



**UPDATE:**  
**Vaccine Adverse Event Reporting System (VAERS) Data on Febrile Seizures after  
Vaccination with Fluzone®,  
a 2010-2011 Trivalent Inactivated Vaccine, in Children  
Data through December 13, 2010**

*Please note: This summary provides additional information about VAERS reports of febrile seizures after vaccination with 2010-2011 Fluzone®.*

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) routinely monitor the safety of all U.S. vaccines by using several vaccine safety surveillance systems, including the [Vaccine Adverse Event Reporting System \(VAERS\)](#). FDA and CDC have recently become aware of an increased number of reports of febrile seizures after vaccination with Fluzone®, a 2010-2011 influenza trivalent inactivated vaccine (TIV) manufactured by Sanofi Pasteur, and febrile seizures in children younger than 5 years of age in the United States, particularly in children aged 6-23 months. Fluzone® is the only product that is both licensed and recommended for 6-23 month olds in the United States this influenza season.

Febrile seizures, which occur with rapid body temperature changes from fevers in young children, can occur with fevers due to natural infections or occasionally with vaccination. Febrile seizures most often occur in children younger than 5 years of age with a peak age of 14 – 18 months. During the 2010-2011 influenza season, febrile seizures after vaccination with TIV were one focus of U.S. vaccine safety monitoring. A review of the U.S. VAERS data showed a higher proportion of reports of febrile seizure than expected after Fluzone® compared with reports from other inactivated vaccines, particularly in children aged 6-23 months. This observation does not mean Fluzone® is causing the febrile seizures, but indicates that further assessment is needed.

Although VAERS is useful for detecting potential vaccine safety concerns, it cannot generally determine whether a vaccine is causing an adverse event. It only indicates that the event occurred after administration of the vaccine. Proof that the event was caused by the vaccine is not required in order for VAERS to accept the report. VAERS data should be used with caution because they do not reflect additional information collected during follow-up, which could change the numbers of a given condition actually observed. Signals of adverse events in VAERS prompt additional more detailed investigations to better understand the relationship between a vaccine and a potential safety concern.

This update summarizes febrile seizure reports after administration of 2010-2011 TIV as reported in the VAERS database. Further studies are being conducted to evaluate the potential association.



- Approximately 4 million doses of TIV were administered to children aged 6 – 23 months between August and mid- December 2010.
- As of December 13, 2010, VAERS received 263 reports among children 6-23 months old.
- Since July 16, 2010, medical doctors at CDC and FDA have been monitoring and reviewing all cases of potential seizure in children younger than 5 years of age. Additional medical records have been requested to verify the diagnosis of febrile seizure.
- There were 53 VAERS reports of confirmed febrile seizures in children younger than 5 years of age received by December 13, 2010 after administration of any 2010-2011 influenza vaccine. Of these, 42 were reports of febrile seizures after vaccination with Fluzone® TIV in children aged 6-23 months.
- The following were characteristics of the 42 verified reports of febrile seizure in children aged 6-23 months after vaccination with Fluzone® TIV:
  - All patients with reported febrile seizures have recovered.
  - Thirty-two or 76% of the cases were classified as non- serious.\*
  - Ten cases were defined as serious\*, with most being hospitalized overnight for observation and released.
  - The median interval from vaccination to seizure was 10 hours (range 3 hours to 10 days) among cases where timing of vaccination and start of seizure was documented.
  - The majority (86%) occurred on the same day or the day after vaccination.
  - Twenty-seven of 42 (64%) reported receiving other vaccines at the same time as influenza vaccine.
  - Medical history: Where information was available, 7 of 42 (17%) had family history of seizure documented, 3 of 42 (7%) had previous history of febrile seizure, and 6 of 42 (8%) reports described illness such as upper respiratory infection or gastrointestinal complaints on the day of vaccination. The elevation in temperature ranged from 100.4 to 104°F.
- There were no patterns seen with similar manufacturer lot numbers or location of those who reported cases.
- No changes in influenza vaccine practices are recommended by either CDC or FDA based on this information.
- CDC and FDA will continue to monitor the safety of 2010-2011 influenza vaccine and are in the process of conducting additional studies to understand what risk, if any, influenza vaccination may pose for febrile seizures in young children.

**Additional information:**

[FDA: Fluzone Vaccine Safety](#)

[CDC: Frequently Asked Questions about Febrile Seizures Following Childhood Vaccinations](#)



\*An adverse event, as defined by the Code of Federal Regulations, is considered serious if it is life threatening, or results in death, a persistent or significant disability or incapacity, congenital anomaly or birth defect, hospitalization, or prolongation of existing hospitalization.