



Summary of 'Adverse Event Following Immunisation' Reports Western Australia, 2010

Produced by the Prevention and Control Program, Communicable Disease Control Directorate, Department of Health, Western Australia

Background

This is the first report of its kind in Western Australia (WA). This annual report of adverse events following immunisation (AEFI) in WA summarises passive surveillance data received by the Western Australian Department of Health (WA DoH).

AEFIs are defined as unwanted or unexpected events following the administration of a vaccine. The fact that an adverse event occurred following immunisation is not conclusive evidence that the event was caused by a vaccine. Factors such as medical history, diagnostic tests, and other medication given near the time of vaccination must be examined to help to determine the cause of adverse events.

In Western Australia there is a statutory requirement for health professionals to report an AEFI to the WA DoH, as specified in Regulation 4 of the Health Regulations, 1995. (For more detail see http://www.public.health.wa.gov.au/3/498/3/adverse_events_following_immunisation.pm). All AEFIs reports received by the WA DoH are forwarded to the Therapeutic Goods Administration (TGA). In addition, the TGA receives AEFI reports directly from clinicians, pharmaceutical companies that manufacture vaccines and the public. On a monthly basis, the TGA provides the WA DoH with data on all reports of 'suspected' AEFI that they have received for residents of WA.

Method

For this summary, AEFI reports were eligible for inclusion in the analysis if:

- a vaccine(s) was recorded as 'suspected' of being involved in the reported adverse event
- the residential address of the individual was recorded as Western Australia
- the vaccination occurred between 1 January 2010 and the 31 December 2010; If the vaccine date was not recorded, the date of symptoms onset was taken as the date of vaccination.

Classification of the type of AEFI reaction(s):

An individual AEFI report can consist of multiple symptoms, signs and tentative diagnoses. For the purpose of this summary, AEFIs were grouped into the following categories:

- Febrile convulsions
- Afebrile convulsions/seizures
- Other febrile reactions (i.e. fever but no convulsion/seizure reported)
- Local reactions (e.g. redness, swelling, and/or pain at the injection site but no fever or convulsion)
- Other reactions, i.e. not in one of the four categories above (includes but is not limited to reports of rash, joint swelling, dizziness, myalgia, headache, nausea and vomiting).





“Hospitalised patients” were defined as those where the AEFI was suspected to have led to a hospital admission of at least one night or in which the AEFI was believed to prolong a hospital stay.

Notes on interpretation of the summary data

1. Young children often receive multiple vaccines during a single health care encounter and because in these circumstances it is usually not possible to attribute a subsequent AEFI to a single vaccine, all the vaccines administered during the clinic visit are usually listed as ‘suspected’ of involvement in the AEFI.
2. The reported symptoms, signs and diagnoses in each adverse event were temporally associated with vaccination, but are not necessarily causally associated with one or more of the vaccines administered.
3. The data below include all reports received by the WA DoH up to 17 January 2011. These data are provisional only and are subject to change because reporting delays, or rarely delayed onset of symptoms, may affect totals, particularly for the fourth quarter of 2010.

Results

A total of 1,075 AEFI were reported to WA DoH, either directly from medical practitioners or from the TGA.

Administration of an influenza vaccine (i.e. inactivated trivalent influenza vaccine [TIV] or pandemic monovalent H1N1 influenza vaccine [MIV]) was recorded, either singly or in combination with other vaccines, in 89% (n=954) of the AEFI reports.

Seventy-four percent (n=795) of AEFIs occurred for vaccinations in the second quarter of the year (Figure 1), most of these being febrile reactions associated with a single brand of TIV.

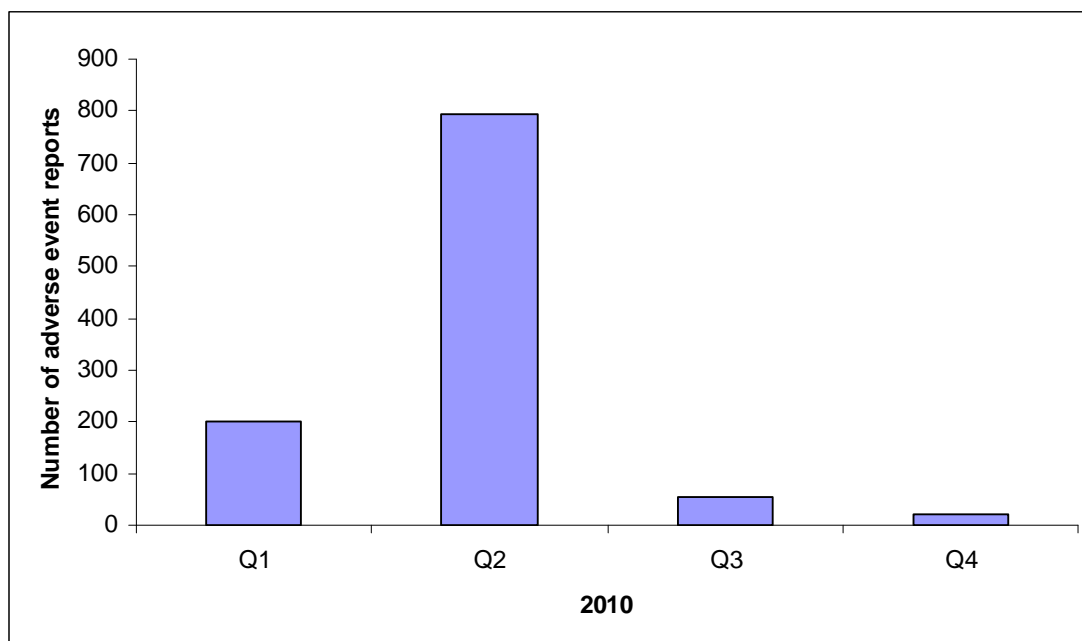


Figure 1 – Reports of adverse events following immunisation, Western Australia, 2010, by quarter of vaccination (for reports where date of vaccination was not recorded, the date of onset was used as a proxy for vaccination date).



Of all AEFI reports, 78% (n=839) were reported among children aged less than five years (Figure 2).

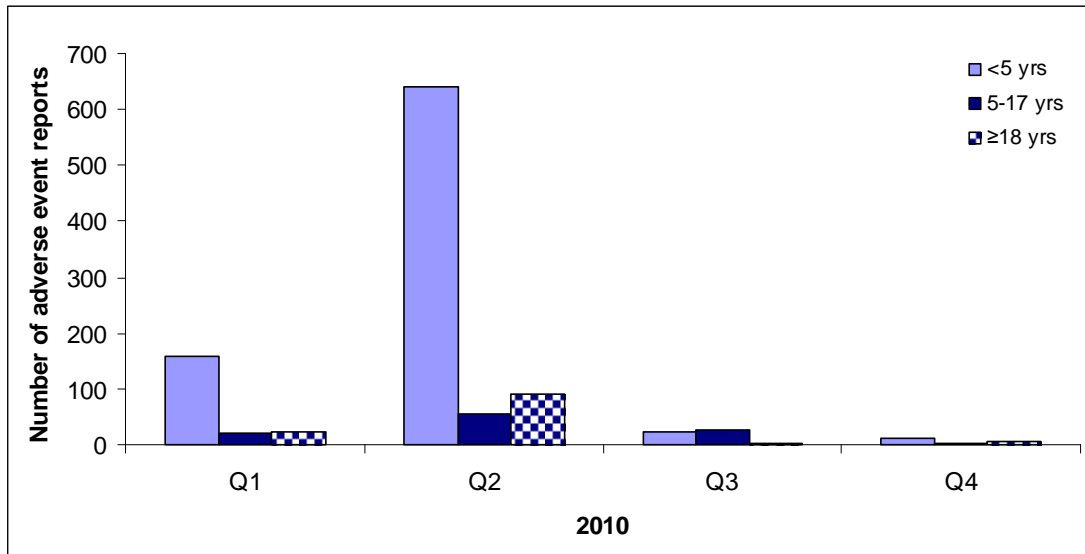


Figure 2 – Reports of adverse events following immunisation, Western Australia, 2010, by quarter of vaccination and age group in years (for reports where date of vaccination was not recorded, the date of onset was used as a proxy for vaccination date).

AEFIs associated with influenza vaccines

In WA, receipt of Fluvax[®]/Fluvax Junior[®] was documented in 761 (71%) of all AEFI reports received. The other influenza vaccines reported included: Panvax[®]/Panvax Junior[®] MIV (44 records, 4% of all reports), Influvac TIV (26 records, 2.4%), Vaxigrip TIV (7 records, 0.6%), Intanza TIV (5 records, 0.5%) and seasonal TIV brand unknown (112 records, 10%).

The most commonly reported type of adverse event following receipt of influenza vaccine, alone or in combination with other vaccines, was a febrile reaction without convulsion (Figure 3)

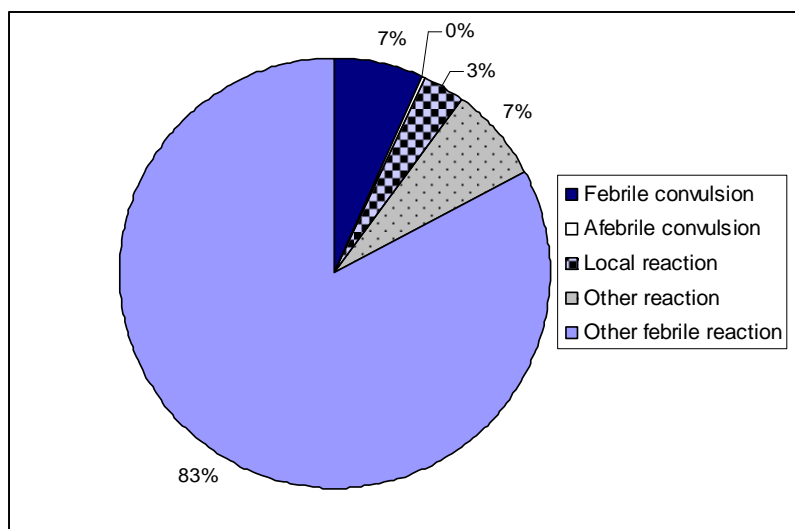


Figure 3 - Categorisation of reactions following influenza vaccines in 2010, Western Australia (n=954).



Eighty-two percent (n=783) of adverse reports to influenza vaccines occurred in children <5 years of age (Table 1).

Table 1 – Age breakdown of all adverse reaction reports to influenza vaccines, by brand, Western Australia, 2010.

	<5 yrs	5 to 17 yrs	≥18 yrs	Unknown	Grand Total
Fluvax®/Fluvax junior®	641	51	65	4	761
Influvac®	14	1	11	0	26
Intanza®	0	1	3	1	5
Panvax®/Panvax junior®	33	6	5	0	44
Vaxigrip®	0	0	7	0	7
TIV, brand unknown	95	9	7	0	111
Total	783	68	98	5	954

A total of 53 (5.6%) reports indicated the patient had been hospitalised for at least one night.

There were no reports of death.

Non-influenza vaccines identified in AEFI reports

The other most frequently identified vaccines specified on AEFI reports were: MMR (n=50, 4.7% of all reports), DTPa-IPV (n=29, 2.7% of all reports), DTPa-IPV-HepB-Hib (n=28, 2.6%), 23-valent pneumococcal vaccine (n=28, 2.6%) and dTpa (26, 2.4%).

Of the adverse events following receipt of all vaccines other than influenza (alone or in combination with other vaccines), there were 2 febrile convulsions (in children <5 years), 3 afebrile convulsions (in children aged 5 to 12 years old), 42 local reactions, 32 other febrile reactions, and 42 other reactions. A total of 8 (6%) reports indicated the patient had been hospitalised.

There were no reports of death.

Discussion

There was an unexpected increase in AEFI to influenza vaccine in the second quarter of 2010. The increase was seen predominantly in children <5 years. In April 2010, the Commonwealth suspended the use of influenza vaccine in children less than 5 years of age. The suspension gained wide media coverage and resulted in heightened levels of AEFI reporting, with an increase in events reported directly to the TGA by members of the public. A subsequent investigation determined that the adverse events were associated with vaccine formulations of just one vaccine manufacturer, i.e. Fluvax and Fluvax Junior, produced by CSL. Vaccination of children under 5 was later re-instated with a recommendation to use non-CSL influenza vaccine formulations (for more details see: <http://www.tga.gov.au/alerts/medicines/fluvaccine-report100702.htm>).

AEFI reports in the last two quarters of 2010 reduced significantly.

The post-licensure surveillance of AEFI is important to detect uncommon events that may not have been identified in previous clinical trials undertaken for licensure. AEFI surveillance in Australia relies on passive reporting from immunisation providers and the public. Although passive reports of AEFI can rarely provide definitive evidence of a causal association between a vaccine and particular risks, spontaneous AEFI reporting enables the early detection of signals that can then be more rigorously investigated.

