



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Ashwin Vasani, MD, PhD
Commissioner

June 21, 2022

Dear Colleague,

On June 18, the Centers for Disease Control and Prevention (CDC) expanded its recommendations for COVID-19 vaccination to include children ages 6 months to 5 years. Specifically, for children who are not moderately or severely immunocompromised, the CDC recommended either:

- Moderna vaccine for children ages 6 months up to and including 5 years (2 doses, 25 mcg per dose, administered intramuscularly 4 to 8 weeks apart)
- Pfizer vaccine for children ages 6 months up to and including 4 years (3 doses, 3 mcg per dose, with the first two doses administered intramuscularly 3 to 8 weeks apart, followed by a third dose at least 8 weeks after the second dose).

As with older age groups, an 8-week interval may be optimal for young children who are not moderately or severely immunocompromised, but the FDA authorizations for [Moderna](#) and [Pfizer](#) vaccines allow for flexibility.

For moderately or severely immunocompromised children in these age groups, the CDC recommends following the minimum interval for administration of the second dose (i.e., 4 weeks for Moderna or 3 weeks for Pfizer). For immunocompromised children who receive Moderna, a third dose should be administered at least 4 weeks after the second dose to complete a three-dose primary series. Immunocompromised children who receive Pfizer should receive the standard three-dose primary series regimen and **not** receive an additional dose.

If a child moves from a younger age group to an older age group during their COVID-19 vaccine primary series or between the primary series and receipt of the booster dose(s) for age 5 years and older (Pfizer only), they should receive the vaccine dosage based on their age at the time the vaccine is being administered.

The New York City Department of Health and Mental Hygiene will be hosting a series of events over the next two weeks to provide information on the new recommendations and answer questions from providers. Please register at the following links:

- Wednesday, June 22, 8:30-9:30am, [registration](#), webinar
- Thursday, June 23, 12:30-1:30pm, [registration](#), webinar
- Wednesday, June 29, 8:30-10:00am, [registration](#), office hours

These recommendations follow the U.S. Food and Drug Administration (FDA) issuing Emergency Use Authorizations for these products and age groups, and meetings of the Advisory Committee on Immunization Practices (ACIP). The FDA's fact sheets for [Moderna](#) and [Pfizer](#) COVID-19 vaccines have been revised and the CDC's [clinical considerations](#) and [vaccination schedule](#) have been updated to

include these younger populations. Summaries of the different vaccine presentations for [Moderna](#) and [Pfizer](#), including vial cap colors and dose volumes, will be updated by the CDC.

Young children are [at risk of severe illness from COVID-19](#) and the risk is similar or higher than for other pediatric vaccine preventable disease. Since January 2020, 202 children ages 6 months to 4 years have died of COVID-19 in the U.S. and COVID-19 is among the top five leading causes of death for children under 5 years of age. Since March 1, 2020, more than two million children ages 6 months to 4 years have been infected with COVID-19. During the winter Omicron wave (December 2021–May 2022), the rate of hospitalization for children ages 6 months to 4 years exceeded the rate of hospitalizations for children ages 5 to 11 years and 12 to 17 years. Overall, more than half of hospitalized children ages 6 months to 4 years had no underlying medical condition.

Vaccination of children with prior infection is recommended to prevent severe disease and future infection. Among children, COVID-19 vaccination induces a broader neutralizing antibody response compared with infection-induced immunity. Specifically, [studies](#) suggest that antibodies produced by prior COVID-19 infection (pre-Omicron) may not neutralize the currently circulating Omicron variants. This builds on [evidence](#) among adults that previous infection provides poor protection against infection with Omicron variants. Parents or guardians of children who recently had COVID-19 may consider delaying their child's COVID-19 vaccine by 3 months after infection; an increased time between infection and vaccination may result in an improved immune response to vaccination and a low risk of reinfection has been observed in the weeks to months following infection.

[Efficacy, immunogenicity and safety data](#) from clinical trials of Moderna (in ages 6 months through 5 years) and Pfizer (in ages 6 months through 4 years) demonstrated that the benefits outweigh the risks for both vaccines. Details of the clinical trials are provided below. Direct comparisons between Moderna and Pfizer vaccines for young children should not be made because of differences in number of clinical trial participants, follow-up time, and circulating variants and incidence levels at the time of the clinical trials.

Moderna conducted a clinical trial with two 25-mcg doses, with dose 1 and dose 2 separated by 28 days. The trial was conducted from December 2021 through February 2022, with approximately 6,400 children ages 6 months to 5 years (approximately 4,800 children received the vaccine and approximately 1,600 received placebo).

- Efficacy of the two-dose Moderna vaccine against symptomatic infection was 37.8% (95% CI: 20.9–51.1%) with a median follow-up time of 2.5 months after dose 2.
- In a sample of 464 children ages 6 months to 5 years, antibody levels 28 days after two doses of Moderna were similar to antibody levels in 18- to 24-year-olds who received two doses of Moderna and for whom vaccine efficacy against COVID-19 has already been demonstrated.

Pfizer conducted a clinical trial with three 3-mcg doses, with dose 1 and dose 2 separated by 21 days and dose 3 separated by at least 8 weeks (range: 8 to 34 weeks). The third dose was administered to a subset of participants originally enrolled in a larger 2-dose trial. The full 3-dose trial was conducted from June 2021 through April 2022, with approximately 1,500 children ages 6 months to 4 years (approximately 1,000 children received the 3-dose vaccine and 500 received placebo).

- Efficacy of the three-dose Pfizer vaccine against symptomatic infection was 80.0% (95% CI: 22.8–94.8%) with a median follow-up time of 1.3 months after dose 3; however, this efficacy estimate is imprecise and should be interpreted with caution because it was based on a very small number of COVID-19 infections and limited follow-up time.
- In a sample of 225 children ages 6 months to 4 years, antibody levels one month after three doses of Pfizer were similar to antibody levels in 16- to 25-year-olds who received two doses of Pfizer and for whom vaccine efficacy against COVID-19 has already been demonstrated.

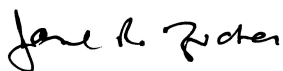
For both the Moderna and Pfizer vaccines, local and systemic adverse reactions were mostly mild to moderate and lasted a few days. There were no cases of myocarditis, pericarditis, or vaccine-associated anaphylaxis in any trial participants, though the sample size was too small to capture rare events. The rate of myocarditis and pericarditis after COVID-19 vaccination in children under age 5 years is unknown, but based on the epidemiology of classic myocarditis and safety monitoring in children ages 5 to 11 years, myocarditis and pericarditis after COVID-19 vaccination in young children is anticipated to be rare.

Although the Moderna and Pfizer clinical trials for young children did not have enough COVID-19 cases to evaluate efficacy against severe disease, both vaccines are expected to provide greater effectiveness against COVID-19 hospitalization and death relative to infection alone, as observed in older children and adults. Planned and ongoing evaluations of effectiveness will help determine subsequent timing and need for boosters for young children.

As a reminder, healthcare providers are required to report serious medical events that occur after vaccination to the Vaccine Adverse Event Monitoring System (VAERS), regardless of whether the event is thought to be caused by vaccination; see [here](#) for reporting instructions.

The NYC Commissioner of Health is urging all pediatric primary care providers to offer COVID-19 vaccine for young children as a part of their routine services. As COVID-19 vaccines can be co-administered with other vaccines, providers can administer any additional vaccinations needed to bring children up to date during the same office visit. Many parents strongly prefer to have their children vaccinated at their regular doctor's office. Your participation in the COVID-19 vaccination program can increase vaccination rates for your patients. Thank you for doing your part to protect the youngest New Yorkers.

Sincerely,



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