LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 21-11: Preparing for Potential Anaphylaxis Management After a COVID-19 Vaccination**
Origination Date: *February 3, 2021*	**Revision Dates (List All Revision Dates):**

Interim Considerations: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination: 02/03/2021

COVID-19 Vaccination Severe/Allergic Reaction Reporting

Immediately (24/7) report severe COVID-19 vaccine reactions requiring hospitalization to the Office of Public Health (OPH) at 800-256-2748. Staff are available 24/7 to take information.

Severe Allergic Reaction Management following COVID-19 Vaccination
Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported 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 mRNA COVID-19 Vaccines Currently Authorized in the United States.

These interim 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 COVID-19 vaccine.

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.

Observation period following COVID-19 vaccination
CDC currently recommends that persons without contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods:

- 30 minutes: Persons with a history of 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, 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

Symptoms of anaphylaxis might be more difficult to recognize in persons 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. Persons with communication difficulties should therefore be monitored closely for the signs and symptoms of anaphylaxis listed above after receiving an mRNA COVID-19 vaccine and should also be monitored for more non-specific signs of possible anaphylaxis including flushing, sudden increase in secretions (from eyes, nose, or mouth), coughing, trouble swallowing, agitation, or acute change in mental status.

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. 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 or more than one body system (e.g., cardiovascular, gastrointestinal) 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, emergency medical services should be contacted, and patients should be transferred to a higher level of medical care. In addition, patients should be instructed 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 site.

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.

The following emergency equipment should be immediately available to the clinical team assessing and managing anaphylaxis.

Medications and supplies for assessing and managing 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 auto-injector 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 more often) 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 at least several 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 sites providing vaccination to older adults, including long-term care facility residents, have healthcare personnel on hand who are able to recognize the signs and symptoms of anaphylaxis. This will help to not only ensure appropriate and prompt treatment in

patients with anaphylaxis, but also to avoid unnecessary epinephrine administration in patients who do not have anaphylaxis.

Pregnant people
Pregnant people with anaphylaxis should be managed the same as non-pregnant people. They should be closely monitored to ensure adequate perfusion, and their fetus should be closely monitored as well, as appropriate.

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: /vsafe

Additional resources
Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States
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
Moderna 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.
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.