severity after a previous dose or known (diagnosed) allergy to a component of a COVID-19 vaccine are <u>contraindications</u> to vaccination.



Trained personnel and appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.

» Recommended observation period following COVID-19 vaccination

CDC recommends the following observation periods after vaccination:

- 30 minutes: Persons with an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis (due to any cause)
- 15 minutes: All other persons

» 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 or tightness, stridor (high-pitched sound while breathing), hoarseness, respiratory distress (such as shortness of breath or wheezing), coughing, trouble swallowing/drooling, nasal congestion, rhinorrhea (runny nose), sneezing
- Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain, or cramps
- Cardiovascular: dizziness; fainting; tachycardia (abnormally fast heart rate); hypotension (abnormally low blood pressure); pulse difficult to find or "weak"; cyanosis (bluish discoloration); pallor; flushing
- Skin/mucosal: generalized hives; widespread redness; itching; conjunctivitis; or swelling of eyes, lips, tongue, mouth, face, or extremities
- Neurologic: agitation; convulsions; acute change in mental status; sense of impending doom (a feeling that something bad is about to happen)
- **Other:** sudden increase in secretions (from eyes, nose, or mouth); urinary incontinence

Symptoms often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear. 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. Not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions.

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as hives, serious or life-threatening symptoms (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or symptoms that involve more than one body system.

» Medications and supplies for assessing and managing anaphylaxis

Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times. Vaccination locations that anticipate vaccinating large numbers of persons (e.g., mass vaccination clinics) should plan adequate staffing and supplies (including epinephrine) for the assessment and management of anaphylaxis.

The following emergency equipment should be immediately available for the assessment and management of anaphylaxis.



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

*COVID-19 vaccination locations should have at least 3 doses of epinephrine available at all times, and the ability to quickly obtain additional doses to replace supplies after epinephrine is administered to a patient. Persons with a history of anaphylaxis who carry an epinephrine autoinjector could be reminded to bring it to their vaccination appointment. Detailed information on storage, handling, administration, and dosage considerations is available in the package inserts for <u>epinephrine (e.g., EpiPen®</u>). Expired epinephrine or epinephrine that appears to be in unacceptable condition (per the manufacturer's package inserts) should be replaced.

+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.

+Either an automated or a manual blood pressure monitor, with appropriate cuff sizes, is acceptable. If a manual blood pressure monitor is used, a stethoscope should also be available.

» 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 (EMS) or 911.
- 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.

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 to a patient with anaphylaxis. Administration of antihistamines to COVID-19 vaccine recipients prior to vaccination to prevent allergic reactions is not recommended. Antihistamines do not prevent anaphylaxis, and their prophylactic use may mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis. Because anaphylaxis may recur after patients begin to recover, **monitoring in a medical facility for at least four hours** is advised, even after complete resolution of symptoms and signs.

- In adults, administer a 0.3 mg intramuscular dose using a premeasured or prefilled syringe, or an autoinjector, in the mid-outer thigh (through clothing if necessary).
- The maximum adult dose is 0.5 mg per dose.
- Epinephrine dose may be repeated approximately every 5-15 minutes if symptoms do not improve or if they return while waiting for EMS. The number and timing of epinephrine doses should be recorded and communicated to EMS.
- Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.

»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, are required to be reported to the Vaccine Adverse Event Reporting System (VAERS) under Emergency Use Authorization. Information on how to submit a report to VAERS is available at <u>https://vaers.hhs.gov</u> or by calling 1-800-822-7967.



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Additional resources

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u>

ACIP Rapid overview: Emergent management of anaphylaxis in adults <u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html#t-02</u>

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html</u>

Immunization Action Coalition: Medical Management of Vaccine Reactions in Adults <u>https://www.immunize.org/catg.d/p3082.pdf</u>

Pfizer-BioNTech COVID-19 vaccine prescribing information <u>https://www.fda.gov/media/144413/download</u>

Moderna COVID-19 Vaccine prescribing information https://www.fda.gov/media/144637/download

Janssen COVID-19 Vaccine (Johnson & Johnson) prescribing information <u>https://www.fda.gov/media/146305/download</u>