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

November 4, 2021

Dear Colleague,

On November 2, 2021, the U.S. Centers for Disease Control and Prevention (CDC) recommended vaccination with the Pfizer COVID-19 vaccine for children ages 5 to 11 years (two 10-mcg doses, administered 3 weeks apart). Vaccination is recommended for all children in this age group, regardless of underlying medical conditions or history of prior COVID-19 infection. After reviewing the evidence, the CDC determined that the benefits of vaccination outweigh the risks in this population. The CDC recommendation follows a unanimous vote of the Advisory Committee on Immunization Practices (ACIP) and authorization by the U.S. Food and Drug Administration (FDA). **The Pfizer vaccine product for children ages 5 to 11 years is different from the Pfizer vaccine product for people ages 12 years and older. The Pfizer vaccine for people ages 12 years and older cannot be used for younger children.**

COVID-19 is a serious public health problem for children ages 5 to 11 years. As of mid-October 2021, there have been more than 8,300 COVID-19-related hospitalizations, 2,316 cases of Multisystem Inflammatory Syndrome in Children (MIS-C), and 94 deaths in children ages 5 to 11 years in the U.S. The rate of COVID-19-related hospitalization in children is similar or greater than that of influenza and other infections prior to introduction of vaccines for those diseases. In addition, high rates of COVID-19 in children have led to loss of in-person learning, extracurricular activities, and other interactions that are critical to children's mental and physical well-being. Black and Latino children have been disproportionately affected by COVID-19 and associated educational, health care, and other disruptions.

In a clinical trial of 2,268 children ages 5 to 11 years, the two-dose Pfizer COVID-19 vaccine had a vaccine efficacy of 90.7% against symptomatic, lab-confirmed COVID-19. Trial participants were followed for a median of 2.3 months, and those who were vaccinated had immune responses similar to those observed in people ages 16 to 25 years who were vaccinated with the full 30-mcg-dose Pfizer vaccine series. Side effects of the vaccine in children ages 5 to 11 years were mostly mild to moderate and resolved within a few days. Compared with reactions in people ages 16 to 25 years, local reactions such as redness and swelling were more common, and systemic reactions, including fever, were less common. Fatigue and headache were the most common systemic reactions in children ages 5 to 11 years.

No cases of myocarditis occurred in the clinical trials for this age group, though the sample size was too small to capture rare events (3,082 children with at least 7 days follow-up, including children in the intervention arm of the efficacy trial and children in an expanded short-term safety study). The rate of myocarditis after COVID-19 vaccination in children ages 5 to 11 years is unknown. However, the rate is likely to be lower compared with older children based on the epidemiology of non-vaccine-related viral myocarditis. Furthermore, the lower 10-mcg dose is expected to reduce the risk of vaccine adverse events in younger children. COVID-19 vaccine

safety monitoring through the Vaccine Adverse Event Reporting System (VAERS) and other systems is ongoing and health care providers are required to report serious adverse events after vaccination, regardless of causality.

Facilities with multiple Pfizer COVID-19 vaccine products (the 10-mcg vaccine for children ages 5 to 11 years, and 30-mcg vaccine for people ages 12 years and older) should establish workflows to prevent vaccine administration errors and ensure the correct vaccine is administered based on the patient's age. Review the Pfizer FDA Provider Fact Sheet, Ages 5 to 11 and the CDC's clinical considerations prior to initiation of vaccination of this age group. The FDA Recipient Fact Sheet, Ages 5 to 11 should be given to parents and guardians prior to vaccination.

Differences between the two Pfizer COVID-19 vaccine products are summarized here. The products are color-coded (orange label and cap for children ages 5 to 11 years, purple label and cap for people ages 12 years and older). The amount of diluent used for the Pfizer vaccine for children ages 5 to 11 years is 1.3 mL and the injection volume is 0.2 mL. **The purple cap formulation should never be used to vaccinate children ages 5 to 11 years.** Use of the purple cap formulation to prepare doses for children ages 5 to 11 years would result in an injection volume for the 10-mcg dose of 0.1 mL, which is generally considered too small for intramuscular injections and has not been studied. Additionally, the buffer is different across products. Take care to separate all vaccine products in the vaccine storage unit, when the vaccine is being prepared and drawn, and at point of administration. Clearly label all storage bins and syringes.

Thank you for your ongoing dedication to keeping New Yorkers of all ages safe and healthy. Your work is essential to our city and our future.

Sincerely,

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