

## Fast Facts for Health Care Providers: Data Points on the Bivalent COVID-19 Vaccinations

The bivalent vaccines provide preventative protection against COVID-19. Both Pfizer-BioNTech and Moderna have now reported safety and immune response data for their updated bivalent mRNA vaccines. These data may be helpful as you have discussions with your patients.

### Points for Patients:

- It is very encouraging to see the high degree of consistency between the two different updated bivalent vaccines in terms of their ability to address the most recent circulating variants.
- Overall, the evidence available for the two updated bivalent vaccines clearly indicates the vaccines are likely to help provide better protection against the currently circulating variants.
- With the increasing prevalence of the BQ.1.1 lineage of the omicron variant and the amount of travel that will take place around the holidays, it is very important for all those eligible, and particularly older adults, to consider getting the updated vaccine if they have not yet done so.

### Pfizer-BioNTech reported the following information from its [study](#):

- A booster dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent elicited approximately 4-fold higher neutralizing antibody titers against the BA.4/BA.5 sublineages of the omicron variant compared to a booster dose of the original monovalent COVID-19 vaccine in individuals older than 55 years of age.
- Although there was not an age-matched control group for the 18- to 55-year-old age range, notable increases in neutralizing antibody titers against omicron BA.4/BA.5 sublineages were also observed.
- One month after a 30- $\mu$ g booster dose of the updated bivalent vaccine, omicron BA.4/BA.5-neutralizing antibody titers increased 13.2-fold from pre-booster levels in adults older than 55 years of age and 9.5-fold in adults 18 to 55 years of age, compared to a 2.9-fold increase in adults older than 55 years or age who received the original booster vaccine.
- The safety and tolerability profile of the bivalent booster remains favorable and similar to the original vaccine.

### Moderna reported the following information from its [study](#):

- A booster dose of the Moderna COVID-19 Vaccine, Bivalent elicited 6.29-fold higher neutralizing antibody titers against the BA.4/BA.5 sublineages of the omicron variant compared to a booster dose of the original monovalent COVID-19 vaccine in those without prior SARS-CoV-2 infection, and 5.11-fold higher neutralizing antibody titers against omicron BA.4/BA.5 sublineages compared to the original COVID-19 vaccine in those with prior infection.
- For the absolute increase in antibody titers, compared with pre-booster levels, one month after a 50  $\mu$ g booster dose of the updated bivalent vaccine, there was 26.4-fold increase in titers in those without prior infection, and a 9.8-fold increase in titers in those with prior infection.
- Results were consistent in the study between participants aged 65 years and older and those 18 to 65 years of age.
- The safety and tolerability profile of the bivalent booster remains favorable and similar to the original vaccine.
- In an exploratory analysis of approximately 40 participants using research assays, the updated bivalent vaccine demonstrated neutralizing activity against BQ.1.1 that is predicted to be protective, despite an approximately 5-fold drop in titers compared to BA.4/BA.5.

For more information from the FDA, go to [www.fda.gov/covid19](http://www.fda.gov/covid19).