



Updates to Interim Clinical Considerations for Use of COVID-19 Vaccines

February 4, 2022 ACIP meeting



Who needs a 4th dose of an mRNA (Pfizer or Moderna) COVID-19 vaccine?

On August 13, 2021, the CDC Advisory Committee on Immunization Practice (ACIP) recommended an additional dose of mRNA COVID-19 vaccine for moderate to severe immunocompromised individuals (liver transplant recipients) and to individuals on the following therapies:

- High-dose corticosteroids (defined at ≥ 20 mg / day of oral prednisone)
- Anti-TNF biologics and biosimilars or immunomodulators (azathioprine, methotrexate, etc.)

This additional dose was intended for people who likely did not mount a protective immune response after initial vaccination.

Who needs a 4th dose of an mRNA (Pfizer or Moderna) COVID-19 vaccine?

- The ACIP's recommendation was based on available evidence about solid organ transplant patients and extrapolated for others who may have similar levels of immunosuppression.
- Many patients with IBD on anti-TNF therapy or thiopurines are eligible for a 4th dose of an mRNA vaccine.
- It's important to recognize that current studies (PREVENT-COVID, CORALE-IBD, and HERCULES) suggest that most (96-99%) patients with IBD can produce an antibody immune response to the vaccination, unlike solid organ transplant recipients.
- Patients should discuss with providers if they should obtain a 4th dose of COVID-19 vaccine.

Rationale for 3 month booster interval after an mRNA COVID-19 Vaccine Primary Series

- New recommendations were made out of abundance of caution because people who are Moderately or Severely Immunocompromised
 - **Are at increased risk for SEVERE COVID-19**
 - SECURE registry have shown patients with IBD are **not** at increased risk for COVID-19
 - **May not mount a protective immune response after initial vaccination**
 - PREVENT, CORALE IBD, HERCULES and other studies have shown majority of patients have a humoral response to primary series and to a third dose

Rationale for 3 month booster interval after an mRNA COVID-19 Vaccine Primary Series

- **Concern that moderately immunosuppressed have waning protection over time**
 - A paucity of studies in patients with IBD, but post third dose studies suggest majority make a robust antibody response.
- Small studies in people with immune compromise demonstrate immunogenicity of a 4th dose when administered 1-3 months after the 3rd dose
 - **These are studies evaluating immune response in solid organ transplant recipients.**

Kamar, N., et al. Infectious Diseases, 4(11), e2136030.

Benotmane, I. et al (2021).. medRxiv. Preprint. doi.org/10.1101/2021.11.25.21266704

Alejo, J.L. et al Transplantation, 105(12), e280-281.

Munro, A et al. Lancet, 398, 2258-76.



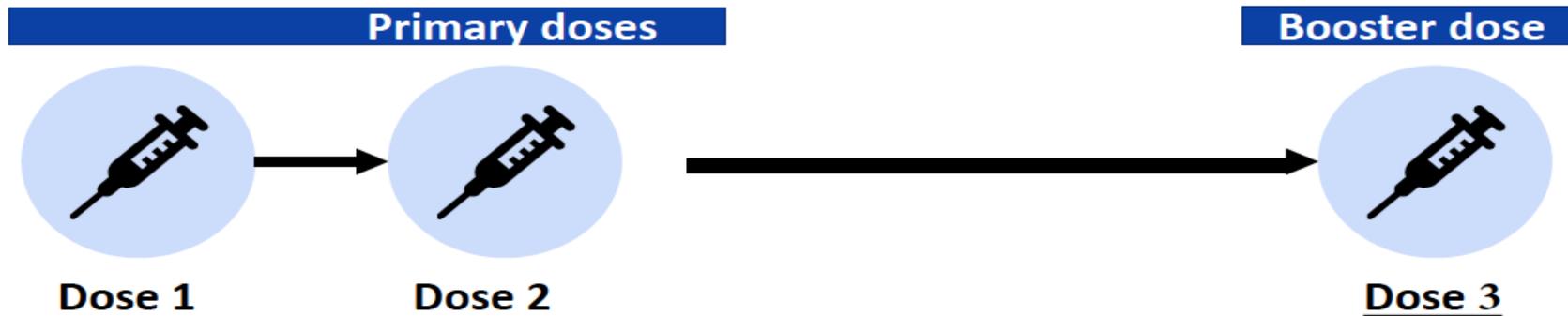
ACIP allows additional COVID-19 doses: Case-by-Case Decision Making Based on Clinical Judgement

- On a case-by-case basis, providers of moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgement when the benefits of vaccination are deemed to outweigh the potential and unknown risks for the recipient.
- However, providers should not routinely administer additional doses of COVID-19 vaccine beyond those recommended in this guidance.

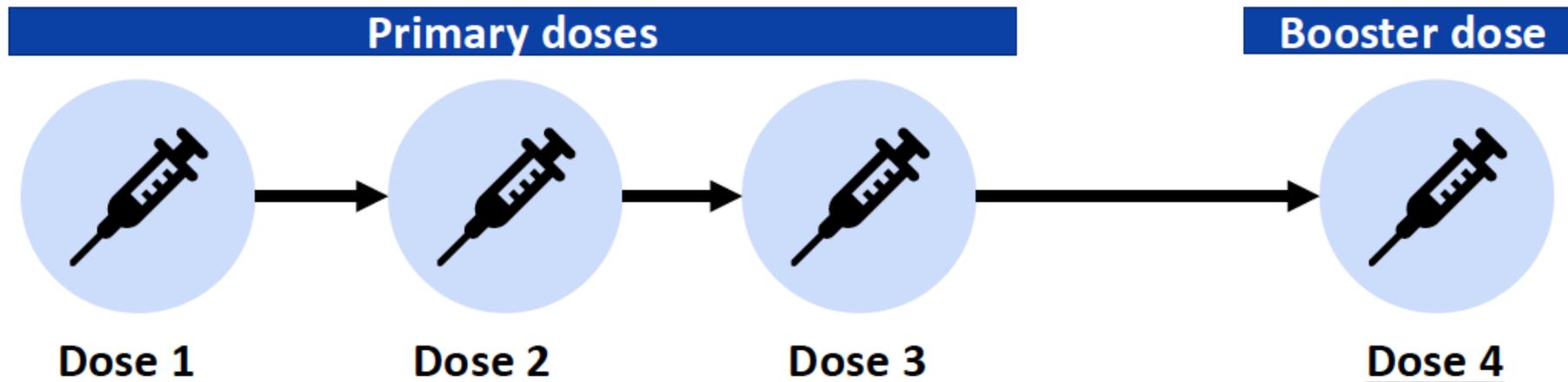
What is the fourth mRNA dose?

(Based on ACIP February 4th meeting)

General population recommendations

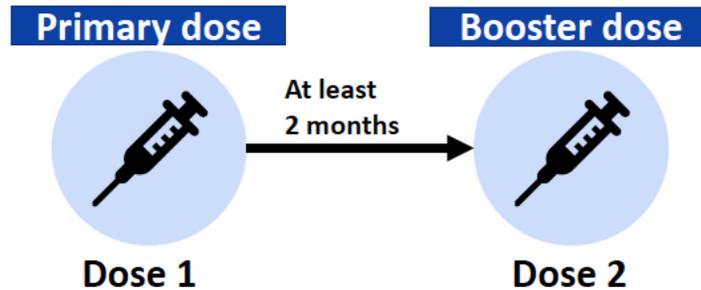


Recommendations for “moderately to severely immunocompromised” per CDC



How do you provide a booster for dose who received a Janssen vaccine? (Based on ACIP February 4th meeting)

General population recommendations



Recommendations for “moderately to severely immunocompromised” per CDC

