

Considerations for Use of an Additional mRNA COVID-19 Vaccine Dose After an Initial 2-Dose Primary mRNA COVID-19 vaccine series for Immunocompromised People

On August 12, 2021 FDA modified the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to allow for administration of an additional dose (i.e., a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for certain immunocompromised people (i.e., people who have undergone solid organ transplantation or have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise). The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series:

- Pfizer-BioNTech: Aged ≥ 12 years
- Moderna: Aged ≥ 18 years

On August 13, 2021, ACIP met and reviewed the data for use of an additional dose of mRNA COVID-19 vaccine for immunocompromised people within the Evidence to Recommendation Framework. ACIP made an interim recommendation for use of an additional dose of Pfizer-BioNTech COVID-19 vaccine (for persons aged ≥ 12 years) or Moderna COVID-19 vaccine (for persons aged ≥ 18 years) after an initial 2-dose primary mRNA COVID-19 vaccine series for moderately to severely immunocompromised people.

Healthcare professionals and public health officials should consider the following for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for moderately to severely immunocompromised people:

- The currently FDA-authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
- Studies indicate some immunocompromised people have a reduced immune response following a primary COVID-19 vaccine series compared to vaccine recipients who are not immunocompromised.
- Studies have further demonstrated that including an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in some immunocompromised populations may enhance immune response.
- The clinical benefit of an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people is not precisely known. However, for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, the potential to increase immune response coupled with an acceptable safety profile, support the recommendation for an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series.
- The additional dose should be administered at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.

The clinical considerations for use of an additional dose of an mRNA COVID-19 vaccine apply only to people who are moderately or severely immunocompromised.

https://www.cdc.gov/vaccines/covid-19/hcp/immunocompromised-patients.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Fclinical-considerations%2Fimmunocompromised-patients.html

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