Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination

Summary of recent changes (last updated March 3, 2021)

- Considerations broadened to include use of Janssen (Johnson & Johnson) COVID-19 vaccine.

Key Points

Under the Emergency Use Authorizations for COVID-19 vaccines, 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. These interim considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination.

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccine Sites [3 pages]

Recognizing and Responding to Anaphylaxis [1 page, 508]

Overview

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported rarely following COVID-19 vaccination. These interim considerations provide recommendations on assessment and management of anaphylaxis following COVID-19 vaccination. Detailed information on CDC recommendations for vaccination, including contraindications and precautions to vaccination, can be found in the Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. Patients should be screened prior to receipt of each vaccine dose, and those with a contraindication should not be vaccinated. A COVID-19 prevaccination questionnaire [6 pages] is available to assist with screening.

Personnel, 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 people (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.

Should be available at all locations	If feasible, include at locations (not required)
Epinephrine (e.g., prefilled syringe, autoinjector)*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine, cetirizine)†	Oxygen
Blood pressure monitor‡	Bronchodilator (e.g., albuterol)
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. People 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 epinephrine (e.g., EpiPen ®). 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 people 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.

Routine observation periods following COVID-19 vaccination*

CDC currently recommends the following observation periods after vaccination:

- 30 minutes for:
  - People with a history of an immediate allergic reaction of any severity to another vaccine or injectable therapy.
  - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination).
  - People with a history of anaphylaxis due to any cause.
- 15 minutes for: All other persons

* Note: People may be observed for longer, based on clinical concern. For example, if a person develops itching and swelling confined to the injection site during their post-vaccination observation period, this period may be extended to assess for development of any hypersensitivity signs or symptoms consistent with anaphylaxis (described below).

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, 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

Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips).

Symptoms of anaphylaxis 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. In addition, symptoms of anaphylaxis might be more difficult to recognize in people with communication difficulties, such as long-term care facility residents with cognitive impairment, those with neurologic disease, or those taking medications that can cause sedation. Not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions.

If anaphylaxis is suspected, administer epinephrine as soon as possible, contact emergency medical services, and transfer patients to a higher level of medical care. In addition, instruct patients to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination location.

Management of anaphylaxis at a COVID-19 vaccination location

If anaphylaxis is suspected, take the following steps:

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

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 in a patient with anaphylaxis should only be administered *after* epinephrine. 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.

Considerations for anaphylaxis management in special populations

Older adults, including long-term care facility residents

There are no contraindications to the administration of epinephrine for the treatment of anaphylaxis. Although adverse cardiac events, such as myocardial infarction or acute coronary syndrome, have been reported in some patients who received epinephrine for treatment of anaphylaxis (particularly among older adults with hypertension and/or atherosclerotic heart disease), epinephrine is the first-line treatment for anaphylaxis. It is important that locations providing vaccination to older adults, including long-term care facility residents, have staff members available who are able to recognize the signs and symptoms of anaphylaxis. This will help not only to ensure appropriate and prompt treatment for patients with anaphylaxis, but also to avoid unnecessary epinephrine administration to patients who do not have anaphylaxis.

Pregnant people

Pregnant people with anaphylaxis should be managed the same as non-pregnant people. As with all patients with anaphylaxis, they should be transported to a medical facility where they and their fetus can be closely monitored to ensure adequate perfusion.

Homebound people requiring home vaccination services

Homebound people who might be at increased risk for anaphylaxis following vaccination (i.e., people with a precaution to vaccination or those with a history of anaphylaxis due to any cause) should consider whether they could be vaccinated in a setting where medical care is immediately available if they experience anaphylaxis following vaccination. If home vaccination is the only option for these people and, through risk assessment, it is determined that the benefits of vaccination outweigh the potential risk for anaphylaxis, home vaccination providers should ensure they are able to manage anaphylaxis. This includes appropriate screening; post-vaccination observation; medications and supplies; staff qualifications for recognition and treatment of anaphylaxis; ability to call for EMS; and location in an area where EMS is available.

Patient counseling

Patients who experience a severe allergic reaction (e.g., anaphylaxis) or an immediate allergic reaction (i.e., hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress, or anaphylaxis that occur within four hours following administration) of any severity after a dose of a COVID-19 vaccine should be instructed not to receive additional doses of the vaccine; if the dose received was an mRNA COVID-19 vaccine, the patient should not receive additional doses of either Pfizer-BioNTech or Moderna COVID-19 vaccine. In addition, patients may be referred to an allergist-immunologist for appropriate work-up and additional counseling.

Reporting anaphylaxis

Report any adverse events, including anaphylaxis, that occur in a recipient following COVID-19 vaccination, 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. Refer to the VAERS website or call 1-800-822-7967for more information on how to submit a report to VAERS. 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 and complete a VAERS report. Learn more about v-safe on CDC's website.

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
- Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)

References

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

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.

Shaker MS, et al. "Anaphylaxis—a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis." Journal of Allergy and Clinical Immunology 2020;145(4):1082-1123. doi: 10.1016/j.jaci.2020.01.017.

Previous Updates

Revisions made February 10, 2021

- Personnel, medications, and supplies for assessing and managing anaphylaxis: This section has been expanded to indicate that trained personnel qualified to recognize and treat symptoms of anaphylaxis should be available at vaccination locations at all times. The recommendations for medications and supplies have also been updated.
- Early recognition of anaphylaxis: This section has been updated to provide additional information related to anaphylaxis symptoms.
- Special populations: This section has been updated with considerations for anaphylaxis management of homebound people requiring home vaccination services.

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