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Recurrence risk of a hypotonic hyporesponsive episode in two Australian specialist immunisation clinics

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ABSTRACT

Background: A hypotonic hyporesponsive episode (HHE) is a well-described adverse event following immunisation (AEFI) in young children. There is limited data regarding recurrence post re-vaccination. **Method:** A retrospective analysis of HHEs reported to two tertiary paediatric hospitals in Australia: The Royal Children's Hospital, Melbourne [2006–11] and the Children's Hospital Westmead, Sydney [1997–2014].

HHE definition level of confidence was allocated according to Brighton Collaboration (BC) criteria and defined immediate if within 30 min post vaccination. The Australian Immunisation Register (AIR) was utilised to document current immunisation status.

Results: 235 HHE cases (135 Melbourne, 100 Sydney) were identified: 47% were female and 67% (157/235) occurred following the routine dose one vaccines at 6–8 weeks of age. Median time following immunisation was 120 min (range 1 min to 14 days) An immediate HHE occurred in 43% (102/235) and by BC criteria, 74% (173/235) were level 1 (definite). Subsequent vaccines were administered under supervision in hospital in 37% overall (86/235); 43% (58/135) in Melbourne and 28% (28/100) in Sydney. HHE recurrence rate was 3% (7/235) [95% confidence interval 1–6%]. AIR records were available in 94% (221/235). At a median age of 3.1 years, 84% (186/221) were up-to-date with recommended vaccines.

Conclusion: This study highlights the importance of specialist immunization clinics in supporting the National Immunisation Program, through follow-up and management of serious adverse events following immunization.

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1. Background

First described in 1961, a hypotonic hyporesponsive episode (HHE) is a neurological adverse event following immunisation

Abbreviations: AIR, Australian Immunisation Register; HHE, Hypotonic Hyporesponsive Episode; MCRI, Murdoch Children's Research Institute; NCIRS, National Centre for Immunisation Research and Surveillance; SAEFVIC, Surveillance of Adverse Events Following Vaccination in the Community; SIC, specialist immunisation clinic.

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(AEFI) in childhood [1]. They have been defined by the Brighton Collaboration as 'pale, floppy (hypotonic), hyporesponsive' episodes in children less than 2 years [2] [see Fig. 1]. An HHE AEFI is a distressing episode for parents to witness and the risk of recurrence of AEFI is a very important question asked by parents. In a 2017 *Pediatrics* editorial, O'Leary et al. noted: "There are few experiences more challenging for a paediatrician than trying to convince a parent to continue vaccinating their child after they have witnessed a febrile seizure or a hypotonic hyporesponsive episode (HHE) not long after vaccination" [3].

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<p>Level 1 of diagnostic certainty is:</p> <p>The sudden onset of:</p> <ul style="list-style-type: none"> Hypotonia (muscle limpness) AND Hyporesponsiveness (reduced responsiveness) or unresponsiveness AND Pallor or cyanosis <p>Level 2 of diagnostic certainty</p> <p>The sudden onset of:</p> <ul style="list-style-type: none"> Hyporesponsiveness (reduced responsiveness) or unresponsiveness AND Pallor or cyanosis AND Muscle tone unknown OR Hypotonia (muscle limpness) AND Hyporesponsiveness (reduced responsiveness) or unresponsiveness AND Skin colour unknown <p>Level 3 of diagnostic criteria</p> <ul style="list-style-type: none"> Hyporesponsiveness (reduced responsiveness) or unresponsiveness AND Pallor or cyanosis AND Normal muscle tone OR Hypotonia (muscle limpness) AND Pallor or cyanosis AND Level of responsiveness unknown
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Fig. 1. HHE according to Brighton criteria [2].

Whilst initially ascribed to whole cell pertussis (Pw) containing vaccines [1,4], HHE's, have in fact been described following all routine infant vaccines, most commonly with the 1st routine infant doses administered between 6 and 8 weeks of age [5]. It has been shown that expert specialist immunisation clinic (SIC) safety review can help facilitate a diagnosis and administration of subsequent doses [6,7]. What has not been previously reported is the proportion of HHE episodes that are immediate events (within 30 min of vaccination) and the number of children who continue, following the AEFI, to receive routine childhood vaccines.

Australia has a secondary referral system for paediatric specialists, so primary care physicians can refer patients to specialist immunisation clinics (SIC) based at tertiary hospitals, with re-vaccination in the clinic provided where applicable [8,9]. These clinics see over 450 AEFI cases annually (Melbourne, Victoria 300; Sydney, NSW 150). There is an annual birth cohort in each state of 80,000 (Victoria) and 95,000 NSW. The aim of the study

was to describe the clinical details, recurrent episodes and immunisation status of children referred to two SICs in Melbourne (Victoria) and Sydney (NSW).

2. Methods

A retrospective analysis of HHEs seen by specialist immunisation clinics (SIC) at two tertiary children's hospitals: Royal Children's Hospital (Melbourne) & Westmead (Sydney). The Melbourne cases came from review of two data sources: Surveillance of Adverse Events Following Vaccination In the Community (SAEFVIC), which was established in 2007 [8] [2007–11] combined with cases from the Royal Children's Hospital Immunisation clinic [2006–07]. The Sydney cases were identified from Children's Hospital Westmead (CHW) clinic records and individual case review 1997–2014 [9]. Melbourne SIC had a lower threshold for admitting HHE cases to hospital for re-vaccination under supervision, with both SIC

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