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What's New about the COVID-19 Bi-Valent Boosters

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Greenwich, 9-16-22: The much-anticipated new COVID-19 booster vaccine is now available. This booster is a bivalent mRNA vaccine, which means it has components of the original vaccine plus new vaccine elements. It offers protection against both the original version of COVID and against the more contagious BA.4 and BA.5 Omicron variants. This newly configured vaccine contains elements that specifically target the spike proteins of the Omicron BA.4 and BA.5 mutations. These spike proteins are responsible for the rapidity by which the Omicron variants have been spreading among our population. This dual action vaccine will restore the protection that has been fading away from the older vaccine, while now also specifically targeting the highly transmissible and predominant BA.4 and BA.5 mutations. These latest variants have been more capable of evading our immune system response, which has been contributory to why many immunized people have still been getting COVID, albeit more mildly than if they were unvaccinated. A virus like the one caused by the Omicron mutations, which can evade our immune response, whether acquired from a vaccine or the illness, is like a burglar who bypasses your locked front door to climb through your open window.

The *Federal Food & Drug Administration* (FDA) has authorized both the Moderna and Pfizer bivalent mRNA booster vaccines. Their use is approved and endorsed by the *Centers for Disease Control and Prevention* (CDC). Dr. Walensky, the CDC Director, and the *CDC Advisory Committee on Immunization Practices* recommend that children 12 to 18 take the Pfizer version of the bivalent vaccine. Those 18 and older can take either version, Moderna or Pfizer, of this newly formulated bivalent vaccine (CDC, 2022).

In order to be eligible to receive the new vaccine the *American Medical Association* (AMA) offers the following guidance (Lubell, 2022):

- You have to meet the age specifications for the vaccine you take
- You have to have completed your primary series of the original COVID-19 vaccine.

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- Children who are between the ages of 5 and 11 who had their original Pfizer vaccine series should still take the original (monovalent) booster vaccine and not the bivalent booster version.
- The *American Medical Association's* recommendation is that people should wait until at least 2-months following their last COVID-19 vaccine before they get a bi-valent booster.

Questions always arise about whether one should get boosted if they have had an actual COVID-19 infection, and if so, how soon after they have been ill. The CDC and the AMA offer different guidance here. The AMA suggests that a person who has had a COVID-19 infection wait until they are out of isolation and are fully recovered, while the CDC is suggesting that the wait period be at least 3-months from symptom onset or the positive test date if you are asymptomatic (CDC, 2022) (Lubell, 2022). In either case, one cannot get the bivalent (new) booster until the primary vaccine series has been completed. Dr. Sandra Fryhofer, the AMA's medical liaison to the CDC's *Advisory Committee on Immunization Practices (ACIP)* shared that the *Omicron Booster Study* found that there was benefit to be had from adding a second COVID virus (the Omicron BA.4 and BA.5 variants) to the original vaccine. It broadens the body's antibody response. The study also showed that the highest antibody titers that occurred from the bivalent vaccine were seen in people who had already had a COVID infection (Lubell, 2022). Adding a new strain to an existing vaccine should not alarm anyone, she noted, because this is not a new practice. It is what the FDA permits with the modifications to our annual flu vaccines. Influenza vaccines, which are given to develop immunity against the influenza virus, contain multiple influenza virus variations.

The CDC's guidance is that we stay current with our COVID-19 vaccines. We are considered up-to-date if we have completed our primary vaccine series (Moderna, Pfizer, or Janssen & Janssen) and we have received our most current CDC recommended booster, which up to now would only have been a monovalent (original) vaccine. As we are heading into flu season, the CDC is recommending that we get both flu and COVID vaccines, and that they can be taken at the same time, but in different arms. This includes the high-dose influenza vaccines for seniors. There were no specific safety concerns identified during the vaccine studies when both were taken at the same time, including when the high dose flu vaccine for seniors was used (CDC, 2022). The side effects of vaccination with a bivalent vaccine were similar to those with the old monovalent vaccines. There were no instances reported by researchers of either pericarditis or myocarditis (heart inflammation) based on the studies done (Lubell, 2022).

The CDC has simplified COVID vaccine and booster recommendations to note that a **2-month waiting period** before getting your bivalent vaccine booster is called for regardless of if you have had just your primary series, if you have had your primary series and one booster, or if you have had your primary series and 2 boosters.

The other simplification is that the new bivalent booster with its recommendations now replaces all previous booster recommendations **for people 12 and older. There are no changes at this time to vaccine/booster**

schedules for children 6 months to 11 years. The previous original monovalent mRNA vaccines are no longer authorized as booster doses for anyone 12 years of age or older. Everyone will henceforth be eligible **for one bivalent mRNA booster dose**. If you are 5-11 years old that booster will continue to be the original monovalent booster. If you are 12 or older, the booster will be the new bivalent booster. Everyone who has completed their original booster series at least 2-months ago is advised to now make arrangements to get their bivalent (new) booster, (but if they are getting over a COVID infection, wait 3 months unless your primary care provider (MD, APRN, PA) suggests you get it sooner. The CDC has noted that if SARS-CoV-2 (COVID-19) becomes a seasonal virus, we may be looking at annual COVID vaccine campaigns similar to our seasonal influenza campaigns. As you consider your options, we urge you to stick to science-based sources for your health and public health information as there is a lot of misinformation and misleading information circulating:

Valid Public Health Information Sources:

Greenwich Department of Health: <https://www.greenwichct.gov/575/Health-Department>

Connecticut Department of Public Health: <https://portal.ct.gov/coronavirus>

Centers for Disease Prevention and Control (CDC): <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

FDA: Multilingual Resources on the COVID-19 Bi-Valent Vaccine Boosters:

<https://cacmap.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/multilingual-covid-19-resources>

American Medical Association: <https://www.ama-assn.org/topics/coronavirus-covid-19>

American Nurses Association: <https://www.apha.org/topics-and-issues/communicable-disease/coronavirus/guidance>

American Public Health Association: <https://www.apha.org/topics-and-issues/communicable-disease/coronavirus/guidance>

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