What Providers Need to Know about COVID-19 Bivalent Boosters for Younger Children

National Association of Pediatric Nurse Practitioners℠
Immunization SIG

Since the beginning of the COVID-19 pandemic, there have been more than 16 million cases, more than 177,000 hospitalizations and almost 2,000 deaths among U.S. children under age 18 with the highest number of deaths in 0-4 year old children, 652 as of January 2023.

Overview of Available Bivalent Boosters

Pfizer BioNTech	Moderna
Phase 2/3 trial: 2,176 children age 6-23 months	Phase 2/3 ongoing trial: 2,350 children age 6-23 months of age
FDA/CDC authorized for 6 months — 4 years of age who received 2– or 3-dose primary vaccine series	**FDA/CDC authorized for 6 months — 5 years of age**
Booster Dose (a/k/a Dose 3): 3 µg/0.2ml given at least 8 weeks after dose 2 of the Pfizer BioNTech vaccine; **maroon** cap	Booster Dose: 10 µg/0.2ml given at least 8 weeks after completing the Moderna COVID-19 primary series ; **dark pink** cap and label with a yellow box
Does NOT contain eggs, preservatives, latex, metals	Does NOT contain eggs, preservatives, latex, metals
Efficacy analysis of 3 COVID-19 cases in participants 6-23 months of age, VE against COVID-19 at least 7 days post-Dose 3 was 75.6% (95% CI: -369.1%, 99.6%), with 1 COVID-19 case in the BNT162b2 group and 2 in the placebo group (2:1 randomization BNT162b2 to placebo). Immunobridging success criteria were met for age group of 6-23 months.	Using the CDC definition for the protocol-specified VE endpoint of COVID-19 cases starting 14 days after Dose 2: VE was 50.6% (95% CI 21.4, 68.6) for participants 2-5 years of age and 6-23 months of age, respectively, during an evaluation period when the Omicron variant was predominant. Immunobridging success criteria were met.
Side effects: 6-23 months of age were irritability (51.2%), drowsiness (27.0%), decreased appetite (22.2%), and tenderness at the injection site (16.6%). In participants 6-23 months of age, the frequencies of unsolicited non-serious AEs reported were similar in the BNT162b2 and placebo groups (29.1% versus 26.3%). There were no reports of myocarditis/pericarditis, no cases of anaphylaxis considered caused by vaccination, and no deaths.	Side effects: Among younger pediatric participants 6-36 months of age, irritability/crying (71-82%) and sleepiness (50-51%) were frequently reported. Rates of fever were 21-26% among participants 6 months through 5 years of age. Pediatric participants >36 months of age frequently experienced fatigue (62%) and headache (23%). Participants 37 months-5 years frequently reported fatigue (73%) and headache (62%). There were no confirmed cases of myocarditis or pericarditis among participants 6 months through 17 years in clinical studies with mRNA-1273.

For more information about COVID-19 vaccines visit: cdc.gov/vaccines/covid-19/info-by-product/index.html