

Hypotonic-Hyporesponsive Episode – A SAEFVIC Case Study

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A healthy full term 6-week old infant was taken to their local council immunisation session for their first scheduled routine immunisations. Infanrix hexa, Prevenar 13 and Rotateq dose 1 vaccines were administered by the immunisation nurse at 10.00am. The family waited for the recommended 15 minutes of observation and then returned home. After 2 hours the infant was noted to be limp "like a sack of potatoes", non-responsive and pale in colour. He was afebrile and remained lethargic over the next few hours. He did not feed well until 2am the following day.

The family called Nurse on Call and were advised to go to a GP or hospital emergency department. They were reassured by a call to their Paediatrician and did not attend hospital.

The next day the infant's mother called the immunisation nurse at their local Council. They had a discussion about the likelihood of a Hypotonic Hyporesponsive episode (HHE). A detailed SAEFVIC report was completed online and submitted to SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community). Consent was gained from the parent for SAEFVIC to contact them for phone follow up.

The parents and infant attended a SAEFVIC Immunisation clinic appointment at Royal Children's Hospital. They had a detailed consultation with the SAEFVIC paediatrician who diagnosed an HHE.

Following the consultation the child was admitted to the Day Medical Unit for observation. Routine 4 month immunisations: Infanrix hexa, Prevenar 13 and Rotateq dose 2 vaccinations were administered using oral Sucrose for pain minimisation.

The infant cried and was comforted by both parents. The infant was observed in the DMU for a further 3.5 hours with no adverse event observed.

A SAEFVIC follow up call was made to the mother the next day who reported that the child was happy on the way home from hospital and slept well overnight. The family were advised that the routine 6 month vaccines could be administered in the community.

Discussion

A hypotonic, hyporesponsive (HHE) episode is described as the sudden onset of pallor or cyanosis, limpness (muscle hypotonia), and reduced responsiveness or unresponsiveness occurring after vaccination, where no other cause is evident, such as a vasovagal episode or anaphylaxis. The episode usually occurs 1 to 48 hours after vaccination and resolves spontaneously.

The Brighton Collaboration case definition for HHE as an adverse event following immunisation in early childhood (< 2 years of age) is:

Level 1 of diagnostic certainty: the sudden onset of: hypotonia (muscle limpness) AND hyporesponsiveness AND pallor or cyanosis.

HHE has been documented to occur after immunisation with all vaccines. There has been a decreased incidence following the change from whole cell pertussis to acellular pertussis vaccine.

In Australia in 2009 3.2 cases of HHE were reported per 100,000 doses of DTPa (diphtheria, tetanus, pertussis) containing vaccine given to infants < 1 year of age.

HHE has been observed mainly after the 1st doses of vaccines at 6 to 8 weeks of age. An immediate HHE (within 30 minutes) has been noted by SAEFVIC in 50% of reports with up to 50% being delayed (over 30 minutes post immunisation).

The episode may last for a few minutes with the child being lethargic for a number of hours later. No long term sequelae have been identified in the small number of children who have had long term follow up following a HHE episode. The recurrence rate for a further HHE is 3.5%.

HHE is not a contra indication to further doses of vaccines. 90% of children are up to date for age on NIP schedule following a HHE episode.

Management of child with suspected HHE

Any infant who is suspected of having a HHE episode should be examined by a doctor either at a local medical centre or closest hospital.

All HHE episodes should be reported to SAEFVIC the adverse reporting service for Victoria.

SAEFVIC will contact the parent and arrange for a clinic appointment at Royal Children's Hospital (RCH) or Monash Children's Hospital (MMC). For rural families a telehealth consultation is available. A GP referral is required for all SAEFVIC appointments.

The next scheduled immunisations should be given under supervision, either in a clinic with observation facilities, at RCH or MMC or a ward setting

The graphs below show cases of HHE reported to SAEFVIC

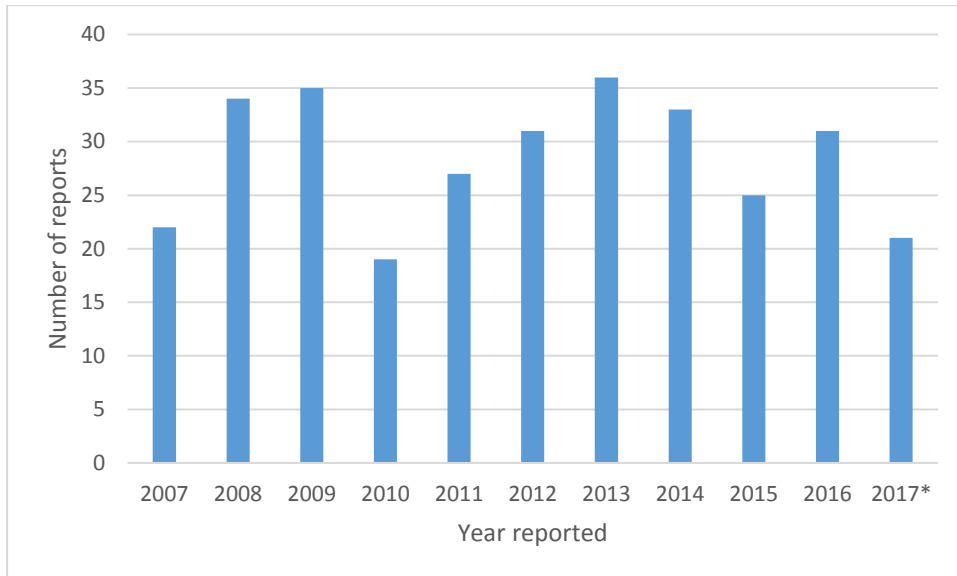


Figure 1: Number of HHE reports received, SAEFVIC, May 2007 to June 2017

Total number of HHE reports received since SAEFVIC started in 2007 to end of June 2017 = 314

Age

The graph below is for the majority, which were all aged 12 months or less (age at vaccination was unknown/not reported for 2 cases)

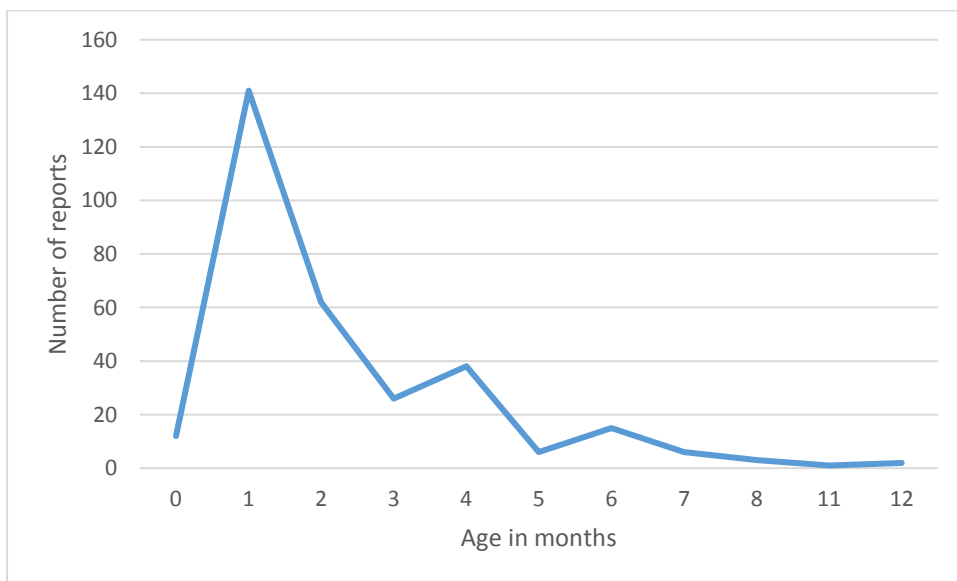


Figure 2: Reports of HHE by age (in months) at time of vaccination, SAEFVIC 2007-2017

Dose

68% (214/314) of HHE reported were following first dose, 23% (73/314) dose 2 and 7% (21/314) dose 3

Time to onset

Almost half of HHE (46%) occurred within 15 minutes of vaccination, three-quarters had occurred within 6 hours and 90% within 12 hours of vaccination.

If you experience an adverse event following vaccination, please call 1300 882 924 (Option 1) between 9 – 4.00pm and report online at www.saefvic.org.au or by fax on (03) 9345 4163.

FURTHER READING

The Australian Immunisation handbook; 10th Edition 2013 (updated January 2014)

[The Australian Immunisation Handbook 10th edition online](#)

Hypotonic-Hyporesponsive Episodes Reported to the Vaccine Adverse Event Reporting System (VAERS) 1996-1998

Hypotonic-hyporesponsive episode (HHE) as an adverse event following immunisation in early childhood: Brighton Collaboration: HHE working group 2007.