DC | HEALTH
GOVERNMENT OF THE DISTRICT OF COLUMBIA

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

May 25, 2021

Health Notice for District of Columbia Health Care Providers
Update: 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 vaccines have been shown to be safe and effective in large-scale clinical trials involving more than 70,000 individuals. Vaccines are now widely available. Real-world clinical experience with the COVID-19 vaccines continues to confirm their safety and efficacy, and have allowed for fully vaccinated person to resume normal activities. 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 COVID-19 vaccine in persons age 12 and older and the Moderna COVID-19 vaccine in persons age 18 and older.[1] 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 adult clinical trials are 95% for the Pfizer-BioNTech vaccine and 94% for the Moderna vaccine. Efficacy for the Pfizer vaccine in ages 12-15 is 100% for preventing symptomatic COVID-19. Evidence is accumulating that the COVID-19 vaccines also prevent asymptomatic SARS-CoV-2 infection, which is critical for containments of the spread of COVID-19. Data suggests full efficacy of COVID-19 vaccines 14 days after the second dose is administered. Immunity from the mRNA COVID-19 vaccines is currently known to last at least 6 months.

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 12 and up	Authorized for age 18 and up
Freezer: Between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks Refrigerator: Between 2°C and 8°C (36°F and 46°F) for up to 31 days.	Freezer: Between -50°C and -15°C (-58°F to 5°F) Refrigerator: Between 2°C and 8°C (36°F and 46°F) for up to 30 days
Mixed with diluent (saline)	No on-site reconstitution needed

VACCINE CONTRAINDICATIONS

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

VACCINE ADMINISTRATION

- 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.
- If more than 6 weeks has passed since a patient's first dose of an mRNA vaccine:
  - It is not recommended to restart the vaccine series.
  - The patient should still receive the 2nd dose of the mRNA vaccine as soon as possible.

[1] These guidelines 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 products are not currently interchangeable.
  - The safety and efficacy of administering a mixed mRNA 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.
  - The safety and efficacy of the Johnson & Johnson/Janssen vaccine administered after one dose of an mRNA vaccine has not been evaluated. However, it may be an option for a patient who is unable to receive the second dose of an mRNA vaccine series (e.g. a contraindication) to receive a single dose of the Johnson & Johnson/Janssen vaccine. At that point, the patient would be considered fully vaccinated from the single-dose vaccine.
- **UPDATE:** No time interval is required between the administration of the COVID-19 vaccine and other vaccines. The COVID-19 vaccine may also be **co-administered** with other vaccines.
  - Previous recommendations against co-administration and recommendation for a 14-day interval between the COVID-19 vaccine and other vaccines were made from an abundance of caution, and not because of any known safety or immunogenicity issues.
  - Note: It is not currently known whether the COVID-19 vaccine may be more reactogenic when co-administered with other vaccines, including when given with other vaccines known to be reactogenic (e.g., live vaccines, adjuvanted vaccines). Healthcare providers should use clinical judgment to weigh the risk of vaccine reactogenicity with risk of delaying needed vaccinations in a given patient.
  - Choose different injection sites when administering more than one vaccine. When administering more than one vaccine associated with local reactions (e.g., tetanus-toxoid-containing, adjuvanted vaccines), choose injection sites on different limbs.
- COVID-19 vaccines are NOT currently recommended for:
  - Patients with an active COVID-19 infection. Vaccination should occur after isolation is completed. If desired, the patient may wait 90 days to vaccinate.
  - Patients under quarantine for COVID-19 in the community, to avoid potentially exposing others. Vaccination should occur after quarantine is completed.
  - Patients 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 (Pfizer-BioNTech) and modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf (Moderna).
- Please see the table "*Triage of persons presenting for COVID-19 vaccination*" at the end of this document for more information.

VACCINATION OF SPECIAL PATIENT POPULATIONS

The mRNA COVID-19 vaccines may be given to patients 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 medical comorbidities including those at highest risk for severe COVID-19 infection as compared to the general population.

- **Immunocompromised patients** with no contraindications may receive the vaccine with the following in mind:
  - People with stable HIV infection were included in the vaccine trials, but data on safety and efficacy in individuals with HIV or other immunocompromising conditions is limited.
  - Immunocompromised patients are generally at increased risk for severe COVID-19.
  - Patients 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.
  - Consistent with standard practice recommendations for other vaccines, the COVID-19 vaccine series should be completed at least 14 days prior to starting immunosuppressive therapies.
- **Patients with autoimmune conditions** and no contraindications may receive the vaccine.

- 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 patients** have an increased risk of developing severe illness from COVID-19 compared to non-pregnant patients. Pregnant patients who contract COVID-19 are also at risk for preterm birth and may be at increased risk for other pregnancy complications/adverse outcomes like preeclampsia, coagulopathy, and stillbirth.
  - Pregnant patients can be vaccinated.
  - Safety and efficacy data for pregnant patients and their babies remain limited. Vaccine clinical trials for pregnant women are in progress. Recent data released by the CDC from 3 vaccine-safety related databases (VAERS, v-safe active surveillance, and v-safe pregnancy registry) have not identified any safety issues.
  - Based on current knowledge about vaccines, the COVID-19 vaccines are unlikely to pose a risk to pregnant patients or their fetuses.
  - Other issues for the pregnant patient and her healthcare provider to consider when making the decision to get the COVID-19 vaccination are the level of community spread and the patient's personal risk of contracting COVID-19.
  - Pregnant patients receiving the vaccine should be counseled to take acetaminophen if they develop fever after vaccination. Fever has been associated with adverse pregnancy outcomes.
- **Patients trying to become pregnant** can be vaccinated.
  - There is no need to avoid pregnancy after vaccination.
  - **There is no evidence that COVID-19 vaccines affect future fertility.**
- **Lactating patients** may receive the vaccine with the following in mind:
  - There are no data on the safety of COVID-19 vaccines in lactating patients 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)**
  - Patients with a history of GBS may receive the vaccine.
  - To date, no cases of GBS have been reported following vaccination with the mRNA COVID-19 vaccines.
  - GBS is generally not considered a contraindication for vaccination.
- **Bell's palsy**
  - Cases of Bell's palsy were reported following the vaccine clinical trials; however, per the FDA, there is currently insufficient evidence for a causal relationship between the vaccine and Bell's Palsy. This issue will continue to be monitored.
  - Patients with a history of Bell's palsy may receive the vaccine.

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). Post-vaccination symptoms are similar in adults and children 12-15.

- 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[2]
  - Frequency of post-vaccination symptoms in adults aged 18 and older:
    - 80-89% experience at least one local symptom.
    - 55-83% experience at least one systemic symptom.
  - Frequency of post-vaccination symptoms is higher in children 12-15.
    - 90.9% experience at least one local symptom.
    - 90.7% experience at least one systemic symptom.
    - Adolescents are more likely to experience syncope shortly after vaccination

[2] In this context, "older persons" refers to: older than 55 (for the Pfizer vaccine) and 65 and older (for the Moderna vaccine)

compared to adults. This is not specific to the COVID-19 vaccine**.** Healthcare providers administering the COVID-19 vaccine are advised to be aware of this and to plan accordingly (e.g., have young patients sit or lie down during their observation period, have procedures in place to manage syncopal reactions).

- Unless patients 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.
- **UPDATE:** In May 2021, the ACIP COVID-19 Vaccine Safety Technical (VaST) Work Group indicated that reports of myocarditis that occurred following mRNA vaccine administration were being investigated. There were relatively few reports that were identified predominantly in adolescents and young adults, more in males than females, more often after the 2nd dose, and typically 4 days after vaccination. Most cases were mild and treated with standard clinical care. At this time the reports of myocarditis have not differed from expected baseline rates, but are continuing to be monitored.
- **UPDATE:** Thrombotic thrombocytopenic syndrome (TTS), which is a rare but serious clotting syndrome similar to heparin- induced thrombocytopenia (HIT) associated with the Johnson & Johnson/Janssen vaccine, has not been reported with either of the mRNA vaccines.
- Encourage patients to utilize *V-Safe.* This is very important to allow for more real-world data to be gathered on vaccine side effects.
  - *V-Safe* is a 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** patients should be observed after receiving the vaccine.
  - 30 minutes for patients 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 patients
- 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

It is critically important for HCPs to identify and report and adverse events associated with the vaccine. 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 patients presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†	Among people without a contraindication, a history of: • Any immediate allergic reaction* to other vaccines or injectable therapies‡ 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.#	Among people without a contraindication or precaution, a history of: • 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
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Actions: • 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