THE EPOCH TIMES

VACCINES & SAFETY

FDA Detects Serious Safety Signal for COVID-19 Vaccination Among Children

The U.S. Food and Drug Administration in White Oak, Md., on July 20, 2020. (Sarah Silbiger/Getty Images)

By Zachary Stieber

May 25, 2023 Updated: May 27, 2023

Print

Children of certain ages who received Pfizer's COVID-19 vaccine face an elevated risk of heart inflammation, according to a new federally funded study.

Vaccinated children aged 12 to 17 face a heightened risk of myocarditis, a form of heart inflammation, and a related condition called pericarditis, U.S. Food and Drug Administration (FDA) researchers found.

The number of myocarditis and pericarditis events in that age group met the threshold for a safety signal, the researchers reported in the Journal of the American Medical Association on May 22.

The elevated risk was present within seven days of vaccination, according to the data.

Researchers identified 89 cases among 12- to 15-year-olds and 64 cases among 16- and 17-year-olds after reviewing records from commercial databases run by CVS Health, HealthCore, and Optum.

The claims were made between Dec. 11, 2020, when Pfizer's vaccine was cleared by the FDA, and mid-2022.

Researchers looked at data to determine whether any of the 20 health problems were experienced at higher rates by the vaccinated. The problems included myocarditis or pericarditis, Bell's palsy, appendicitis, and stroke.

Only myocarditis or pericarditis met the criteria for a safety signal, which may be related to vaccination.

U.S. officials have already concluded that the conditions are caused by the Pfizer and Moderna COVID-19 vaccines, although the vaccines didn't carry a warning for months after authorization. One possible mechanism is excessive immune responses triggered by lipid nanoparticles. Novavax's vaccine, authorized in 2022, can also cause the heart conditions, authorities say.

More on Study

Researchers looked at health plan members who received a Pfizer vaccination, excluding those who lost their insurance during a certain window of time, which was 365 days for most outcomes.

Researchers then examined the number of each outcome in a different window of time, referred to as a risk window, which varied from a single day to as long as 42 days after vaccination.

The study then took the rates of problems from each database and compared them with expected rates, which are based on pre-pandemic numbers.

Out of 3 million children who received at least one vaccine dose, 153 cases of myocarditis or pericarditis were identified in the 12- to 17-year-old age group. More cases were identified among children aged 5 to 11, but not enough to trigger a signal.

A medical record review of the 37 cases for which records were obtainable confirmed 27 cases as true myocarditis or pericarditis.

None of the other 19 outcomes examined met the signal criteria, according to researchers.

“These results provide additional evidence for the safety of the COVID-19 vaccines in the pediatric population,” the researchers said.

Dr. Peter McCullough, a cardiologist, disagreed.

“My concern is that these data represent a gross under-reporting of the frequency and severity of COVID-19 vaccine-induced myocarditis,” McCullough, who has called for the withdrawal of the Pfizer vaccine, told The Epoch Times via email.

Since the FDA and the U.S. Centers for Disease Control and Prevention acknowledged in mid-2021 concerns that the vaccines might cause heart inflammation, “there have been [more than] 200 papers in the peer-reviewed literature and over 100 fatal documented cases largely among young men, peak ages 18–24 years, some with autopsy proven COVID-19 vaccine heart inflammation resulting in death,” according to McCullough.

That includes five people who suddenly died in Germany and six people who perished in the Nordic countries.

A request for comment sent to Steven Anderson, the FDA official listed as the study’s corresponding author, sparked a response by an FDA spokesperson, who declined to provide additional citations for the safety claim.

Anderson’s co-authors included researchers with Acumen, Optum, HealthCore, CVS, and IQVIA, with multiple members reporting connections with Pfizer. The time period included when the old Pfizer vaccine, which is no longer available in the United States, was used.

‘Pretty Ludicrous’

Norman Fenton, emeritus professor of risk at the Queen Mary University of London, said the researchers’ safety claim doesn’t hold up in light of the facts that the study shows a signal for myocarditis and pericarditis and that children are unlikely to benefit from the COVID-19 vaccines.

“The conclusion that ‘these results provide additional evidence that COVID-19 vaccines are safe in children’ is pretty ludicrous,” Fenton told The Epoch Times in an email.

The researchers also failed to take into account what’s known as the healthy vaccine bias; previous research has found that people who decide to get vaccinated tend to be healthier than those who don’t.

“They are comparing a highly select group of child and adolescent insured vaccine recipients to a historical baseline population consisting of everyone in the relevant age group who were insured,” Hebrew University lecturer Josh Guetzkow said.

Experts also said the risk windows appeared short, as post-vaccination conditions can sometimes crop up months afterward, and noted that the signal criteria were structured so that some outcomes would need to happen at more than double the rate among the vaccinated to meet them.

The shortest risk window was just one day, for anaphylaxis, or severe allergic shock. Some others were just one week. The rest were 28 days or 42 days.

In their protocol (pdf) for conducting the research, FDA officials said they chose risk windows based on pre-pandemic studies, including one from 2007.

RELATED TOPICS

FDA COVID-19 Vaccines