

Adverse reactions to BNT162b2 mild, moderate for 5- to 11-year-olds

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Among children aged 5 to 11 years, most reported adverse events to BNT162b2 COVID-19 vaccination are mild-to-moderate, with few reports of myocarditis, according to a study recently published in *Pediatrics*.

Anne M. Hause, Ph.D., M.S.P.H., from the U.S. Centers for Disease Control and Prevention COVID-19 Response Team in Atlanta, and colleagues describe adverse events observed during the first four months of the U.S. COVID-19 vaccination program among children ages 5 to 11

years. Data were analyzed from three U.S. safety monitoring systems: v-safe, a voluntary smartphone-based system that monitors reactions and [health effects](#); the Vaccine Adverse Events Reporting System (VAERS), a national spontaneous reporting system; and the Vaccine Safety Datalink (VSD), an active surveillance system that monitors [electronic health records](#) for prespecified events.

The researchers found that most reported reactions among the 48,795 children aged 5 to 11 years enrolled in v-safe were mild-to-moderate, most were reported the day after vaccination, and they occurred more often after the second dose. A total of 7,578 adverse event reports were received by VAERS; 97 percent were nonserious. Fifteen cases of myocarditis were verified on review of 194 serious VAERS reports; eight occurred in boys after dose 2 (reporting rate, 2.2 per million doses). No safety signals were identified in weekly sequential monitoring after administration of 726,820 doses in VSD.

"The updated safety findings presented here, collected during the administration of ~16 million doses of BNT162b2 vaccine to [children](#) ages 5 to 11 years, are consistent with previous findings for this age group and demonstrate a favorable safety profile," the authors write.

Several authors disclosed financial ties to the [pharmaceutical industry](#), including companies involved in manufacturing COVID-19 vaccines.

More information: Anne M. Hause et al, Safety of COVID-19 Vaccination in US Children Ages 5–11 Years, *Pediatrics* (2022). [DOI: 10.1542/peds.2022-057313](https://doi.org/10.1542/peds.2022-057313)

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