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

June 29, 2022

Dear Colleague,

**On June 24, 2022, the Centers for Disease Control and Prevention (CDC) expanded its COVID-19 vaccine recommendations to include Moderna vaccine for children ages 6 to 17 years.** The recommendations follow updates to the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for Moderna. The FDA's fact sheets and the CDC's clinical considerations, vaccination schedule, and summary of Moderna vaccine presentations have all been revised. Key resources are also available on the NYC Department of Health and Mental Hygiene Vaccine Information for Providers website.

**All people ages 6 months and older can now receive either Pfizer or Moderna COVID-19 vaccine for their primary series.** The expanded primary series options for Moderna vaccine for children who are not moderately or severely immunocompromised are as follows:

- **Ages 6 to 11 years: 2 doses of Moderna, 50 mcg per dose**
  This is a new product and ordering is available starting today. The Moderna vaccine for this age group is supplied as multiple-dose 2.5 mL vials with dark blue caps and labels with a purple border. There are 5 doses per vial (50 mcg/0.5 mL per dose). The CVX code for this presentation is 221, and the NDC code is 80777-0275-05.

  Note that Moderna vaccine for children ages 6 to 11 years will be erroneously labeled as "BOOSTER DOSES ONLY," but this product is authorized and intended for use as the primary vaccine series for children ages 6 to 11 years.[1]

- **Ages 12 to 17 years: 2 doses of Moderna, 100 mcg per dose**
  This is the same product as authorized for the adult primary series and NYC providers enrolled in the Vaccine Provider Agreement System (VPAS) can order now through the Citywide Immunization Registry (CIR). The NDC and CVX codes are the same as the Moderna vaccine for people ages 18 years and older.

**For both age groups, the 2 primary series doses should be administered intramuscularly and spaced 4 to 8 weeks apart.** An 8-week interval may be optimal for children and adults younger than age 65 years who are not immunocompromised or at high risk of severe disease, and especially for adolescent males to lower the risk of myocarditis; peak antibody responses and vaccine effectiveness may also be increased with an interval longer than 4 weeks, but the FDA authorization allows for flexibility.

**Children ages 6 to 17 years who are moderately or severely immunocompromised** and receive Moderna for their primary vaccine series should receive 3 doses (50 mcg per dose for ages 6 to 11 years, 100 mcg per dose for ages 12 to 17 years), with dose 1 and dose 2 spaced 4 weeks apart, and dose 2 and dose 3 spaced at least 4 weeks apart.

[1]It is permissible based on the EUA to use this product for booster doses in people who are eligible (ages 18 years and older); however, the product is primarily intended to be used as a primary series for children ages 6 to 11 years.

If a child moves from a younger age group to an older age group during their COVID-19 vaccine primary series, they should receive the vaccine dosage based on their age at the time the vaccine is administered.

The recommendations were based on a review of the benefits and risks of the Moderna COVID-19 vaccine for these age groups. In Moderna's clinical trial of 3,946 children ages 6 to 11 years, vaccine efficacy against symptomatic COVID-19 was 80.6% (95% CI: 18.8%, 95.3%). In a clinical trial of 3,187 children ages 12 to 17, vaccine efficacy against symptomatic COVID-19 was 89.2% (95% CI: 49.9%, 97.6%). The trial for ages 6 to 11 years was conducted when the Delta variant was dominant and the trial for ages 12 to 17 years was conducted when the original strain and the Alpha variant were dominant, so efficacy during the current period with Omicron variant dominance was not assessed. In a small subset of both age groups (320 children ages 6 to 11 years, 340 adolescents ages 12 to 17 years), antibody levels after vaccination were similar to antibody levels in vaccinated adults ages 18 to 25 years. Local and systemic adverse reactions in Moderna trial participants were mostly mild to moderate and lasted a few days.

There were no confirmed cases of myocarditis or pericarditis in the Moderna trials for ages 6 to 17 years, though the sample size was too small to capture rare events. Myocarditis and pericarditis are known, rare risks associated with both authorized mRNA COVID-19 vaccines. The CDC has verified 635 myocarditis case reports in children ages 5 to 17 years after 54.8 million Pfizer doses were administered in this age group. Risk appears greatest in adolescents ages 12 to 15 and 16 to 17 years. Risk is generally higher after dose 2 compared with dose 1 of the primary series and in males compared with females. COVID-19 infection is also associated with myocarditis and pericarditis; among males ages 12 to 17 years, the risk of adverse cardiac outcomes was 1.8 to 5.6 times higher after SARS-CoV-2 infection than after COVID-19 vaccination. In age groups for which product comparisons can be made (e.g., ages 18 to 39 years), some evidence suggests that myocarditis and pericarditis risk may be higher after Moderna than after Pfizer; however, findings are not consistent in all U.S. monitoring systems. Extending the COVID-19 vaccine primary series interval between dose 1 and dose 2 to 8 weeks may further lower myocarditis risk.

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

Since the beginning of the COVID-19 pandemic, among U.S. children ages 5 to 17 years, there have been over 10 million COVID-19 cases, over 45,000 hospitalizations and over 600 deaths.

Your participation in the COVID-19 vaccination program can increase vaccination rates for your patients and prevent severe outcomes. Thank you for promoting and protecting the health of New Yorkers.

Sincerely,

Jane R. Zucker

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