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# Vaccinating children with a history of serious reactions after vaccination or of egg allergy

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[Abstract](#) - [Introduction](#) - [Methods](#) - [Results](#) - [Discussion](#) - [Acknowledgements](#) - [References](#) - [Authors' details](#)  
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## Abstract

**Objective:** To describe the results of vaccinating children with a history of serious adverse reactions after vaccination or of egg allergy at a special clinic established for that purpose.

**Design:** Retrospective case series.

**Patients:** Children who attended the clinic between 1 August 1994 and 31 July 1996 after being referred by vaccine providers.

**Setting:** A clinic conducted in the Emergency Department of The Canberra Hospital, Australian Capital Territory.

**Main outcome measures:** Reasons for referral; vaccinations given; and subsequent adverse vaccination events.

**Results:** 91 children received 155 vaccinations at the clinic, and only one serious event -- a hypotonic/hyporesponsive episode (HHE) after diphtheria-tetanus-whole-cell pertussis (DTPw), oral polio and *Haemophilus influenzae* type b vaccination -- was subsequently reported; this child recovered spontaneously. Fifty-three children referred because of a previous serious adverse vaccination event were revaccinated at the clinic with whole-cell pertussis vaccine (47), combined diphtheria and tetanus vaccine (4), tetanus toxoid (1), and typhoid vaccine (1). Three children (referred because of previous meningitis, subdural haemorrhage or parental suspicion of allergy to DTPw) received their first dose of pertussis vaccine at the clinic. The remaining 35 children had a history of egg allergy and were given measles-mumps-rubella vaccine.

**Conclusions:** We successfully vaccinated children with histories of serious reactions to vaccination, including HHEs, convulsions, apnoea, high temperatures and persistent screaming, as well as those with egg allergy. We believe special clinics can improve vaccination coverage.

## Introduction

In 1995, there were almost 10 000 reported cases of vaccine-preventable disease in Australia.<sup>1</sup> In that same year, an Australian Bureau of Statistics survey found only 52% of children were fully vaccinated, and that advice against vaccination or concern about the side effects were among the main reasons for missing vaccination.<sup>2</sup> Reactions do occur after vaccination, but these are usually mild. They are often caused by the whole-cell pertussis component.<sup>3</sup> While it is rarely necessary to delay or avoid subsequent vaccinations in children who have had reactions<sup>4</sup> if the reaction was serious, continuing vaccination can be a very difficult decision for both parents and vaccination providers.

The Canberra Hospital (formerly Woden Valley Hospital) in the Australian Capital Territory services a population which includes approximately 22 000 children aged less than five years. In August 1994, a special clinic was established to provide vaccination under close medical supervision for children who had had a serious adverse event after a previous vaccination or who had a history of egg allergy (at one time considered a contraindication to measles-mumps-rubella vaccination). We report the results of vaccinations provided to children in the first two years of the clinic. Similar clinics have been established in the United Kingdom,<sup>5,6</sup> but data from an Australian setting have not previously been published.

## Methods

The clinic was conducted fortnightly (occasionally more frequently) in The Canberra Hospital's Emergency Department. We accepted children who met the national surveillance definition of a serious adverse event after vaccination (Box 1, below),<sup>7</sup> except those who had had encephalopathy within seven days of vaccination or an immediate severe allergic or anaphylactic reaction, both of which contraindicate further vaccination.<sup>8</sup> We also accepted children with egg allergy who required measles- mumps-rubella (MMR) vaccine.

### **1: National surveillance definitions of serious events after vaccination<sup>7</sup> in use at the time of the study**

- Within 48 hours of vaccination — persistent screaming (more than three hours), temperature 40.5 °C unexplained by any other cause, anaphylaxis, shock, or hypotonic-hyporesponsive episode;
- Within 30 days of vaccination — encephalopathy, convulsions, aseptic meningitis, thrombocytopenia, acute flaccid paralysis, death or other serious event thought to be associated with vaccination.

Local vaccination providers, including medical practitioners and community nurses, received a written protocol for referral of children and were asked to direct referrals through the Immunisation Coordinator at ACT Health & Community Services. Medical practitioners were also advised about the clinic through a seminar series and in bulletins from ACT Health & Community Services. We asked providers to establish the nature and severity of the reaction and not to refer children whose parents were merely anxious about vaccination. On referral, parents were provided with written information about the risks and benefits of vaccination and, if appropriate, an appointment was made with the clinic. Parents were advised to give children paracetamol (15 mg/kg) at 8:00 am on the day of the clinic and to attend at 8:50 am.

A paediatrician examined each child before vaccination and discussed the relevant history with the parent; we did not confirm egg allergy by means of skin tests. For each child, the injection site, vaccine, batch number and any adverse event after vaccination at the clinic was recorded. Electronic images of these records were stored in the hospital database. Parents were advised that children should remain under observation at the clinic for two hours after vaccination, and were provided with an information sheet on paracetamol use after vaccination. They were urged to contact the clinic if any adverse event occurred after leaving the hospital, but were not otherwise routinely followed up. We used the national surveillance criteria (Box 1)<sup>7</sup> to define serious events after vaccination at the clinic.

The reason for each referral and, where applicable, vaccines associated with the previous adverse event were retrospectively recorded in a database. Data on vaccines given at the clinic, length of stay and subsequent adverse events were obtained retrospectively from hospital records. Any record of subsequent attendance at the hospital was also checked to identify adverse events after vaccination at the clinic (The Canberra Hospital is the only public hospital with paediatric services in the ACT).

The two-year study period was from 1 August 1994 to 31 July 1996. Epi Info version 6.04 was used to analyse the data.<sup>9</sup>

## Results

Fifty-two clinics were conducted over the two years. No more than five children attended on any one day. Overall, 91 children received 155 vaccinations during 110 visits (eight children attended twice, three attended three times, and one attended six times). Reasons for attendance were a serious adverse vaccination event (53), egg allergy (35), seizure associated with meningitis (1), subdural haemorrhage in infancy (1), and possible allergy to diphtheria-tetanus-whole-cell pertussis (DTPw) vaccine on the basis of family history (1). The median age of all children attending the clinic at the first visit was 14 months (range, 2 months to 15 years). Of the 53 children attending because of a previous vaccination event, 21 (40%) were aged 3 to 8 months; those attending because of egg allergy were aged 10 months to 15 years, while the three remaining children were aged 2 to 5 months. The male:female ratio was 1.2:1.

Five children were referred to the clinic but did not attend; three were subsequently vaccinated by their general practitioners and two -- one referred because of a previous adverse vaccination event and one because of egg allergy -- were lost to follow-up.

**Box 2** shows that, of the previous serious adverse vaccination events for which 53 children were referred, all but one occurred after DTPw vaccination, and persistent screaming (> 3 hours) was the most frequent reaction. For 29 of these children (55%) the adverse event occurred after the first dose of vaccine, for 15 (28%) after the second, for six (11%) after the third, and for three (6%) after the fourth. At the clinic, 47 of these children were revaccinated with one dose of whole-cell pertussis vaccine in the form of DTPw or monovalent pertussis, four received combined diphtheria and tetanus vaccine (CDT), one received tetanus toxoid, and one received typhoid vaccine. *Haemophilus influenzae* type b vaccine (Hib), oral polio vaccine (OPV), and MMR vaccines were also provided where appropriate. Three other children (referred because of previous meningitis, subdural haemorrhage or parental suspicion of allergy to DTPw) received their first dose of pertussis vaccine at the clinic. None of the 35 children referred because of egg allergy had experienced anaphylaxis after egg or were considered severely allergic; all were vaccinated at the clinic with MMR vaccine.

During 110 visits, 88 children were observed for two hours, 16 for three hours, two for four hours and one for six hours (19 children were observed for longer than the stipulated period because of parental concern only). The three remaining children were observed for one hour (leaving at the request of their parents) and included two who received MMR and one (referred because of suspected allergy to DTPw) who received DTPw, OPV and Hib. No adverse events were recorded during the clinic observation period. No child vaccinated with MMR had any adverse event reported after discharge from the clinic. Similarly, no adverse events were reported after discharge for any of the 20 children referred because of persistent screaming; of these, 19 received one dose of a whole-cell pertussis vaccine at the clinic. The remaining child received CDT.

One child aged six months had a serious adverse event (hypotonic-hyporesponsive episode [HHE]) eight hours after vaccination with DTPw, OPV and Hib at the clinic. This child had been referred because of similar episodes, once three hours after receiving the first course of DTPw, OPV and Hib, and then again six hours after receiving the second course. The episode, which occurred at home, lasted only a few minutes and the child recovered spontaneously; a doctor was not consulted. This child was subsequently vaccinated with MMR at 12 months and revaccinated with DTPw and Hib (fourth dose) at 18 months by the child's usual vaccine provider. The parent reported that the child had suffered no further episodes. Four other children who had previously had an HHE after DTPw vaccination were revaccinated with DTPw at the clinic and no further episodes were reported. The absence of further episodes was confirmed for three of these children when they made subsequent visits to the clinic; the parent of the fourth child was contacted and confirmed that no further episodes had occurred (vaccination was completed through the child's usual vaccine provider).

Mild reactions were reported for two children vaccinated at the clinic. The first, aged two months, screamed persistently for an unspecified duration after receiving DTPw, OPV and Hib. The child had not been previously vaccinated and was attending because of a suspected allergy to DTPw. After assessment, the paediatrician did not consider the child's reaction severe enough to warrant supervision of subsequent vaccinations at the clinic and recommended routine vaccination by the child's usual vaccine provider. The second child, aged 16 months, had a high temperature (level unspecified) and local reaction after receiving DTPw (third dose) and Hib. Although this is considered a mild reaction, the parent did not consent to a further dose of DTPw. CDT was provided at a subsequent visit, without any reported reaction.

## Discussion

We successfully vaccinated children with a history of serious reactions to vaccination, including HHEs, convulsions, apnoea, high temperatures and persistent screaming, as well as children with a history of egg allergy. HHEs are rare, but are known to occur after receipt of pertussis vaccines.<sup>3</sup> They have previously been shown to have no neurological or long term sequelae on follow-up.<sup>10</sup> One child vaccinated at the clinic with DTPw (third dose), OPV and Hib reportedly had an HHE (which we were not able to validate as it occurred after discharge from the clinic). As recovery from these episodes can be quick,<sup>10</sup> it is often necessary to rely on a parent's description. This child, who had also had an HHE after each of the two previous DTPw vaccinations, received a fourth dose of DTPw from the child's usual vaccine provider, and the parent confirmed that no further HHE had occurred. We successfully revaccinated four other children who had had an HHE. We believe the results from our clinic support the National Health and Medical Research Council (NHMRC) recommendation that an HHE does not usually contraindicate further doses of pertussis vaccine.<sup>3</sup>

We cannot discount the possibility that serious reactions occurred after vaccination at the clinic, but were not reported. However, as serious reactions had been reported previously for these children, and as they had attended the clinic and their parents had been encouraged to report any adverse event after discharge, we consider this unlikely.

Only two children vaccinated with DTPw at the clinic experienced mild reactions (these would not contraindicate further doses of pertussis-containing vaccines).<sup>3,4</sup> However, we had expected that more mild to moderate reactions would be reported. Deloria et al found that children who had had common reactions to pertussis vaccination (including a temperature of over 38°C and swelling and redness at the injection site) were approximately 1.5 to 8 times more likely to experience the same reaction at a subsequent vaccination.<sup>11</sup> After DTPw vaccination, about 50% of children will have swelling or redness at the injection site, 30% will have a high temperature and approximately 30% will be inconsolable or cry persistently.<sup>3</sup> The small number of minor reactions detected in our study may reflect under-reporting after discharge, but may also be the result of prophylactic paracetamol use.<sup>3</sup>

We do not know the total number of ACT children who experienced a serious adverse vaccination event making them suitable for referral to the clinic. However, we do know that 36 618 doses of DTPw vaccine were given in the ACT during the period of our study (Julie Donda, ACT Health & Community Services, personal communication). The *Australian immunisation handbook* estimates that the rate for persistent screaming (> 3 hours) after DTPw vaccination is about 1/100 doses, while for HHEs and convulsions the rates are 1/300 to 1/30 000 doses, and about 1/1750 doses, respectively.<sup>3</sup> In comparison, the referral rates for children attending our clinic were persistent screaming, 1/1800 doses; HHEs, about 1/7000 doses; and convulsions, about 1/12 000 doses. This suggests that referral rates were low, except, possibly, for HHE. Perhaps there is a need to raise awareness among vaccine providers and parents of both the existence of the clinic and of the importance of reporting serious adverse events.

Hospital-based clinics such as ours provide an important service in addressing the immediate concerns of both parents and providers. We used whole-cell pertussis vaccine, but the recent introduction of acellular pertussis vaccine may further improve acceptability, particularly for parents who are not prepared to continue with DTPw vaccine. The use of acellular pertussis vaccines should reduce the incidence of mild to moderate reactions, but its impact on the incidence of serious reactions is not yet clear.<sup>12</sup> Active follow-up after vaccination at the clinic is now being undertaken and we believe this should improve identification of delayed reactions and encourage completion of outstanding vaccinations. It is possible that detection of serious adverse events after vaccination at the clinic would be further improved by increasing the observation time if this is indicated by previous history.

Over time, the clinic should provide reassurance to both parents and vaccine providers by practically demonstrating the safety of vaccines, but the service should be reserved for those most at need. Children with egg allergy and those with persistent screaming after vaccination made up over half of the patients attending the clinic, and all were successfully vaccinated. The NHMRC currently recommends that a paediatrician be consulted if there is genuine concern over possible egg allergy, with a view to vaccination under controlled conditions such as those in our clinic.<sup>3</sup> What constitutes genuine concern is unclear, but we believe that only those with severe reactions considered appropriate by an experienced paediatrician, such as anaphylaxis to egg, should be referred to the clinic. Both parents and vaccine providers need to be reassured that most children with egg allergy, those who have screamed persistently after vaccination, and perhaps some others, can and should be vaccinated through their usual vaccine providers.<sup>3,13</sup>

We believe the clinic is an essential component of the ACT's immunisation program, improving vaccination coverage by vaccinating children who may otherwise remain unvaccinated or incompletely vaccinated, and by encouraging reporting of adverse vaccination events. Similar clinics for children with serious adverse reactions to vaccination and severe allergies, such as anaphylaxis to egg, should be encouraged in all States and Territories. We believe children with mild to moderate reactions (including persistent screaming) should be revaccinated through their usual vaccine provider. It is essential that all vaccine providers are well informed of the recommendations for vaccination, particularly with respect to contraindications.<sup>3</sup> We should all endeavour to ensure that children are vaccinated in accordance with the recommended schedule.

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