



Health Update: Bivalent COVID-19 Vaccine Boosters

Sept 8, 2022

Recent Action

On 8/31/22 FDA announced that bivalent COVID-19 booster doses have been authorized, and monovalent COVID-19 booster doses are no longer authorized, for persons aged \geq 12 years. On 9/1/22 SFDPH notified San Francisco COVID-19 vaccine providers to cease use of the monovalent boosters for this age group, while awaiting delivery of the bivalent booster doses which are expected to arrive in the coming days.

The new bivalent boosters from Moderna and Pfizer-BioNTech augment the monovalent boosters by adding spike protein mRNA from the currently prevalent BA.4/BA.5 COVID-19 variant strains, in a process analogous to the annual updating of influenza vaccines, according to the endorsement statement by the <u>Western States Scientific Safety Review Workgroup</u>.

Detailed evidence review by the <u>Advisory Committee on Immunization Practices</u> has shown the bivalent boosters to be more immunogenic, but not more likely to cause adverse reactions, compared with the monovalent booster products.

Booster Guidance

SFDPH aligns with this most recent change to booster recommendations as described in detail in CDC's updated <u>interim considerations for COVID-19 vaccine</u>. In brief:

- Persons aged ≥12 years, including those with moderate-severe immune compromise, are recommended to receive 1 age-appropriate **bivalent** mRNA booster dose **at least 2** months after completion of any FDA-approved/authorized monovalent primary series or monovalent booster dose. This replaces all prior booster recommendations for this age group. See updated COVID-19 vaccine schedules from <u>CDC</u> or <u>CDPH</u>.
- Pfizer-BioNTech bivalent booster doses are authorized for ages ≥12 years, while Moderna bivalent boosters are authorized for ages ≥18 years. Either brand of ageappropriate, bivalent mRNA booster can be used, regardless of the product(s) given as primary series or prior booster doses.
- The bivalent products are currently authorized as **booster doses only**.
- For persons aged ≥12 years, the monovalent Pfizer-BioNTech or Moderna products may still be given but as **primary series doses only**.





- **Coadministration**. Bivalent booster doses may be administered without regard to timing of other vaccines, including seasonal influenza vaccine. Best practices for multiple immunizations at one visit include labeling each syringe and administering vaccines at different injection sites or in different limbs.
 - There is <u>no minimum interval</u> between receipt of JYNNEOS vaccine for MPX and COVID-19 vaccines; co-administration is not contraindicated. Receipt of JYNNEOS is high priority during the MPX outbreak and should not be delayed.
 - Per CDC adolescent and young adult males "might consider" waiting 4 weeks after JYNNEOS to receive an mRNA or Novavax vaccine, as CDC has not fully ruled out the possible risk of myopericarditis after JYNNEOS. We note however that to date, myopericarditis following JYNNEOS has not been reported in the <u>VAERS</u> data and did not occur in JYNNEOS clinical trial participants.
- The COVID-19 vaccination schedules and authorized products recommended for children ages 6 months to 4 years and 5 to 11 years have not changed. In the future, bivalent booster products may undergo evaluation in these younger age brackets.

Update to Guidance on Post-COVID-19 Vaccination Observation Periods

Recognizing that anaphylaxis has been reported rarely following COVID-19 vaccination, CDC has updated the guidance for observation periods following COVID-19 vaccination. Previously, a 15-minute post-vaccination observation period was required for all vaccinees (30 minutes for persons at higher risk of severe allergic reactions).

<u>CDC now recommends</u> that providers should consider observing all vaccine recipients for 15 minutes after vaccination for syncope, per its <u>General Best Practice guidelines</u> and that 30 minutes of observation should be considered for persons with:

- Allergy-related contraindications to different type of COVID-19 vaccine,
- Non-severe, immediate (within 4 hours) allergic reaction after any previous dose of COVID-19 vaccine, or
- anaphylaxis after any non-COVID-19 vaccine or injectable therapy.

Vaccine providers must still be prepared to recognize and treat severe allergic reactions.

Additional Resources

CDC COVID Vaccination Guidance for Clinicians | CDPH COVID-19 Vaccination Program Info

SF.gov Vaccination Resources https://sf.gov/get-vaccinated-against-covid-19