

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

September 27, 2021

Dear Colleague,

On September 24, 2021, the U.S. Centers for Disease Control and Prevention (CDC) recommended that the following populations receive a single Pfizer-BioNTech COVID-19 booster dose, to be administered at least six months after completion of the primary Pfizer vaccine series:

- People ages 65 years and older should receive a booster
- Residents ages 18 years and older in long-term care facilities **should** receive a booster
- People ages 50 to 64 years with certain underlying medical conditions should receive a booster
- People ages 18 to 49 years who are at high risk for severe COVID-19 due to <u>certain underlying medical</u> <u>conditions</u> **may** receive a booster, based on their individual benefits and risks
- People ages 18 to 64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster, based on their individual benefits and risks

The recommendation for a Pfizer booster dose is limited to people who have completed a primary series with the Pfizer vaccine. Recommendations for booster doses for people who received a primary series with the Moderna or Johnson & Johnson COVID-19 vaccine are expected in the near future.

These recommendations come after the <u>U.S. Food and Drug Administration</u> (FDA) expanded the Pfizer vaccine emergency use authorization (EUA) to include a single booster dose for these populations. Despite these recommendations, it is important to highlight that the vast majority of cases, hospitalizations, and deaths due to COVID-19 continue to occur in people who are unvaccinated. The most critical strategy for reducing COVID-19 morbidity and mortality and controlling the pandemic remains vaccinating patients who are unvaccinated.

The CDC's recommendations were based on a <u>review</u> of vaccine effectiveness data, an assessment of the benefits and risks of booster doses, and considerations about equity and feasibility. Recent data has shown declines in <u>mRNA vaccine effectiveness</u> against COVID-19 infection in people ages 65 years and older, including residents of long-term care facilities. mRNA vaccine effectiveness against hospitalization in this age group has declined, though to a lesser degree than against infection. Declines in vaccine effectiveness are more pronounced for Pfizer vaccine recipients compared with Moderna and are likely due to a combination of waning immunity over time and circulation of the delta variant.

Among adults younger than 65 years of age, all authorized and approved COVID-19 vaccines remain effective in preventing severe illness. Because the risk of severe illness from COVID-19 increases with age and can also increase for adults of any age with certain underlying medical conditions, the CDC recommended booster doses for people 50 to 64 years of age with underlying conditions. The CDC's recommendation that people 18 to 49 years of age with underlying medical conditions may receive a booster was intended to allow health care providers to exercise their clinical judgment. While COVID-19 vaccine effectiveness against severe disease remains high for health care personnel and other essential workers, even those with mild illness often cannot work, causing potentially critical staffing shortages. In addition, people who care for or live with at-risk people, such as people who are immunocompromised, or live in congregate settings such as homeless shelters or correctional facilities may have an elevated risk of COVID-19 exposure. For these reasons, the CDC recommends that adults at increased risk of COVID-19 from occupational and institutional exposures may receive a booster dose based on their individual benefits and risks.



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In terms of the <u>benefits and risks of booster doses</u>, observations of 306 people found that a single booster dose of the Pfizer vaccine effectively increased antibody response in those who completed a primary Pfizer series approximately six months earlier. Larger studies to assess the benefits of boosters will be conducted in the coming months. <u>Safety</u> data for Pfizer boosters and additional doses reported to the Vaccine Adverse Event Reporting System (VAERS) and v-safe are limited, but no initial concerns have been identified. Safety monitoring will continue as more people receive booster doses. The individual benefit-risk balance for booster doses is expected to be most favorable for adults 65 years of age and older because this population has the highest rates of COVID-19 hospitalizations and the lowest risk of myocarditis.

Dosage and administration for the Pfizer booster dose are the same as for the primary series (a 0.3-ml dose, administered intramuscularly). The booster dose should be administered at least six months after completion of the primary Pfizer series. Because immunity wanes gradually over time, a booster may be given at an interval greater than six months. Pfizer booster doses can be received at any location that offers Pfizer vaccine. People will be required to show proof of age and those younger than 65 years must attest that they have a qualifying health condition or increased risk of exposure due to occupational or institutional setting.

Administration of a third dose of Pfizer vaccine (for people ages ≥12 years) or Moderna vaccine (for people ages ≥18 years) after an initial two-dose primary mRNA COVID-19 vaccine series continues to be recommended for <u>moderately to severely immunocompromised people</u>. The additional dose should be given at least four weeks after the second dose. The need for an additional dose in this group is due to a reduced immune response to the primary vaccine series. A fourth COVID-19 vaccine dose for this population is not recommended at this time.

All COVID-19 vaccines, whether given as a primary series, additional dose, or booster dose, may be administered without regard to timing of other non-COVID-19 vaccines. Providers should recommend COVID-19 vaccines to eligible patients at every visit and administer COVID-19 vaccines with flu and other recommended vaccines.

Continue to refer to the FDA fact sheets for the <u>Pfizer</u>, <u>Moderna</u> and <u>Johnson & Johnson</u> COVID-19 vaccines, the CDC's <u>clinical considerations</u> and <u>New York State guidance</u> for further information. As a reminder, COVID-19 vaccination providers are responsible for adhering to all requirements in the <u>CDC COVID-19 Vaccination Program</u> <u>Provider Agreement</u>. Use of these products outside of those that have been approved and authorized by FDA (off-label use) and recommended by the CDC is not allowed under the agreement.

Finally, some patients will be highly motivated to seek out booster doses, while others may have questions about booster dose recommendations. We urge you to reach out to patients who received the Pfizer vaccine and who can most benefit from a booster dose, especially those 65 years of age and older. At the same time, our main priority must continue to be to encourage COVID-19 vaccination in people who have yet to receive any doses. Providers and public-health authorities must ensure that unequal access to booster doses does not contribute to racial and socioeconomic inequities in COVID-19 outcomes.

Sincerely,

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