

February 17, 2022

Dear Colleague,

On February 11, 2022, the Centers for Disease Control and Prevention (CDC) updated its <u>Interim Clinical Considerations for Use of COVID-19 Vaccines</u> with new guidance for people who are moderately or severely immunocompromised and recommendations on vaccination following monoclonal antibody therapy. Updates included:

- A shortened, three-month interval between an mRNA COVID-19 vaccine primary series (including the third additional primary dose) and a booster dose in people who are moderately or severely immunocompromised
- Recommending an additional primary dose of mRNA vaccine after at least 28 days for people who received a single Johnson & Johnson primary dose and are moderately or severely immunocompromised
 - People who receive this additional dose should receive a booster dose at least 2 months after the additional dose
 - Patients who received the Johnson & Johnson vaccine and already received their booster dose can get their additional dose at least two months after their booster dose
- An allowance for providers who care for moderately or severely immunocompromised patients to administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgment
- Elimination of the deferral period for COVID-19 vaccination after receipt of passive monoclonal antibody products; however, tixagevimab/cilgavimab (EVUSHELD) for preexposure prophylaxis should be deferred for at least two weeks after vaccination
- Adding history of myocarditis or pericarditis after an mRNA COVID-19 vaccine as a precaution to any COVID-19 vaccination

In addition, on February 4, the Advisory Committee on Immunization Practices (ACIP) voted unanimously to move from an interim recommendation to a standard recommendation for the Moderna COVID-19 vaccine two-dose primary series for people ages 18 years and older. This vote follows full approval (licensure) of the Moderna two-dose primary series in this age group from the U.S. Food and Drug Administration (FDA). The vaccine will now be marketed as Spikevax. The Moderna vaccine continues to be available under emergency use authorization (EUA) for the administration of additional doses in certain immunocompromised individuals and for the administration of booster doses. On January 31, the Moderna FDA fact sheets for health care providers and recipients and caregivers were revised.

ACIP's recommendation is based on <u>a review of the benefits and risks</u> of Moderna COVID-19 vaccination. A randomized controlled trial demonstrated high efficacy against symptomatic disease (92.7%) and hospitalization (95.9%) and was further supported by observational studies

conducted during the period prior to the emergence of the Omicron variant. <u>Safety data</u> from monitoring systems continue to show an association between myocarditis, pericarditis and Moderna COVID-19 vaccination. The highest risk of myocarditis has been seen after the second dose among males ages 18 to 39 years (67.5 cases per million doses in 7-day post-vaccination risk period), but overall risk remains low. Most people with post-COVID-19 vaccination myocarditis recovered. The benefits for the Moderna COVID-19 vaccine, including prevention of cases, hospitalizations, and deaths, <u>far outweigh</u> any possible vaccine-associated risks.

ACIP also reviewed <u>evidence from Canada</u> and <u>other countries</u> that has shown that extended intervals for the COVID-19 vaccine primary series may increase the immune response and vaccine effectiveness and reduce the risk of myocarditis. ACIP expressed support for potentially extending intervals for mRNA vaccines and will continue to consider this topic in future meetings.

Further, on February 11, CDC issued Emergency Use Instructions (EUI) for the Moderna vaccine for health-care-providers and recipients and caregivers. The EUI provides information about use of the Moderna vaccine as an additional dose for people who are moderately or severely immunocompromised, to complete a primary series, or as a booster dose for people who received COVID-19 vaccines authorized by the World Health Organization but not the FDA. These changes are reflected in the CDC's updated Interim Clinical Considerations for Use of COVID-19 Vaccines.

We urge you to leverage the Moderna recommendation and approval to talk to your patients about COVID-19 vaccination and to offer vaccination at every opportunity. Your strong recommendation can play a crucial role in vaccination decisions. For the latest information on COVID-19 vaccines in NYC, visit our website. Thank you for your continued efforts to protect New Yorkers from COVID-19.

Sincerely,

Jane R. Zucker, MD, MSc Assistant Commissioner

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Bureau of Immunization