

September 16, 2022

Dear Colleague,

The Centers for Disease Control and Prevention (CDC) has recommended that everyone ages 12 years and older should receive one age-appropriate bivalent mRNA COVID-19 booster dose at least 2 months after completion of any FDA-approved or FDA-authorized monovalent COVID-19 primary series or last monovalent booster dose. All providers should stop administering Moderna and Pfizer monovalent COVID-19 vaccine boosters to people ages 12 years and older, effective immediately.

The bivalent boosters contain two mRNA components of SARS-CoV-2 virus, one of the ancestral strain of SARS-CoV-2 and one of common portions of the BA.4 and BA.5 lineages of the Omicron variant. People cannot get a bivalent COVID-19 booster without first completing at least a monovalent primary series. Age-appropriate homologous and heterologous boosters are allowed; there is no preference for homologous or heterologous boosters. These recommendation follow Emergency Use Authorizations (EUAs) by the U.S. Food and Drug Administration (FDA). The CDC's Clinical Considerations have also been updated.

The recommendations for children under 12 years of age are unchanged. Children ages 5 through 11 years who received the Pfizer primary series should receive 1 monovalent booster dose. At this time, children ages 6 to 11 years who received the Moderna primary series and children under 5 years of age cannot receive any type of booster.

People who recently had COVID-19 infection may consider delaying any COVID-19 vaccination, including bivalent booster vaccination, by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Individual factors such as risk of severe COVID-19 disease, community level of COVID-19, or characteristics of the predominant SARS-CoV-2 strain should be considered when determining whether to delay getting a COVID-19 vaccination after infection.

Two bivalent COVID-19 booster formulations are now available:

- **Pfizer bivalent booster,** authorized for people ages 12 years and older: Gray cap, 30 mcg / 0.3 mL dose, no dilution, storage in an ultra-cold freezer until expiration or refrigerator (2°C-8°C) up to 10 weeks
- Moderna bivalent booster, authorized for people ages 18 years and older: Dark blue cap, gray label border, 50 mcg / 0.5 mL dose, no dilution, storage in a freezer (-15°C to -50°C) until expiration or refrigerator (2°C to 8°C) up to 30 days

Given that the bivalent formulations have identical or similar cap colors as the monovalent formulations for each manufacturer, providers must pay careful attention to the vial labels to prevent vaccine administration errors. Additional information about vaccine labeling and formulations is available <a href="https://example.com/here/beach-monovalent-formulations-for

The rationale for bivalent boosters is based on observed declines in neutralizing antibodies and <u>vaccine</u> <u>effectiveness</u> after monovalent primary series and booster doses, as well as <u>modeling projections</u> about the impact of potential future variants. Studies conducted by <u>Pfizer</u> and <u>Moderna</u> demonstrated that inclusion of a second SARS-CoV-2 variant in the vaccine broadens the antibody response, though these studies used bivalent boosters containing ancestral and BA.1 strains, whereas the available bivalent boosters contain ancestral and BA.4/BA.5 strains. Both the Pfizer and Moderna bivalent booster trials found that, compared with the monovalent booster, the bivalent booster resulted in higher antibody titers for Omicron variants and other

SARS-CoV-2 variants, as well as titers that were as high or higher for ancestral SARS-CoV-2. Reactogenicity profiles were similar for recipients of bivalent and monovalent boosters; risk of myocarditis is unknown but expected to be similar to monovalent boosters.

Providers should offer other vaccines for which a person is eligible at the same visit, including influenza and COVID-19 vaccines. Getting multiple vaccines at the same visit increases the chance that a person will be up to date with their vaccinations. Generally, COVID-19 vaccines administered with seasonal influenza vaccine showed similar immunogenicity and similar or slightly higher reactogenicity; no safety concerns were identified.

The only exception to coadministration of COVID-19 vaccines is for JYNNEOS vaccine for monkeypox virus. In the current outbreak, JYNNEOS post-exposure prophylaxis should not be delayed because of recent receipt of a COVID-19 vaccine. However, people, particularly adolescent or young adult males, might consider waiting 4 weeks after JYNNEOS vaccination before receiving a COVID-19 vaccine due to the unknown risk of myocarditis and/or pericarditis with coadministration.

As a reminder, patients 12 years and older who are <u>moderately to severely immunocompromised</u> are recommended to receive both COVID-19 vaccine and Evusheld as an additional layer of protection since they may not mount an adequate immune response to COVID-19 vaccination. Timing and detailed recommendations for Evusheld can be found here.

Thank you for continuing to promote and protect the health of New Yorkers through vaccination.

Sincerely,

Jane R. Zucker, MD, MSc Assistant Commissioner Bureau of Immunization New York City Department of Health and Mental Hygiene