

March 10, 2021

Health Notice for District of Columbia Health Care Providers
Updated Guidance on the COVID-19 Messenger RNA Vaccines

SUMMARY:

In December of 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech and Moderna COVID-19 vaccines in the United States. The District of Columbia Department of Health (DC Health) continues to implement distribution administration recommendations as outlined in the District’s *COVID-19 Vaccination Plan*. The vaccines have been shown to be safe and effective as determined by the data from the manufacturers and large-scale clinical trials of more than 70,000 individuals drawn from diverse ethnic and socioeconomic backgrounds. Current evidence demonstrates that the known and potential benefits of the vaccine outweigh the known and potential harms associated with COVID-19. This health notice provides information on safe administration, clinical considerations, reporting requirements, and highlights important resources for healthcare providers.

BACKGROUND:

The Advisory Committee on Immunization Practices (ACIP) has provided interim recommendations to the Centers for Disease Control and Prevention (CDC) for administration of the Pfizer-BioNTech and Moderna COVID-19¹ vaccines to prevent COVID-19. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. The vaccines’ reported efficacies in preventing symptomatic COVID-19 in clinical trials are 95% for the Pfizer-BioNTech vaccine and 94% for the Moderna vaccine. Current data suggests full efficacy of the vaccine 14 days after the second dose is administered. Further study is needed to answer multiple outstanding questions, including what antibody titer levels are consistent with SARS-CoV-2 immunity, duration of vaccine-induced immunity, and whether the vaccine prevents asymptomatic SARS-CoV-2 infection. Since it is still not proven that the vaccine prevents asymptomatic infection, the possibility exists that vaccinated persons could still spread the virus to others. For this reason, **it is important that vaccinated individuals be instructed to continue following mitigation measures such as wearing masks and social distancing in public to protect those around them.** Duration of vaccine-induced immunity at this point can be said to be at least 90 days, but this is continuously being evaluated. Detailed information on recommendations for fully vaccinated people will be published on www.coronavirus.dc.gov.

VACCINE COMPARISON OVERVIEW

PFIZER-BioNTech VACCINE	MODERNA VACCINE
mRNA vaccine, 2 doses (0.3 ml each), 21 days apart	mRNA vaccine, 2 doses (0.5 ml each), 28 days apart
Reported and peer-reviewed 95% effective	Reported and peer-reviewed 95% effective
Authorized for age 16 and up	Authorized for age 18 and up
Requires ultra-cold storage (at least -60° Celsius)	Requires standard frozen storage temperatures (between -25° to -15 ° Celsius)
Mixed with diluent (saline)	No on-site reconstitution needed
5 doses per vial	10 doses per vial

¹ These guidelines only apply to the currently authorized mRNA vaccine products (Pfizer-BioNTech and Moderna COVID-19 vaccines). Updates will be provided when more information is available, or if additional vaccine products are authorized.

VACCINE CONTRAINDICATIONS

- The mRNA vaccines should not be administered to:
 - Individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccines.
 - Individuals who experienced a severe allergic reaction to a previous dose of the vaccine.
 - Individuals outside the authorized age range.

VACCINE ADMINISTRATION

- Individuals should not be scheduled to receive the second dose earlier than recommended.
 - Second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are considered acceptable.
 - Doses inadvertently administered earlier than the grace period do not need to be repeated.
- **UPDATE:** The maximum recommended interval between the first and second doses is 6 weeks (42 days). There is limited data available regarding vaccine efficacy beyond this 6-week window. However, if more than 6 weeks has passed since a patient's first dose of the vaccine, restarting the vaccine series is not currently recommended.
- Vaccine products are NOT currently interchangeable.
 - The safety and efficacy of administering a mixed COVID-19 vaccine product (i.e., first and second dose not from the same manufacturer) has not been evaluated. Both doses in the series should be the same product.
 - If two different products are administered inadvertently, no further dosing is recommended.
- COVID-19 vaccines are NOT currently recommended to be co-administered with other vaccines.
 - The safety and efficacy of administering a COVID-19 vaccine along with another vaccine has not been evaluated.
 - A minimum of 14 days is recommended before or after an individual has received any other vaccine.
- COVID-19 vaccines are NOT currently recommended for:
 - Individuals with an active COVID-19 infection. Vaccination should occur after isolation is completed. If desired, the individual may wait 90 days to vaccinate.
 - Individuals under quarantine for COVID-19 in the community, to avoid potentially exposing others. Vaccination should occur after quarantine is completed.
 - Persons who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment in the previous 90 days.
 - Managing a COVID-19 outbreak or as post-exposure prophylaxis
- Vaccine Fact Sheets may be found at [fda.gov/media/144414/download](https://www.fda.gov/media/144414/download) (Pfizer-BioNTech) and [modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf](https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf) (Moderna).

CLINICAL CONSIDERATIONS

The mRNA COVID-19 vaccines may be given to individuals with chronic or underlying health conditions provided they have no contraindication for administration. Similar safety and efficacy profiles were demonstrated in clinical trials in individuals with certain underlying medical conditions including those at highest risk for severe COVID-19 infection as compared to the general population.

- **Immunocompromised individuals** with no contraindications may receive the vaccine with the following in mind:
 - Immunocompromised individuals are generally at increased risk for severe COVID-19.
 - Persons with stable HIV infection were included in the vaccine trials, but there is currently insufficient data to establish vaccine safety and efficacy in individuals with HIV infection or other immunocompromising conditions.

- Individuals should be counseled about the unknown safety and efficacy profiles in the immunocompromised, the potential for decreased immune response to the vaccination, and the need to continue the same everyday prevention measures utilized prior to receiving the vaccine.
- Re-vaccination is not currently recommended once immune competence is regained such as during chemotherapy or after discontinuation of immunosuppressive drugs.
- **Individuals with autoimmune conditions** and no contraindications may receive the vaccine with the following in mind:
 - No data is currently available that establishes safety and efficacy in individuals with autoimmune conditions.
 - No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo.
- **Pregnant individuals** or those trying to become pregnant may receive the vaccine with the following in mind:
 - Potential risks of mRNA vaccines to the pregnant individual and the fetus are unknown due to lack of completed clinical trials in this population.
 - Experts believe that mRNA vaccines are unlikely to pose a risk to pregnant individuals or fetuses because mRNA vaccines are not live vaccines. The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell.
 - The decision to receive the vaccine should consider the level of community spread, the pregnant individual's level of risk, the efficacy and side effects of the vaccine, and the lack of data during pregnancy.
 - Pregnant individuals receiving the vaccine who may develop fever should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes.
- **Lactating individuals** may receive the vaccine with the following in mind:
 - There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.
 - mRNA vaccines are not thought to be a risk to the breastfeeding infant.
- **Guillain-Barré syndrome (GBS)**
 - To date, no cases of GBS have been reported following vaccination in clinical trials.
 - The ACIP generally does not include GBS as a contraindication or precaution for vaccination.
 - Individuals with a history of GBS may receive the vaccine provided they have no other contraindications.
- **Bell's palsy**
 - Cases of Bell's palsy were reported following the vaccine clinical trials; however, the FDA determined the frequency was within normal expectations for any population.
 - Currently there is no causal evidence to suggest these occurrences were related to the vaccine.
 - Individuals with a history of Bell's palsy may receive the vaccine provided they have no other contraindications.
- Please see the table "*Triage of persons presenting for mRNA COVID-19 vaccination*" at the end of this document.

VACCINE SAFETY

Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about possible post-vaccination symptoms, 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).

- 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.
- Symptoms are more frequent and severe following the second dose and among younger persons compared to older persons.
- Unless persons develop a contraindication to vaccination, they should be encouraged to complete the series even if they develop local or systemic symptoms following the first dose.
- Antipyretics (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration is not currently recommended, as information on the impact on mRNA COVID-19 vaccine-induced antibody response is unknown.
- Encourage patients to utilize [*V-Safe*](#).
 - *V-Safe* is a new, voluntary, smartphone-based tool developed by the CDC 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 enter into the Vaccine Adverse Event Reporting System (VAERS). More information on VAERS can be found in the reporting section of this document.

Anaphylaxis

While rare, there have been reports of anaphylactic reactions following administrations of the COVID-19 vaccine.

- A history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) is considered a precaution but not a contraindication.
 - Risk of exposure, and risk of severe disease or death due to COVID-19 should be considered.
 - If the person has a recent history of COVID-19 infections, consider deferral for 90 days from infection to allow for more information to be learned about the risk of anaphylaxis.
 - Recommend vaccination at a site where appropriate medical care for anaphylaxis is immediately available.
- **ALL** individuals should be observed after receiving the vaccine.
 - **30 minutes** for individuals with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and/or a history of anaphylaxis due to any other cause
 - **15 minutes** for all other individuals
- Symptoms often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear.
 - Inform patients on what to look for and what to do after leaving the vaccine clinic.
- Sites providing vaccination must have healthcare personnel trained and available to recognize the signs and symptoms of anaphylaxis and provide initial treatment.

REPORTING

Vaccine Administration Reporting

- Vaccine administration must be reported to the District of Columbia Immunization Information System, ([DOCIIS](#)) **within 24 hours of administration**.
- DOCIIS is the Immunization Program’s key tool for tracking individual- and population- level immunization data in DC. Health care providers use DOCIIS to check immunization history to ensure their patients receive recommended vaccines as prescribed, and schools and LCDCs use

DOCIIS to track compliance with immunization laws and regulations (e.g. DC Law 3-20). For more information on DOCIIS please visit dchealth.dc.gov/dociis.

- **ALL** vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS) as described below.

Adverse Event Reporting

Adverse events that occur in a recipient following mRNA COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the Food and Drug Administration to report the following that occur after mRNA COVID-19 vaccination under Emergency Use Authorization:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is 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 vaers.hhs.gov or by calling 1-800-822-7967

ADDITIONAL RESOURCES

- **District of Columbia's COVID-19 Vaccine website** coronavirus.dc.gov/vaccine
- **District of Columbia's COVID-19 Vaccination Plan:** coronavirus.dc.gov/sites/default/files/dc/sites
- **CDC's COVID-19 Vaccine Website:** www.cdc.gov/vaccines/covid-19/index.html
- Emergency Use Authorizations of the mRNA vaccines on the FDA website: fda.gov/media/144413/download and fda.gov/media/144637/download.
- **Full ACIP interim recommendations** for use of the vaccines: www.cdc.gov/mmwr/volumes/69/wr/mm6950e2 and <https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1>.
- **More information on clinical considerations for vaccine administration:** cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

The guidelines above will continue to be updated as the outbreak evolves. Please visit coronavirus.dc.gov/vaccine for the most current information.

Please contact DC Health regarding COVID-19 at:
Phone: 202-576-1117 Fax: 202-442-8060 | Email: coronavirus@dc.gov

Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccinet Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccinet 	<p>Among people without a contraindication, a history of:</p> <ul style="list-style-type: none"> Any immediate allergic reaction* to other vaccines or injectable therapies‡ <p>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#</p>	<p>Among people without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> Allergy to oral medications (including the oral equivalent of an injectable medication) History of food, pet, insect, venom, environmental, latex, etc., allergies Family history of allergies
<p>Actions:</p> <ul style="list-style-type: none"> Do not vaccinate. Consider referral to allergist-immunologist. Consider other vaccine alternative.† 	<p>Actions:</p> <ul style="list-style-type: none"> Risk assessment Consider referral to allergist-immunologist 30-minute observation period if vaccinated 	<p>Actions:</p> <ul style="list-style-type: none"> 30-minute observation period: people with history of anaphylaxis (due to any cause) 15-minute observation period: all other people

† See [Appendix C](#) for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡ Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a consultation from the [Clinical Immunization Safety Assessment COVIDvax](#) project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Table above can be found at cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B