

## Pfizer/BioNTech and Moderna COVID-19 vaccines, bivalent – CDC recommends bivalent booster dose

- On September 1, 2022, the Centers for Disease Control and Prevention's (CDC) [Advisory Committee on Immunization Practices \(ACIP\)](#) recommended a booster dose of [Moderna COVID-19 vaccine, bivalent](#) for individuals **18 years of age and older** and [Pfizer COVID-19 vaccine, bivalent](#) for individuals **12 years of age and older**, under the emergency use authorization (EUA) issued by the FDA.
  - The bivalent booster dose should be given at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
  - Monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals ages 12 years and older.
  - The [Pfizer/BioNTech COVID-19 vaccine](#) remains authorized for administration of a single booster dose for individuals 5 through 11 years of age at least five months after completing a primary series of the Pfizer/BioNTech COVID-19 vaccine.
  - The ACIP vote for the Moderna COVID-19 vaccine, bivalent was 13 yes votes and 1 no vote in favor of the recommendation.
  - The ACIP vote for the Pfizer/BioNTech COVID-19 vaccine, bivalent was 13 yes votes and 1 no vote in favor of the recommendation.
  - This recommendation follows closely after the [FDA announced](#) an EUA of the Moderna COVID-19 vaccine, bivalent and the Pfizer/BioNTech COVID-19 vaccine, bivalent for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on August 31, 2022.
- COVID-19 continues to cause hospitalizations and death in individuals. The BA.4/BA.5 Omicron variants currently are the largest circulating strains of COVID-19.
- To support the Moderna COVID-19 vaccine, bivalent, data from a [clinical study](#) of 814 adult individuals who received a second booster of original strain vaccine or bivalent vaccine containing BA.1 was conducted.
  - Omicron BA.1 neutralizing titers were significantly higher following the 2nd booster using Omicron BA.1 bivalent vaccine than with the original strain vaccine.
  - In addition, the BA.1 Omicron bivalent booster resulted in higher neutralizing antibody titers against Omicron BA.4 & BA.5 than the original strain vaccine in adults.
  - Non-clinical data showed increased neutralization against BA.4/BA.5 using monovalent and bivalent BA.4/BA.5 containing vaccines.
  - Non-clinical data showed increased neutralization against BA.5 using a bivalent BA.4/BA.5 containing vaccine vs. minimal boost from the original strain vaccine.
- To support the Pfizer/BioNTech COVID-19 vaccine, bivalent, data from a [clinical study](#) of 610 individuals ≥ 55 years of age who received a second booster of monovalent Omicron BA.1 or bivalent vaccine containing BA.1 was conducted.
  - Omicron BA.1 neutralizing activity increased following the 2nd booster using Omicron BA.1 bivalent vaccine.
  - In addition, the bivalent BA.1 vaccine elicited improved Omicron BA.1 neutralization response and BA.4/BA.5 was neutralized to a lesser extent.

- Non-clinical data showed increased neutralization against BA.4/BA.5 using monovalent and bivalent BA.4/BA.5 containing vaccines.
- In addition, efficacy and safety data from the existing monovalent COVID-19 vaccines was presented. It is felt that this information can be extrapolated to the bivalent vaccines because they are manufactured in the same way as the monovalent vaccines. This is a similar process used to develop the yearly influenza vaccine, where the composition changes based on the circulating strains, but the vaccine platform remains the same and new clinical data is not used to support the new product.
- There is no information available for myocarditis risk when using a bivalent COVID-19 booster vaccine. CDC will continue to monitor for safety of the new bivalent vaccines as they have done with previous COVID-19 vaccines.
- The [CDC will provide](#) educational materials to help prevent errors of administration due to many of the vials of monovalent and bivalent vaccines being similar.
- The CDC clinical considerations for vaccine administration can be found on the CDC website [here](#).

#### What's next:

- The CDC Director will need to endorse ACIP's recommendations. Once this occurs, bivalent booster vaccines can be given to the appropriate patients.



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