A review of more than 245,000 doses of mRNA COVID-19 vaccines given to young children (most of them age 4 and younger) found no indications of serious side effects. The study, published June 6 in
Pediatrics, was led by the Kaiser Permanente Division of Research in partnership with the Centers for Disease Control and Prevention.

The data came from the Vaccine Safety Datalink, which collects patient medical information from 8 health systems (5 Kaiser Permanente regions along with Marshfield Clinic in Wisconsin, HealthPartners in Minneapolis, and Denver Health in Colorado). The researchers examined patient records from June 2022 to March 2023 for both the Pfizer and Moderna vaccines.

Importantly, there was no indication of the heart inflammation called myocarditis among the young vaccinated children, said lead author Kristin Goddard, MPH, research project manager with the Kaiser Permanente Vaccine Study Center. "We haven't seen any myocarditis or pericarditis in this youngest age group, which is very reassuring," Goddard said.

Myocarditis has emerged as a rare side effect of COVID-19 vaccination, mostly among teenage or young adult men. Rates of myocarditis for children over 5 years old and young adults following COVID-19 vaccination in the Vaccine Safety Datalink have been previously published.

The Pediatrics study marks the first analysis looking for serious side effects from the mRNA vaccines in young children. The study examined medical records for 23 serious potential side effects, including outcomes such as blood clots, seizures, stroke, and brain inflammation. Analyses showed no safety concern for any of the selected serious side effects. In particular, the study found no concern for seizures after vaccination, something occasionally seen following other routine childhood immunizations in children under 2 years old.

Meanwhile, the CDC previously reported on mild side effects from
immunization, such as sore arms or brief fevers.

The analysis covered a large and diverse group of children. It included 135,005 doses of the Pfizer COVID-19 vaccine given to children age 6 months to 4 years and 112,006 doses of the Moderna COVID-19 vaccine given to children age 6 months to 5 years.

"Parents can be assured that this large study found no serious side effects from the mRNA vaccines," said senior author Nicola Klein, MD, Ph.D., director of the Kaiser Permanente Vaccine Study Center and research scientist with the Division of Research. "Parents can protect their young children from COVID-19 in the same way they vaccinate their children to protect from other serious childhood diseases."

"Even as the COVID-19 emergency has ended, we know that the coronavirus poses a long-term, serious threat to all ages, including children," Dr. Klein added. "Vaccinating children against COVID-19 benefits them by reducing the burden of illness, avoiding spreading the virus to family and others, and mitigating the small but real risk of serious illness."

publications.aap.org/pediatrics/online-first

Provided by Kaiser Permanente
