

Q&A » BIVALENT COVID BOOSTERS

WHAT ARE THE BIVALENT COVID BOOSTERS?

Bivalent Covid vaccines, or bivalent boosters, contain two different components for the immune system to respond to. Pfizer-BioNTech and Moderna's mRNA bivalent Covid-19 vaccines contain the mRNA for the spike protein for two different strains of the virus: (1) the wildtype strain that was in the original or monovalent vaccines and (2) the Omicron BA.4 and BA.5 subvariants.¹

WHO IS RECOMMENDED TO RECEIVE A BIVALENT COVID BOOSTER?

It is currently recommended that people ages five years and older receive one updated (bivalent) booster if it has been at least two months since their last Covid-19 vaccine dose, whether that was a final primary series dose or an original (monovalent) booster.² People who have gotten more than one original (monovalent) booster are also recommended to get an updated (bivalent) booster.

HOW DO THE BIVALENT COVID BOOSTERS WORK?

mRNA Covid vaccines teach the immune system to recognize the SARS-CoV-2 virus so that, if you become infected, your immune system knows to fight the virus. The amount of mRNA in the bivalent boosters is the same as the monovalent Covid vaccine but is split halfway to target both the wildtype strain and Omicron subvariants BA.4 and BA.5.

mRNA Covid vaccines contain the genetic material of messenger RNA or mRNA that instructs the body to manufacture copies of the spike protein, thereby producing immune memory against SARS-CoV-2. The mRNA is coated in lipid nanoparticles to enable and enhance cellular uptake of the vaccine. If exposed to the real SARS-CoV-2 virus later, the immune system will recognize the spike proteins as foreign antigens and can quickly mount an immune response against the virus.

For more information on how mRNA Covid-19 vaccines work, visit https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/COVID-19-mRNA-infographic_G_508.pdf.

HOW ARE THE BIVALENT COVID BOOSTERS DIFFERENT FROM PREVIOUS BOOSTERS?

Bivalent boosters work exactly like the mRNA Covid vaccines currently in use but are updated to encode both the spike protein of both the wildtype or original SARS-CoV-2 strain and Omicron subvariants, BA.4 and BA.5.

WHAT DATA WAS USED TO SUPPORT THE FDA'S AUTHORIZATION OF THE BIVALENT BOOSTERS?

The Food and Drug Administration's (FDA) emergency use authorization of bivalent mRNA Covid-19 boosters is based on clinical human trial data examining bivalent vaccine containing the Omicron BA.1 subvariant and the wildtype strain. The BA.1 bivalent vaccine was similar to the original (monovalent) vaccine in terms of both



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safety and efficacy; although, efficacy of the BA.1 bivalent vaccine was enhanced against multiple variants including Omicron compared to the original (monovalent) vaccine.

The FDA also used data from trials in mice that were made to express human angiotensin converting enzyme-2 (ACE-2) receptors, which are the receptors that SARS-CoV-2 uses to enter human cells. These animal trials showed that the immune response was comparable between the BA.1 bivalent vaccine and the BA.4/BA.5 bivalent booster.

WHY IS GETTING A BIVALENT BOOSTER IMPORTANT?

There are several reasons why getting a bivalent booster is important, including:

- » The original (monovalent) Covid vaccines are protective against severe illness, hospitalization, and death, but that protection declines over time. For example, the UK Health Security Agency found that 20 weeks or more after a Pfizer or Moderna booster dose vaccine effectiveness dropped to almost no effect.³
- » While previous Covid vaccine boosters restored protection of the vaccines, the rise of the Omicron variant and other new variants that are immune evasive mean that an updated Covid vaccine is needed. Studies have found reduced effectiveness of the original (monovalent) vaccines against the Omicron variant.^{4,5}
- » Bivalent boosters are designed to match the currently dominant Omicron subvariants, BA.5 and BA.4, and appear to provide more diverse response overall, likely improving immune response to future SARS-CoV-2 variants.
- » Hundreds of millions of mRNA Covid vaccine doses have been safely administered in the United States and around the world.

HOW ARE THE BIVALENT BOOSTERS MANUFACTURED?

Bivalent boosters follow the same manufacturing process as the monovalent mRNA Covid vaccines.

IS THIS APPROACH USED FOR ANY OTHER TYPES OF VACCINES?

Yes, vaccines that are intended to protect against more than one virus strain have been in use for many years. For example, influenza vaccines can contain three or four different strains. In addition, a similar strategy is used for updating the annual influenza vaccines, where the vaccines are updated each year based on the virus strains expected to be most prevalent but no new clinical trial data is gathered.

1 Food and Drug Administration, "COVID-19 Bivalent Vaccine Boosters," page last reviewed Oct 12, 2022, <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccine-boosters>.

2 CDC, "Stay Up to Date with COVID-19 Vaccines Including Boosters," updated Oct 14, 2022, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

3 UK Health Security Agency, "COVID-19 vaccine surveillance report Week 40," October 6, 2022, available at <https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports>.

4 Andrews et al., "Covid-19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant," *New England Journal of Medicine*, April 21, 2022, <https://www.nejm.org/doi/full/10.1056/NEJMoa2119451>.

5 Ferdinands JM, Rao S, Dixon BE, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance — VISION Network, 10 States, August 2021-January 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:255-263. DOI: <http://dx.doi.org/10.15585/mmwr.mm7107e2>.