



Summary of 'Adverse Event Following Immunisation' Reports, Western Australia, 2011

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Background

This is the second 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 Vaccine Safety Surveillance (WAVSS) system.

WAVSS is a Western Australian Department of Health (WA DoH) initiative to monitor vaccine safety and was established in March 2011, in collaboration with Child and Adolescent Health (CACH) and the Central Immunisation Clinic. WAVSS was developed on the Victorian Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) model. WAVSS began taking reports of suspected AEFI on 03 March 2011, from health providers but also for the first time from the public. .

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 WA 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) on a daily basis (Monday to Friday). 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 and these are cross-checked with WAVSS and entered were missing.

WAVSS operational update

A regular teleconference between WAVSS, SAEFVIC and representatives from New South Wales and South Australia was established in April 2011.

A regular monthly teleconference between WA stakeholders of WAVSS was also introduced in August 2011.



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 2011 and the 31 December 2011; 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 WAVSS for 2011 as at 11 September 2012. These data are subject to change.

Surveillance data analysis

AEFI reports

A total of 323 individual AEFI reports were received by WAVSS for persons vaccinated in 2011, compared with 1,075 reports received in 2010.





Persons reporting AEFIs described 557 adverse events: 414 met established case definitions and 143 were recorded verbatim (note that a vaccinee may describe multiple AEFI reactions).

A total of 533 vaccines had been administered, with a median number of 1 vaccine per person reported (range 1-4 vaccines).

The months with the highest number of AEFI reports were March, April and May (Figure 1), coinciding with the influenza vaccination program launch and roll-out, seen mainly in adult's ≥ 18 years (Figure 2). An increase in reports seen in August of 2011 corresponded to the initiation of the Prevenar13 catch-up program.

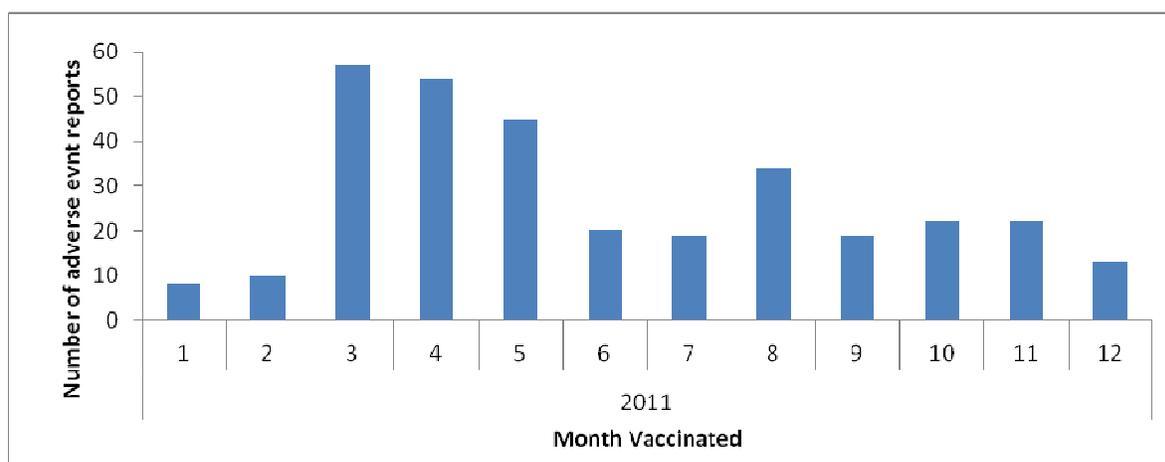


Figure 1 – Reports of adverse events following immunisation, Western Australia, 2011, by month of vaccination.

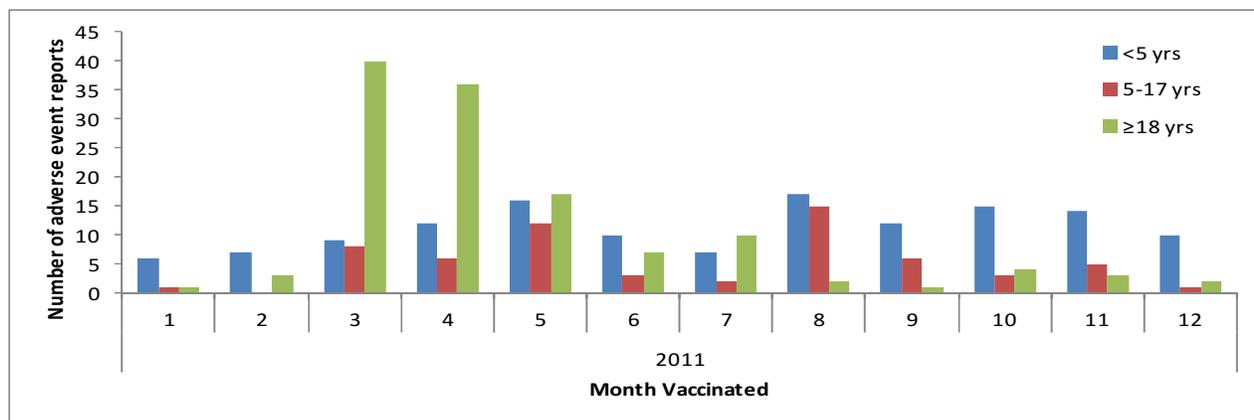


Figure 2 – Reports of adverse events following immunisation, Western Australia, 2011, by month of vaccination and age group in years.

Of all AEFI reports, 42% (135/323) were reported among children aged less than five years, compared with 78% (839/1075) of 2010 reports. In 2011 more than 750,000 doses of National Immunisation Program childhood vaccines were distributed in WA.



AEFIs associated with influenza vaccines

Administration of an influenza vaccine (inactivated trivalent influenza vaccine [TIV]) was recorded, either singly or in combination with other vaccines, in 21% (67/323) of the AEFI reports, compared with 89% (795/1075) of reports in 2010.

Table 1 shows the brand and age breakdown of the reports. Ten percent (n=7) of adverse reports to influenza vaccines occurred in children <5 years of age (Table 1) this is markedly down on 2010 in which 82% of all reports were influenza vaccine-related reports in children <5 years. In 2011 approximately 340,000 doses of influenza vaccine were distributed in WA.

The most commonly reported type of adverse event following receipt of influenza vaccine, alone or in combination with other vaccines, was an 'other reaction', followed by local reactions.

Table 1 – Age breakdown of all adverse reaction reports to 2011 influenza vaccines, by brand, Western Australia, 2011.

Vaccine Name	<5 yrs	5-17 yrs	≥18 yrs	Grand Total
Brand unspecified			1	1
Fluarix®			2	2
Fluvax®		2	20	22
Influvac®		2	4	6
Intanza®			11	11
Vaxigrip®	6	6	12	24
Vaxigrip Junior®	1			1
Grand Total	7	10	50	67

A total of 3 reports indicated the patient had been hospitalised for at least one night.

Non-influenza vaccines identified in AEFI reports

The other most frequently identified vaccines specified on AEFI reports were:

- MMR (n=58, 18% of all reports)
- DTPa-IPV-HepB-Hib (n=52, 16% of all reports)
- DTPa (n=45, 14% of all reports)
- 23-valent pneumococcal vaccine (n=45, 14%)
- dTpa-IPV (44, 14%)
- Rotavirus vaccine (40, 12%)

Of the adverse events following receipt of all vaccines other than influenza (alone or in combination with other vaccines), there were 3 febrile convulsions (in children <5 years), 2 afebrile convulsions (in children <5 years), 118 local reactions, 57 other febrile reactions, and 149 other reactions. A total of 14 (5%) reports indicated the patient had been hospitalised.

There were no reports of anaphylaxis, Guillain Barre Syndrome or death.



WAVSS clinical activity

Of the AEFIs reported 18 were invited to and attended a WAVSS clinic, and three were invited but failed to attend.

Publications

- Kelly, Skowronski, De Serres and Effler, Adverse events associated with 2010 CSL and other inactivated influenza vaccines. *MJA* 2011; 195 (6): 318-320.
- Leeb, Carcione, Richmond, Jacoby and Effler. Reactogenicity of two 2010 trivalent inactivated influenza vaccine formulations in adults. *Vaccine* corrected proof Available online 22 August 2011.
- Armstrong PK, Dowse GK, Effler PV, Carcione D, Blyth CC, Richmond PR, Geelhoed GC, Mascaro F, Scully M, Weeramanthri TS. Epidemiological study of severe febrile reactions in young children in Western Australia caused by a 2010 trivalent inactivated influenza vaccine. *BMJ Open* doi:10.1136/bmjopen-2010-000016.
- Blyth CC, Markus TY, Effler PV, & Richmond PC. Ensuring safety of the 2011 trivalent vaccine in young children. *MJA* 6 June 2011 Rapid online publication.
http://www.mja.com.au/public/issues/195_01_040711/letters_bly_fm.html
- Blyth CC, Currie AJ, Wiertsema SP, Conway N, Kirkham AS, Fuery A, Mascaro F, Geelhoed GC and Richmond PC. Trivalent influenza vaccine and febrile adverse events in Australia, 2010: Clinical features and potential mechanisms. *Vaccine* Volume 29, Issue 32, 18 July 2011, Pages 5107-5113.

User Satisfaction Survey

In February 2012, a quality assurance audit of WAVSS system was implemented to ascertain if immunisation providers and the public who reported to WAVSS in 2011 were satisfied with the system.

Of those who had used WAVSS to report an AEFI, 100 health providers were randomly selected and all parent/public reporters (64) were selected for the survey. Overall 108 WAVSS reporters were contacted and completed the survey (64/100 health providers and 42/64 members of the public). A summary of the results are provided below:

- 81% said reporting through the WAVSS system was 'Easy' or 'Very Easy'.
- 79% were 'Satisfied' or 'Very Satisfied' with the feedback received about the adverse event they reported to WAVSS.
- Overall 88% were 'Satisfied' or 'Very Satisfied' with the WAVSS reporting system.





Discussion

WAVSS was a recommendation that came out of the WA Parliamentary Enquiry (Stokes Review) into the handling of AEFIs following 2010 seasonal influenza vaccination in children. With the assistance of SAEFVIC the WA DoH was able to launch WAVSS to health providers and prior to the start of the 2011 influenza vaccination program. For the first time in WA AEFI reports were accepted from the public as well as health providers. This report summarised the AEFIs experienced following vaccination in 2011.

The numbers of reports received following vaccination given in 2011 were a third of that in 2010.

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.