



To: CAHAN San Diego Participants

Date: September 6, 2022

From: Public Health Services

Health Advisory Update #56: Coronavirus Disease 2019 (COVID-19) Vaccine Update: Bivalent Boosters

Key Messages

- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have authorized bivalent Pfizer COVID-19 boosters for those ≥ 12 years of age and bivalent Moderna boosters for those ≥ 18 years of age.
- FDA deauthorized the use of monovalent COVID-19 boosters for the same age groups.
- A single bivalent booster can be administered when appropriate to all eligible persons. Bivalent boosters should not be denied based on the total number of doses an individual has received.
- COVID-19 vaccines may be co-administered with other recommended vaccines, including the seasonal influenza vaccine.

Situation

Following scientific evaluation and discussion, federal agencies granted bivalent mRNA COVID-19 boosters Emergency Use Authorization (EUA) and issued recommendations for use in persons ≥ 12 years of age. FDA has deauthorized the use of monovalent mRNA boosters in this age group.

Background

Vaccines

Compared with monovalent boosters, both the Pfizer and Moderna bivalent boosters demonstrated a superior immune response to the Omicron variant challenge and yielded non-inferior (i.e., similar) responses to the ancestral SARS-CoV-2 strain challenge. The rate of side effects from both the Pfizer and Moderna bivalent boosters (as 4th dose/2nd booster) were the same or lower compared to earlier monovalent boosters.

Administration

- A single dose of a bivalent booster is authorized in place of or in addition to a monovalent booster as follows:
 - The Pfizer COVID-19 bivalent booster can be used in persons ≥ 12 years of age.
 - The Moderna COVID-19 bivalent booster can be used in persons ≥ 18 years of age.
- Single doses of a bivalent booster can be administered at least 2 months after either:
 - Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccines (e.g., Pfizer, Moderna, Novavax, Janssen); or
 - Receipt of the most recent booster with any authorized or approved monovalent COVID-19 boosters (e.g., Pfizer, Moderna).
- Mixing or matching of the bivalent booster is allowed based on preference among eligible persons.
- **If eligible, a bivalent booster should not be denied based on the total number of doses.**
- Administration of a monovalent booster to a person eligible for a bivalent booster is considered a vaccine administration error and should be reported to the [Vaccine Errors Reporting Program \(VERP\)](#).

- A bivalent booster can be administered after 2 months, as noted above.
- The bivalent boosters can be administered with other approved vaccines, including the seasonal influenza vaccine.
- Pfizer monovalent COVID-19 boosters should continue to be administered to 5- to 11-year-old children.
- Monovalent mRNA COVID-19 vaccines should continue to be used to complete primary series, including third doses for [persons with moderate to severe immune compromise](#).

Approval Process

On August 31, 2022, the FDA amended the EUAs of the Pfizer and Moderna COVID-19 vaccines authorizing the administration of the updated bivalent boosters. In addition, the amendment removed the authorization of the monovalent versions of these boosters for the eligible age groups.

On September 1, 2022, the Advisory Committee on Immunization Practices (ACIP) met to discuss bivalent boosters (presentation slides are available [here](#)). On September 2, the CDC updated its [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) page to include the ACIP recommendations. A Clinical Outreach Communication Activity (COCA) call on bivalent boosters is scheduled for 11 AM PST on September 13, 2022. Free CME will be offered. The call will be recorded and made available [here](#) after the meeting.

On September 1, 2022, the Western States Scientific Safety Review Workgroup concurred with the ACIP recommendations. Their statement is available [here](#).

Scheduling

MyTurn.ca.gov is currently being updated to include appointments for the bivalent COVID-19 vaccine. Existing MyTurn appointments for monovalent boosters for persons eligible for bivalent boosters will be rescheduled.

Actions Requested

1. Remain up-to-date on COVID-19 with the CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) page.
 - a. **Cease administering monovalent COVID-19 boosters to persons \geq 12 years of age. Reschedule persons eligible for a bivalent booster to a date when a bivalent booster will be available.**
 - b. Administer Pfizer bivalent COVID-19 booster to eligible persons 12- through 17 years of age.
 - c. Administer either Pfizer or Moderna bivalent COVID-19 boosters to eligible persons \geq 18 years of age.
 - d. Submit a [\(VERP\) report](#) when a monovalent booster is inadvertently administered to a person eligible for a bivalent booster.
2. Report vaccine-related adverse events, deaths, and vaccine administration errors to the [VAERS](#) and the County Immunization Program at IZINFO.HHSA@sdcounty.ca.gov or Fax: (619) 692-5677.

Resources

- FDA Fact Sheets on Pfizer COVID-19 Bivalent Booster for [Healthcare Providers](#) and [Recipients/Caregivers](#)
- FDA Fact Sheets on Moderna COVID-19 Bivalent Booster for [Healthcare Providers](#) and [Recipients/Caregivers](#)
- [Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC](#)

Thank you for your participation.

CAHAN San Diego

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