

FDA Acknowledges COVID Vaccine Safety Signal for Seizures Among Toddlers



A new safety signal associated with mRNA COVID-19 vaccination has been detected by the U.S. Food and Drug Administration (FDA) among toddlers, prompting calls for further evaluation and more robust studies.

According to a [preprint study](#) published Oct. 15 on medRxiv, a statistical signal was detected for seizures/convulsions in children aged 2 to 4 who received Pfizer's COVID-19 vaccine and for children aged 2 to 5 who received Moderna.

A vaccine safety signal indicates that an adverse health outcome may occur more frequently following vaccination and may be causally linked to a vaccine.

Researchers with the FDA and three large healthcare companies analyzed 21 pre-specified health outcomes among 4,102,106 vaccinated enrollees from three commercial claims databases following COVID-19 vaccination with Pfizer, Moderna, and

Novavax among the U.S. pediatric population aged 6 months to 17 years.

The health claims databases are part of the FDA's Biologics Effectiveness and Safety System—a safety monitoring system that identifies any side effects not reported to the Vaccine Adverse Event Reporting System.

Of the 21 pre-specified health outcomes, 15 were sequentially tested by researchers using near real-time surveillance following vaccination. The rates were then compared among children aged 6 months to 17 years old to background rates from 2019, 2020, or both.

Researchers identified 72 cases of seizures/convulsions within seven days of receiving a vaccine among toddlers and other young children.

When analyzing data by dose, researchers identified signals following doses one and two of Pfizer's COVID-19 vaccine in two of three databases in children aged 2 to 4 and a signal following dose two of Moderna in children aged 2 to 5.

Although the study noted a signal for seizures/convulsions “has not been previously reported for this age group in active surveillance studies of mRNA COVID-19 vaccines,” the FDA concluded that the “known and potential benefits of COVID-19 vaccination outweigh the known and potential risks of COVID-19 infection.”

The researchers pointed out several limitations of the study and said results should be interpreted cautiously as the signal varied based on the background rate of various years. At the same time, a strength of the study is that it covered a large and geographically diverse population.

Researchers also detected a signal for myocarditis and pericarditis in older children aged 12 to 17, consistent with existing literature, but did not address it further.