



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD, MSc
Commissioner

December 24, 2020

Dear Colleague:

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the [Moderna](#) vaccine against COVID-19 on December 18, and the Advisory Committee on Immunization Practices (ACIP) voted to approve use of this vaccine on December 19. Vaccine efficacy was estimated at 94%. High efficacy ($\geq 86\%$) was observed across age, sex, and race/ethnicity demographics. The two-dose vaccine is authorized for use in individuals ages 18 years and older. The purpose of this letter is to summarize ACIP recommendations regarding the vaccine, including details of administration in special populations.

Vaccine Program Enrollment

The NYC Department of Health and Mental Hygiene (NYC Health Department) is now enrolling private practices, independent pharmacies and other facilities that will immunize individuals in the NYC COVID-19 Vaccination Program. Enrollment in the program is required for COVID-19 vaccine delivery. If your facility chooses to participate, you will need to complete the COVID-19 Vaccination Program Provider Agreement in the online Citywide Immunization Registry (CIR). Access to the Provider Agreement is now available, and instructions may be found in the provider [enrollment letter](#).

Recommendation for use of Moderna COVID-19 vaccine:

The Moderna COVID-19 vaccine is recommended for people ages 18 and older in the United States (U.S.) under the EUA. The vaccine is administered intramuscularly as a series of two doses (0.5 mL) four weeks apart. Administration of the second dose within a four-day grace period (i.e., Day 24 to 28) is considered valid; however, if the second dose is administered earlier than Day 24, it does not need to be repeated. If more than 28 days have passed since the first dose, the second dose should be administered at the earliest opportunity (and the series does not need to be restarted).

The Moderna COVID-19 vaccine is not interchangeable with other COVID-19 vaccines. Individuals who have received one dose of Moderna COVID-19 vaccine should receive a second dose of Moderna vaccine to complete the vaccination series. However, if one dose each of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

Special Populations

Individuals with underlying medical conditions

Vaccines may be administered to individuals with underlying medical conditions who have no contraindications to vaccination. Phase 2 and 3 clinical trials demonstrate similar safety and efficacy profiles in people with underlying medical conditions, such as obesity and diabetes, compared to individuals without comorbidities.

Immunocompromised individuals

Data are not currently available to establish the safety and efficacy of vaccine in individuals with immunocompromising conditions. These individuals may still receive mRNA COVID-19 vaccination unless otherwise contraindicated. They should be counseled about the unknown vaccine safety and efficacy profiles in immunocompromised individuals and the potential for a reduced immune response to the vaccine. They should continue to follow all current guidance to protect themselves against COVID-19.

People with autoimmune conditions

No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials. People with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

People with a history of Guillain-Barré syndrome (GBS)

To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials. People with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following vaccination should be reported to the [Vaccine Adverse Event Reporting System](#) (VAERS).

People with a history of Bell's palsy

People with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS.

People who are pregnant

There are no available data on the safety of mRNA COVID-19 vaccines in people who are pregnant. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant or to the fetus they are carrying. People who are pregnant and who are members of a group recommended to receive COVID-19 vaccine may choose to be vaccinated. Discussion with a health care provider may be helpful. Considerations for discussion are presented in the Centers for Disease Control and Prevention's (CDC's) [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](#). People who are pregnant who experience fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes. Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended. Those who are trying to become pregnant do not need to avoid pregnancy after mRNA COVID-19 vaccination.

People who are breastfeeding or lactating

There are no data on the safety of COVID-19 vaccines in people who are lactating or the effects of mRNA vaccines on an infant being breastfed or on milk production and excretion. However, mRNA vaccines are not live virus vaccines and are not thought to be a risk to an infant who is

being breastfed. People who are lactating and are members of a group recommended to receive COVID-19 vaccination may choose to be vaccinated.

Adolescents

Children and adolescents younger than 18 years of age are not authorized to receive the Moderna COVID-19 vaccine at this time.

Individuals with current COVID-19 or who had COVID-19 within the last 90 days

Vaccination should be deferred in individuals with current symptomatic or asymptomatic SARS-CoV-2 infection until criteria have been met to discontinue isolation. Because evidence suggests that reinfection is uncommon in the 90 days after initial infection, individuals with documented acute SARS-CoV-2 infection in the preceding 90 days may be vaccinated after they have recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation or they may choose to delay vaccination until near the end of the 90-day period.

Persons with a known SARS-CoV-2 exposure

For individuals with a known SARS-CoV-2 exposure, vaccination should be deferred until the quarantine period has ended unless the person resides in a congregate residential setting. Residents of congregate settings with a known SARS-CoV-2 exposure may be vaccinated but precautions should be taken to limit mixing of these individuals with other residents or staff.

Individuals with history of COVID-19

Previous SARS-CoV-2 infection, whether symptomatic or asymptomatic, is not considered a contraindication to vaccination. Data from Phase 2 and 3 clinical trials suggest that vaccination is safe and likely efficacious in these individuals. Viral or serologic testing is not recommended for the purpose of vaccine decision-making. See “Individuals with current COVID-19” above for recommendations on those whose history of COVID-19 was within the last 90 days.

Individuals who received passive antibody therapy for COVID-19

There are currently no data on the safety or efficacy of vaccination in individuals who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Vaccination should be deferred for at least 90 days in these individuals to avoid interference of the treatment with vaccine-induced immune responses.

Coadministration with other vaccines

The Moderna COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration of any other vaccines because there is a lack of data on the safety and efficacy of this vaccine being administered simultaneously with other vaccines. If the Moderna COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses of either vaccine do not need to be repeated. The second dose of the Moderna vaccine (if not already given) should be administered 28 days after the first dose.

Reactogenicity

Before vaccination, providers should counsel vaccine recipients about expected local post-vaccination symptoms (e.g., pain, swelling, erythema at the injection site, localized axillary

lymphadenopathy on the same side as the vaccinated arm) and systemic post-vaccination symptoms (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 one to three days of onset. Generally, these symptoms were more common and more prominent after the second dose than after the first dose, and in participants who were younger (ages 18 to 64), compared to participants who were older (ages 65 and above). Unless a person develops a contraindication to vaccination (e.g., they are determined to have had a severe allergic reaction such as anaphylaxis to an mRNA COVID-19 vaccine), they should be encouraged to complete the series, even if they develop post-vaccination symptoms, in order to optimize protection against COVID-19. Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms. Routine prophylaxis to prevent symptoms is not recommended due to the lack of information on the impact of prophylaxis on vaccine-induced antibody responses.

Some systemic signs and symptoms such as cough, shortness of breath, rhinorrhea, sore throat, and loss of taste or smell are **not** typical post-vaccination signs and symptoms. Individuals with these symptoms should be evaluated for possible etiologies, including SARS-CoV-2 or other infections. The CDC provides additional guidance for managing systemic signs and symptoms following COVID-19 vaccination in [health care personnel](#) and [long-term care facility residents](#).

Adverse Effects

No serious safety concerns have been identified thus far from the ongoing Phase 3 clinical trial. The FDA requires that providers report to [VAERS](#) vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine. Reports may be submitted online. Assistance is available by calling 1-800-822-7967.

Contraindications and precautions

The Moderna COVID-19 vaccine is contraindicated in individuals with a history of severe allergy to any of the vaccine components. The Moderna COVID-19 Vaccine includes the following ingredients: mRNA, lipids (SM-102 [proprietary to Moderna] polyethylene glycol 2000 dimyristoyl glycerol, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

A history of severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous or subcutaneous) is a precaution to vaccination at this time but is not a contraindication. A risk assessment should be conducted to determine type of reaction and certainty of information, and the individual should receive counseling about the unknown risks of developing a severe allergic reaction, balancing these risks against the benefits of vaccination. Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions. Individuals with a history of anaphylaxis due to any cause should be observed for 30 minutes, and all other persons should be observed for 15 minutes. Six cases of anaphylaxis after administration of the Pfizer-BioNTech COVID-19 vaccine outside of clinical trials have been reported in the U.S. These cases occurred within the recommended observation window and were promptly treated. These cases will undergo

clinical case review by CDC's [Clinical Immunization Safety Assessment](#) (CISA) Project. Additional case reports have been reviewed and determined not to be anaphylaxis. Providers should ensure that appropriate medical treatment used to manage immediate allergic reactions is immediately available in the event an acute anaphylactic reaction occurs. See CDC's [Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites](#). Persons who are determined to have had a severe allergic reaction (e.g., anaphylaxis) to an mRNA COVID-19 vaccine should not receive a second dose.

SARS-CoV-2 testing in individuals previously vaccinated

Prior receipt of the Moderna COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests. Positive results on serologic tests that assess antibodies to the SARS-CoV-2 spike protein may indicate either prior infection or vaccination. To evaluate for evidence of prior infection in an individual with a history of Moderna COVID-19 vaccination, a test specifically evaluating antibodies to the nucleocapsid protein should be used.

Public health recommendations for vaccinated persons

Vaccine recipients should be informed that protection from the vaccine is not immediate; the vaccine is a two-dose series and it will take one to two weeks following the second dose to be considered fully vaccinated. Moreover, no vaccine is 100% effective. Individuals who are vaccinated must continue to follow all current guidance to protect themselves and others, including wearing a mask when outside the home, staying at least 6 feet from others, and washing hands frequently. Individuals who are vaccinated should also follow quarantine guidance following a recent exposure or [travel](#).

Reporting to the CIR

Reporting of all administered COVID-19 vaccine doses to the [CIR](#) is required within 24 hours of administration. See the "Prepare to Report COVID-19 Vaccinations to the CIR" section in our [vaccine enrollment letter](#). New York State [Executive Order 202.82](#) removes the requirement that adults must consent to have their immunization information reported to the CIR.

COVID-19 vaccine communication resources

- CDC: [Engaging in Effective COVID-19 Vaccine Conversations](#)
- CDC: [Toolkit for Medical Centers, Clinics, and Clinicians](#)

The NYC Health Department will continue to release information as it becomes available to help providers plan for allocation, distribution, and administration of COVID-19 vaccine.

Sincerely,

Jane R. Zucker, MD, MSc
Assistant Commissioner
Bureau of Immunizations