CDC Core COVID-19 Vaccine Competencies

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1. **EUA Video** - 2 minutes https://youtu.be/iGkwaESsGBQ
    a. The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious that causes COVID-19.

2. Clinical Considerations

a. Review policies and procedures

b. Under the EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: ages ≥16 years
- Moderna: ages ≥18 years
- Janssen: ages ≥18 years

c. COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose.

Vaccine	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	100 µg	0.5 ml	2	1 month (28 days)
Janssen	5×10^{10} viral particles	0.5 ml	1	N/A

A single, valid vaccination series (i.e., either a two-dose mRNA COVID-19 vaccine series or a single dose of Janssen COVID-19 vaccine) should be administered. People are not recommended to receive more than one complete COVID-19 vaccination series.

d. The second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines

a. May be administered up to 6 weeks (42 days) after the first dose. Currently, only limited data are available on efficacy of mRNA COVID-19 vaccines administered beyond this window.

e. Strategies to ensure that patients receive the second dose with the appropriate product and interval between doses include:

a. Providing COVID-19 vaccination record cards to vaccine recipients, asking recipients to bring their card available for their appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the card with their phone)
b. Encouraging vaccine recipients to enroll in **v-safe**, a free smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins as well as second-dose reminders
c. Encouraging vaccine recipients to enroll in VaxText[SM], a free text-message-based platform that provides COVID-19 vaccination second-dose reminders
d. Recording vaccine administration information in the patient's medical record
e. Making an appointment for the second dose to increase the likelihood that patients will present for the second dose

f. Co-administration with other vaccines

a. None of the currently authorized COVID-19 vaccines are live virus vaccines. Because data are lacking on the safety and efficacy of COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine

g. Booster Doses

a. The need for and timing for COVID-19 booster doses have not been established. No additional doses are recommended at this time.

h. COVID-19 Vaccination and SARS-CoV-2 Infection

a. Data from clinical trials indicate that the currently authorized COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection. People should be offered vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
b. Vaccination of people with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation.

i. Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks

a. COVID-19 vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis to prevent SARS-CoV-2 infection in a person with a known exposure.

j. Considerations for vaccination of people with certain underlying medical conditions

a. Any currently authorized COVID-19 vaccine can be administered to people with underlying medical conditions who have no contraindications to vaccination.
b. Immunocompromised People
    i. The currently authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
    ii. Ideally, COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies.

k. Contraindications

a. CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:
    i. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
    ii. Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

3. Administration Requirements

a. Patient Counseling

- Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms.
- Depending on vaccine product (Pfizer-BioNTech vs. Moderna), age group, and vaccine dose, approximately 80–89% of vaccinated people experience at least one local symptom and 55–83% experience at least one systemic symptom following vaccination.
- Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset.
- Overall, symptoms are more frequent and severe following the second dose and among younger people compared with older people (i.e., aged >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]).
- People with prior SARS-CoV-2 infection may be more likely to experience symptoms such as fever, chills, and myalgia after the first mRNA COVID-19 vaccine dose.
- Unless people have a contraindication to vaccination, they should be encouraged to complete the series to optimize protection against COVID-19 even if they experience local or systemic symptoms following the first dose.
- For all currently authorized COVID-19 vaccines, antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.

- Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines to COVID-19 vaccine recipients before vaccination to prevent allergic reactions is not recommended. Antihistamines do not prevent anaphylaxis, and their use might mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis.

a. 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
    - 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

4. Anaphylaxis guidance

a. 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.
b. 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.
c. 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
    - location in an area where EMS is available
d. Should have **at least three doses** of epinephrine available at all times.
e. 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 (**see Attachment #1**)

f. 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).
g. Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear.
h. 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 0.5 mg intramuscular dose in the mid-outer thigh (through clothing if necessary).
    - 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.
i. 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.

5. Vaccination documentation and reporting requirements

a. Health care providers are required by law to record certain information in a patient's medical record.

6. Required and additional information for vaccine recipients

a. Vaccinated people who subsequently develop COVID-19
    - For vaccinated people who subsequently experience COVID-19, prior receipt of a COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.
    - If a person is fully vaccinated (i.e., ≥2 weeks after completion of a two-dose mRNA series or single dose of Janssen vaccine) and tests positive for SARS-CoV-2, healthcare providers and local health departments are encouraged to request the specimen be held and to report the case to their state health department. CDC will work with the state health department to collect information about the case. In addition, information about these cases should be reported to VAERS.

b. At this time, vaccinated people should continue to follow current guidance to protect themselves and others, including wearing a mask, staying at least 6 feet away from others, avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands often, following CDC travel guidance, and following any applicable workplace or school guidance, including guidance related to personal protective equipment use for SARS-CoV-2 testing.

c. Vaccinated people with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet all of the following criteria:
    - Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
    - Are within 3 months following receipt of the last dose in the series
    - Have remained asymptomatic since the current COVID-19 exposure

Reference: CDC Website