Department of Public Health
CITY OF PHILADELPHIA

Philadelphia Department of Public Health
Division of Disease Control

CHERYL BETTIGOLE, MD, MPH
Acting Health Commissioner

COLEMAN TERRELL
Acting Director, Division of Disease Control

Health Advisory

Additional mRNA COVID-19 Vaccination for Immunocompromised Individuals

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Studies have found that moderately to severely immunocompromised individuals have a higher risk of developing severe COVID-19 with prolonged infections and viral shedding. Other existing evidence has suggested that immunocompromised individuals may produce lower levels of antibody protection against COVID-19 after receiving two doses of mRNA COVID-19 vaccines, compared to immunocompetent individuals. Moreover, research findings have suggested that vaccination in immunocompromised individuals may experience lower vaccine effectiveness with a higher rate of hospitalized breakthrough cases.

The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) endorse providing an additional mRNA COVID-19 vaccine to moderately to severely immunocompromised individuals who have completed a two-dose mRNA primary series. The additional mRNA COVID-19 vaccine dose must be provided at **least 4 weeks (28 days)** after the second dose of Pfizer-BioNTech or Moderna vaccines.

SUMMARY POINTS

- People who are moderately to severely immunocompromised should receive an additional dose of mRNA COVID-19 vaccine at least 4 weeks (28 days) after two-dose mRNA primary series.
- There is not enough evidence to support the use of additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccine series in immunocompromised people.
- Additional dose of COVID-19 vaccine should be the same vaccine product as the initial 2-dose mRNA vaccine series, but if it is not available, another product may be given.

Moderate to severely immunocompromised individuals are defined as those having:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Individuals should discuss their health conditions with their healthcare provider and discuss whether getting a third dose is appropriate. Utilizing serologic testing or cellular immune testing to assess the immune response to vaccination outside of the context of research studies is not recommended at this time. Other than moderately to severely immunocompromised individuals, no other groups are eligible to receive an additional mRNA COVID-19 vaccine at this time.

Efforts should be made for the additional mRNA COVID-19 vaccine dose to be the same vaccine product as the initial two-dose mRNA COVID-19 vaccine series (Pfizer-BioNTech or Moderna). However, if the original product is not available, individuals may receive the other product.

The CDC and FDA have not approved the use of an additional mRNA vaccine dose after a single-dose Janssen COVID-19 vaccine series in any population. They are currently reviewing the literature and data and may make a recommendation in the future.

Resources:

- COVID-19 Vaccines for Moderately to Severely Immunocompromised People
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- Evidence to Recommendations Framework: Additional doses of mRNA COVID-19 vaccines as part of a primary series for immunocompromised
- 2021-587-8-17-ADV-COVID-19 Vaccines for Moderately to Severely Immunocompromised People