

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

August 16, 2021

Dear Colleague,

We are pleased to announce two important updates to COVID-19 vaccination recommendations. First, an additional dose of Pfizer and Moderna COVID-19 vaccine is now authorized and recommended for people with moderate to severe immunosuppression. Second, the Centers for Disease Control and Prevention (CDC) has strengthened its recommendation that all people who are pregnant or nursing should receive COVID-19 vaccination. See below for more detail, along with information about other clinical considerations as well as ordering and distributing COVID-19 vaccine.

## **People Who Are Immunocompromised**

On August 12, 2021, the U.S. Food and Drug Administration (FDA) amended the Emergency Use Authorizations for <a href="Pfizer">Pfizer</a> and <a href="Moderna">Moderna</a> COVID-19 vaccines to allow for an additional (third) dose for individuals with certain immunocompromising conditions. On August 13, 2021, the Advisory Committee on Immunization Practices (ACIP) recommended use of an additional dose of mRNA COVID-19 vaccine for people with moderate to severe immunosuppression. This recommendation was based on <a href="mailto:data">data</a> showing the reduced immune response to vaccination in some people with immunocompromising conditions, the potential for an additional dose to increase immune response, and an acceptable safety profile. The CDC's updated Interim Clinical Considerations for Use of COVID-19 Vaccines can be found here.

At this time, additional doses are not authorized for immunocompromised individuals who receive Johnson & Johnson/Janssen COVID-19 vaccine due to limited information about safety and immune response in immunocompromised individuals after this vaccine. Data will continue to be reviewed to guide future recommendations.

Additional doses of Pfizer or Moderna vaccine should be administered at least 28 days after the second dose. There is no maximum time period for when a third dose can be given after the second dose. The minimum age for an additional dose of the Pfizer vaccine is 12 years, and 18 years for the Moderna vaccine. The additional dose should be the same mRNA vaccine product as the primary two-dose series. However, an alternate mRNA vaccine (Pfizer or Moderna) may be used if the original vaccine product (Pfizer or Moderna) is not available.

The additional mRNA dose is intended for people with a level of immunosuppression that is comparable to a solid-organ transplant recipient. Examples of moderate to severe immunosuppression include:

- Active treatment for solid tumor and hematologic malignancies,
- Receipt of solid-organ transplant and taking immunosuppressive therapy,
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy),
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome),

- Advanced or untreated HIV infection,
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in <u>general best practices for vaccination of people with altered immunocompetence</u>, the <u>CDC Yellow Book</u>, and the Infectious Diseases Society of America (IDSA) policy statement, <u>2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host</u>.

Serologic testing to assess immune response to vaccination is not recommended. Although certain chronic medical conditions, such as diabetes and cardiovascular disease, may be associated with varying degrees of immune deficit, these conditions are not considered moderately to severely immunosuppressive and thus a third dose of vaccine is not recommended at this time. Providers should identify and notify eligible patients of the recommendation for an additional dose. Consider sharing the New York City Department of Health and Mental Hygiene's (NYC Health Department's) COVID-19 Vaccine: Third Dose for People Who are Immunocompromised patient handout. Patients who are vaccinated at a site other than their medical provider's office must personally attest that they have a qualifying condition; they do not need to provide a doctor's note or other medical documentation.

Immunocompromised individuals should be informed about the potential for a reduced immune response to vaccination, even after a third dose, and the need to continue other COVID-19 prevention measures, such as masking, distancing, and avoiding crowds and poorly ventilated indoor spaces. Providers should strongly recommend that household members and others with regular interaction with people who are immunocompromised be vaccinated.

Regardless of vaccination status, providers should discuss monoclonal antibody treatment options with their immunocompromised patients and encourage them to seek care right away if they have COVID-19 symptoms or an exposure to someone confirmed with COVID-19. The FDA has authorized monoclonal antibody treatments for emergency use for people ages 12 years and older (weighing at least 40 kilograms/88 pounds) who test positive for COVID-19 and are at high risk for progressing to severe disease. One monoclonal antibody product is also authorized for post-exposure prophylaxis following an exposure to someone confirmed with COVID-19. To find a treatment site, visit here.

At this time, an additional dose of COVID-19 vaccine is not recommended for any other group. Currently authorized vaccines are <a href="https://high.nlm.nih.gov/high.nlm.nih.go

## **Vaccination and Pregnancy**

The CDC now strongly recommends COVID-19 vaccination for all people who are pregnant, nursing, trying to get pregnant now, or might become pregnant in the future. The <u>American College of</u>

Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine also strongly recommend vaccination for these groups. The CDC's recommendation is based on growing evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy. This includes an analysis of data from the v-safe pregnancy registry that found there was no increased risk for miscarriage among people who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy. Additionally, findings from three safety monitoring systems did not find any safety concerns for people who were vaccinated late in pregnancy or for their babies. This evidence demonstrates that the benefits of COVID-19 vaccination outweigh any known or potential risks. There has been low COVID-19 vaccination uptake among people who are pregnant. The increased circulation of the delta variant and increased risk of severe illness and pregnancy complications from COVID-19 make vaccination for this population urgent.

## Other Clinical Considerations for Vaccination

We want to emphasize that COVID-19 vaccines are recommended for all people with underlying medical conditions, including and especially for people with <u>conditions</u> that put them at greater risk for severe COVID-19 illness. The only <u>contraindications</u> to COVID-19 vaccines are severe allergic reaction (such as anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or immediate allergic reaction of any severity to a previous dose or diagnosed allergy to a component of the vaccine. A list of ingredients in COVID-19 vaccines is available <u>here</u>.

People who have had COVID-19 should also be vaccinated. Emerging <u>evidence</u> supports that vaccination is a safe way to strengthen immune response and decrease the chance of reinfection, including with more dangerous variants of the virus. Data indicate that the risk of reinfection from the delta variant may be higher than for other variants if prior infection was more than 6 months ago.

## **COVID-19 Vaccine Orders, Distribution, and Reporting**

Providers in NYC should order COVID-19 vaccine using the <u>Citywide Immunization Registry (CIR)</u>. Providers no longer have a weekly deadline to submit orders. Vaccine will be shipped throughout the week, three to four business days after an order is placed. For smaller practices, the NYC Health Department can send 150 dose trays of Pfizer vaccine. Please email <u>COVIDvax@health.nyc.gov</u> to request smaller Pfizer trays or to ask questions about COVID-19 vaccine distribution. All COVID-19 doses administered must be reported to the CIR, including all third doses.

We urge you to continue having conversations about COVID-19 vaccination with your patients and to offer vaccination at every opportunity. Your strong recommendation can play a crucial role in vaccination decisions. For the latest information on COVID-19 vaccines in NYC, visit our <a href="website">website</a>. Thank you for your continued efforts in protecting New Yorkers from COVID-19.

Sincerely,

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

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