Delayed adverse events – A SAEFVIC Case Study

A 12-month-old child received her routine vaccinations – MMR and Hib-MenCCV – at her local GP. She was well on the day of vaccination.

Approximately eight days following vaccination she awoke with a mild fever, cough and runny nose. As the day progressed her fever spiked to 39.9 °C. While sitting on the floor playing with her mum, her eyes rolled back, she lost consciousness and her whole body began to shake and twitch. This lasted for approximately two minutes. Her mother called an ambulance and the child was transferred to the local emergency department (ED).

The child had a routine examination in the ED and her urine culture returned negative. She was observed for four hours with no further seizures and was discharged home with a diagnosis of febrile convulsion secondary to a viral upper respiratory tract infection. She remained well at home with no further spikes in fever.

The local GP practice nurse reported this event to SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community). The child and her family were seen in the specialist immunisation clinic at The Royal Children’s Hospital to discuss this event and further immunisation. The child went on to successfully undergo her 18-month-old vaccination with the MMRV (measles-mumps-rubella-varicella) vaccine with no recurrence of a febrile seizure.

Discussion

One of the most common adverse events following immunisation (AEFI) is a mild to moderate fever. Some vaccines are known to cause a higher fever. For example, a fever greater than 39.4 °C is expected in approximately five to 15 per cent of children who receive an MMR vaccination. The timing and co-administration of some vaccines can increase the risk of a febrile seizure.

A febrile seizure is a convulsion or fit caused by a sudden rise in temperature, usually a fever more than 38 °C. Approximately one in 30 children aged between six months to six years will have a febrile seizure at one time, with a peak onset in the second year of life.

Febrile seizures are usually associated with a viral or bacterial infection; however, anything that causes a fever – vaccination for example – can cause a febrile seizure. They are usually not harmful and are not known to have any long-term sequelae; however, they are very distressing for parents and family to witness.

When Prevenar 13® (PCV13) was introduced onto the market, evidence from a study conducted in the United States found a small increased risk of fever and febrile seizures when the MMR vaccination is co-administered with the trivalent influenza vaccine. When PCV13 was introduced onto the National Immunisation Program, to help decrease this risk it was recommended that these two vaccines could be separated by an interval of at least three days. Currently The Royal Children’s Hospital and Monash Medical Centre separate these vaccines for children less than six years of age.
The recent introduction of the MMRV vaccine (Priorix-tetra®) has renewed concern regarding the potential of a febrile seizure following vaccination. It is recommended that MMRV is not given as the first dose of an MMR-containing vaccine in children less than four years of age. When MMRV is given correctly as a second dose of MMR-containing vaccine the risk of a febrile convulsion is approximately 1:15,500. However, if given as a first dose the risk is increased to 1:2,300. Adverse events in general are much less common after the second dose of an MMR-containing vaccine than after the first dose, with no statistical increase in febrile convulsion risk.

Recommendations

This case study highlights the need to be aware of the potential for delayed adverse events following administration of live attenuated vaccines. Providers need to remember that common adverse events like fever that follow vaccines such as MMR, MMRV or varicella are usually delayed, most commonly by seven to 10 days (with a full range of five to 12 days).

These delayed reactions can often be overlooked by those who are not familiar with common AEFI; therefore, events such as a febrile seizure are not linked to vaccination and consequently are not reported to SAEFVIC for appropriate follow-up. Families should be given the Vaccine side effects handout so they are aware of common and rare side effects of vaccination. Order your free immunisation resources at <ideas.health.vic.gov.au/resources-immunisation.asp>.

References and further reading

*Australian Technical Advisory Group on Immunisation (ATAGI) statement: clinical advice for immunisation providers regarding the administration of 2013 trivalent seasonal influenza vaccines – March 2013, ATAGI seasonal influenza advice*


*The Australian Immunisation Handbook 10th Edition*

[http://www.rch.org.au/kidsinfo/fact_sheets/Febrile_Convulsions/]