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

National Association of Pediatric Nurse Practitioners℠
Immunization SIG

Since the beginning of the COVID-19 pandemic, there have been more than 17 million cases and more than 2,000 deaths among U.S. children under age 18 with the highest number of deaths in 0-4 year old children, 761 as of April 2023.

Overview of Available Vaccines

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	**FDA/CDC authorized for 6 months — 5 years of age**
3 doses: 3 µg/0.2ml , **maroon** cap Dose 1: week 0 Dose 2: week 3 Dose 3: > 8 weeks after Dose 2	2 doses: 10 µg/0.25ml, **dark pink** cap Dose 1: week 0 Dose 2: 30 days later
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 (2:1randomization BNT162b2 to placebo). Immunobridging success criteria were met for age group of 6-23 months. The safety of Pfizer-BioNTech COVID-19 Vaccine, Bivalent in individuals 6 months of age and older is based on previously reviewed safety data from clinical studies which evaluated primary and booster vaccination with Pfizer BioNTech COVID-19 Vaccine, booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, Bivalent, and a booster dose of bivalent vaccine (Original and Omicron BA.1); and post-marketing safety data with Pfizer-BioNTech COVID-19 Vaccine.	Two 25 µg doses of mRNA-1273 in participants 6 months to under 6 years met primary endpoint with robust neutralizing antibody titers similar to adults mRNA-1273 was generally well tolerated in this age group 6,700 participants 6 months to under 6 years of age were enrolled into this age cohort. Vaccine efficacy in children 6 months to 2 years was 43.7% and vaccine efficacy was 37.5% in the 2 to under 6 years age group.
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: Rates of fever greater than 38°C among vaccine recipients were consistent with other commonly used and recommended pediatric vaccines and were 17.0% and 14.6% in the 6 months to under two years and the two to under six years age groups, compared to 23.9% in the six to under 12 years age group, which received a 50 µg two-dose primary series. Fever greater than 40°C was seen in only a few children (0.2% in each age group). There were no confirmed cases of myocarditis or pericarditis and no multisystem inflammatory syndrome in children (MIS-C).