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Report: Safety of updated COVID vaccine boosters similar to original boosters

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Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

A new report supports the safety of bivalent COVID-19 vaccine boosters for adolescents and adults.

"Health care providers and patients can be reassured that adverse events reported after a bivalent booster are consistent with those reported after monovalent doses," authors from the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) wrote in a new *Morbidity and Mortality Weekly Report*. "Health impacts after COVID-19 vaccination are less frequent and less severe than those associated with COVID-19 illness."

The report looks at data on bivalent COVID vaccine booster doses given to people ages 12 years and older during the first seven weeks after authorization. When they were authorized, the available human data on bivalent boosters included a different omicron strain than the one currently being used.

Nearly 212,000 adolescents and adults out of 22.6 million who received bivalent boosters provided feedback to the CDC's v-safe smartphone-based system, which includes daily check-ins during the week after vaccination. About 40% of these registrants received another vaccine at the same time, most commonly flu vaccine.

About 69% of adolescents ages 12-17 years and 61% of all people reported an injection site reaction. The most common was pain, which was reported by 67% of adolescents.

About 60% of adolescents and 55% of all people reported a systemic reaction to v-safe. The most common among adolescents were fatigue (45%), headache (36%), muscle aches (34%) and fever (26%). About 1% of adolescents needed medical care, about the same percentage as the overall population who received the booster

Authors noted the system is voluntary and might not be representative of all people who have been vaccinated.

There were 5,542 reports to the Vaccine Adverse Event Reporting System (VAERS) managed by the CDC and FDA following a bivalent COVID vaccine booster. VAERS reports can be filed by health care providers and the public. Reports do not mean vaccination caused the adverse event. Authors noted VAERS is subject to underreporting, especially of non-serious events.

The median age of vaccine recipients reporting adverse events was 60 years. About 95.5% of reports were not serious.

Vaccination errors were involved in 35% of the VAERS reports, almost all of which did not have a serious health event.

Among nonserious reports, the most common were headache, fatigue and fever. There were 251 serious reports, which were reviewed by CDC physicians. These included 31 thrombotic events, 20 cases of COVID, five cases of myocarditis (ages 12-78 years) and four cases of pericarditis (ages 46-78 years).

There were 36 deaths reported with a median age of 71. Among four with sufficient information, causes were cardiac arrest, dementia, metastatic prostate cancer and myocardial infarction.

“CDC and FDA will continue to monitor vaccine safety and will provide updates as needed to help guide COVID-19 vaccination recommendations.” authors wrote.

In October, authorization of bivalent booster was expanded to include younger children. People ages 5 years and older who have completed a primary series are eligible for a single bivalent booster two months after previous doses. About 61% of adolescents ages 12-17 years and 32% of children 5-11 years have completed a primary series, according to CDC data. Children can receive a bivalent booster with a different brand than their primary series.

Resources

- CDC information on COVID-19 vaccine boosters
- CDC clinical considerations for administering COVID-19 vaccines
- AAP COVID vaccination resources
- AAP pediatric COVID-19 vaccine dosing quick reference guide
- AAP/Health and Human Services COVID vaccine toolkit
- Information from HealthyChildren.org on preparing children for a COVID-19 vaccine