

**PAEDIATRIC ACTIVE ENHANCED DISEASE SURVEILLANCE  
(PAEDS)**

**Study Protocol – Seizures in Infants Greater than 1 month but less than 8 months of age**

**BACKGROUND**

Infantile seizures are uncommon, however most occur in children with tuberous sclerosis, hypoxic-ischaemic injury, congenital infections, inborn errors of metabolism, malformations in cortical development, genetic syndromes and chromosomal abnormalities.<sup>2</sup> Although there are now sound data to demonstrate that encephalopathy does not occur following pertussis-containing vaccines, especially acellular vaccines, the rare but severe group of seizure disorders which have their onset in the first 4 months of life continue to cause concern regarding vaccine safety.<sup>1,3</sup> Recently, it has been demonstrated that some children previously labelled as vaccine-related encephalopathy have a defined disorder in the passage of sodium across neuronal membranes.<sup>4</sup> A retrospective review showed that the majority of these children had the condition of severe myoclonic epilepsy of infancy and had de novo mutations of the sodium channel genes, SCN1A. Severe mutations of this gene seem to have a strong predictive value for an epileptic encephalopathy, suggesting that the vaccine was not causative.

Currently there is no APSU study or other network monitoring severe infantile seizures. The PAEDS network will provide an opportunity to gather important prospective data on severe infantile seizures from 4 of the largest tertiary referral centres in Australia and serve as the prototype for surveillance of other severe AEFI resulting in hospitalisation.

**STUDY OBJECTIVES**

To identify the incidence of seizures in infants greater than one month but less than eight months of age admitted with seizures and to determine temporal relationship with vaccination.

Exclusion criteria: Children who experience seizures following trauma and newborn infants who have not yet been discharged from hospital.

**CASE DEFINITION AND REPORTING INSTRUCTIONS**

Report all cases of seizures that meet the following criteria

The child aged greater than one month and less than or equal to 8 months of age

**AND**

this is their first seizure presentation

**AND**

with no identifying trauma eg head injury

**AND**

admission to hospital is a stay of 4 hours or more.

All cases are required to have a PAEDS questionnaire completed and results of the following clinical investigations recorded.

**SPECIMEN COLLECTION**

Please ensure that results of any of the following clinical investigations recorded.

- |                      |   |
|----------------------|---|
| 1. C.S.F.            | Glucose/micro/culture<br>Lactate<br>Other |
| 2. Ca/Mg/PO4         |   |
| 3. Blood Sugar Level |   |
| 4. Metabolic screen  | Blood<br>Urine                            |
| 5. EEG               |   |
| 6. Cerebral Imaging  | MRI<br>CT<br>MRI                          |
| 7. Genetic           |   |

8. FBC
9. Head circumference
10. Weight and Length

## **INVESTIGATORS**

Chief investigator to be determined

## **RERERENCES**

1. Le Saux N, Barrowman N, Moore D et al. Decrease in hospital admissions for febrile seizures and reports of hypotonic-hyporesponsive episodes presenting to hospital emergency departments since switching to acellular pertussis vaccine in Canada : A report from IMPACTPediatrics 2003; 112: e348-e353
2. Wolf s, McGoldrick P. Recognition and management of pediatric seizures. *Pediatr Ann.* 2006 May;35(5):332-44.
3. Jackson L, Carste B, Malais D et al. Retrospective population based assessment of medically attended injection site reactions, seizures, allergic responses and febrile episodes after acellular pertussis vaccine combined with diphtheria and tetanus toxoids. *PIDJ* 2002; 21: 781-786
4. Berkovic S, Harkin L, McMahon J et al. De-novo mutations of the sodium channel gene SCN1A in alleged vaccine encephalopathy: a retrospective study. *Lancet Neurol.* 2006 Jun;5(6):488-92