Clinical considerations for use of an additional mRNA COVID-19 vaccine dose after a primary mRNA COVID-19 vaccine series for immunocompromised people

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COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future.

- COVID-19 vaccine safety in pregnancy
  - COVID-19 vaccines do not cause infection in the pregnant person or the fetus
  - No safety signals in animal studies
  - Reassuring early safety data on mRNA COVID-19 vaccines during pregnancy
  - Early data suggest mRNA COVID-19 vaccines during pregnancy are effective

- There is no evidence that any of the COVID-19 vaccines affect current or future fertility

Additional doses in immunocompromised people

**Review data:**
- Assess safety, immunogenicity, and implementation

**FDA**
- **Regulatory allowance:**
  - EUA amendment would allow recommendations under EUA
  - BLA would allow for ‘off label’ recommendations

**CDC/ACIP**
- **Clinical update:**
  - Clinical considerations/recommendations for use

**Abbreviations:**
- EUA= Emergency Use Authorization; BLA= Biologics License Application
Roles of an Additional Dose

There are two distinct potential uses for an additional vaccine dose:

- **Additional dose after an initial primary vaccine series**: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.

- **Booster dose**: a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established.
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Focus of Clinical Considerations

For people with moderate to severe immune compromise due to a medical condition or immunosuppressive treatment, the potential to increase immune response coupled with an acceptable safety profile support consideration for an additional dose of mRNA COVID-19 vaccine following an initial 2-dose primary mRNA COVID-19 vaccine series in this population.
Moderately and severely immunocompromised people*

- 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, Wiskott-Aldrich syndromes)
- 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, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

*ACIP General Best Practice Guidelines for Immunization; CDC Yellow Book; 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host
Additional considerations

- Chronic medical conditions may be associated with varying degrees of immune deficit.

- Patient’s clinical team is best able to assess the degree of altered immunocompetence and optimal timing of vaccination, with specific attention paid to current or planned immunosuppressive therapies.

- Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be given at least two weeks before initiation of immunosuppressive therapies.

- Factors to consider in assessing the general level of immune competence of patients with chronic diseases include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

- Utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., need for an additional dose) has not been established and is not recommended at this time.
Implementation Considerations

- The additional dose should be the same mRNA vaccine as the primary series.
- Alternate mRNA product can be used if primary series product not available.
- Until more data are available, the additional dose should be administered at least 28 days after completion of the initial primary series.
- Currently there are not data to support the use of an additional mRNA COVID-19 vaccine dose after a primary Janssen COVID-19 vaccine in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue.
Importance of infection prevention measures

- Immunocompromised people (including those who receive an additional mRNA dose) should be counseled about the potential for reduced immune response to COVID-19 vaccination and need to follow prevention measures*
  - Wear a mask
  - Stay 6 feet apart from others they don’t live with
  - Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider

- Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19

Updates to additional clinical resources

Updates will be posted at: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
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