Government of Western Australia
Department of Health

# Western Australia Vaccine Safety Surveillance – Annual Report, 2013

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

## Background

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 initiative to monitor vaccine safety and was established in March 2011, in collaboration with Child and Adolescent Health and the Central Immunisation Clinic. WAVSS was developed on the Victorian Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) model. WAVSS accepts reports of suspected AEFI from health providers but also directly 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 Western Australia (WA) there is a statutory requirement for health professionals to report an AEFI to the WA Department of Health (the Department), as specified in Regulation 4 of the Health Regulations, 1995 (see http://www.public.health.wa.gov.au/3/498/3/adverse_events_following_immunisation.pm for more detail). All AEFI reports received by the Department 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 Department 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 where missing.

In 2012, the TGA launched an online Database of Adverse Event Notifications (DAEN). The DAEN contains information from reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia. The DAEN is available to members of the public as part of TGA initiatives to be more transparent about its activities. For more information on the DAEN visit http://www.tga.gov.au/safety/daen.htm.

## 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 WA, and
- the vaccination occurred between 1 January 2013 and the 31 December 2013; if the vaccine date was not recorded, the date of report submission 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) - Note: in cases in which multiple vaccines were given where possible the vaccine associated with the local reaction was attributed as being associated with the adverse event.
- 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. 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 2013 as at 21 January 2014. These data are subject to change.

## Surveillance data analysis

### *AEFI reports*

A total of 338 individual AEFI reports were received by WAVSS for persons vaccinated in 2013, compared with 311 in 2012 and 290 in 2011. Of the 338 reports, 23 were reviewed and determined to be unrelated to vaccination and were removed from further analysis.

From the remaining 315 reports, 518 adverse events were described (compared with 598 in 2012 and 498 in 2011); 336 met established case definitions and 177 were recorded verbatim (note that a vaccinee may describe multiple AEFI reactions).

A total of 537 vaccines had been administered (compared with 522 in 2012 and 468 in 2011), with a median number of 1 vaccine per person reporting (range 1-4 vaccines per person).

A comparison of the number of reports received by month vaccinated in 2011, 2012, and 2013 is pictured in Figure 1. The months with the highest number of AEFI reports were March and April 2013, which is reflective of the influenza vaccination program launch and roll-out. The reactions reported in these months are seen mainly in adults ≥18 years (Figure 2).

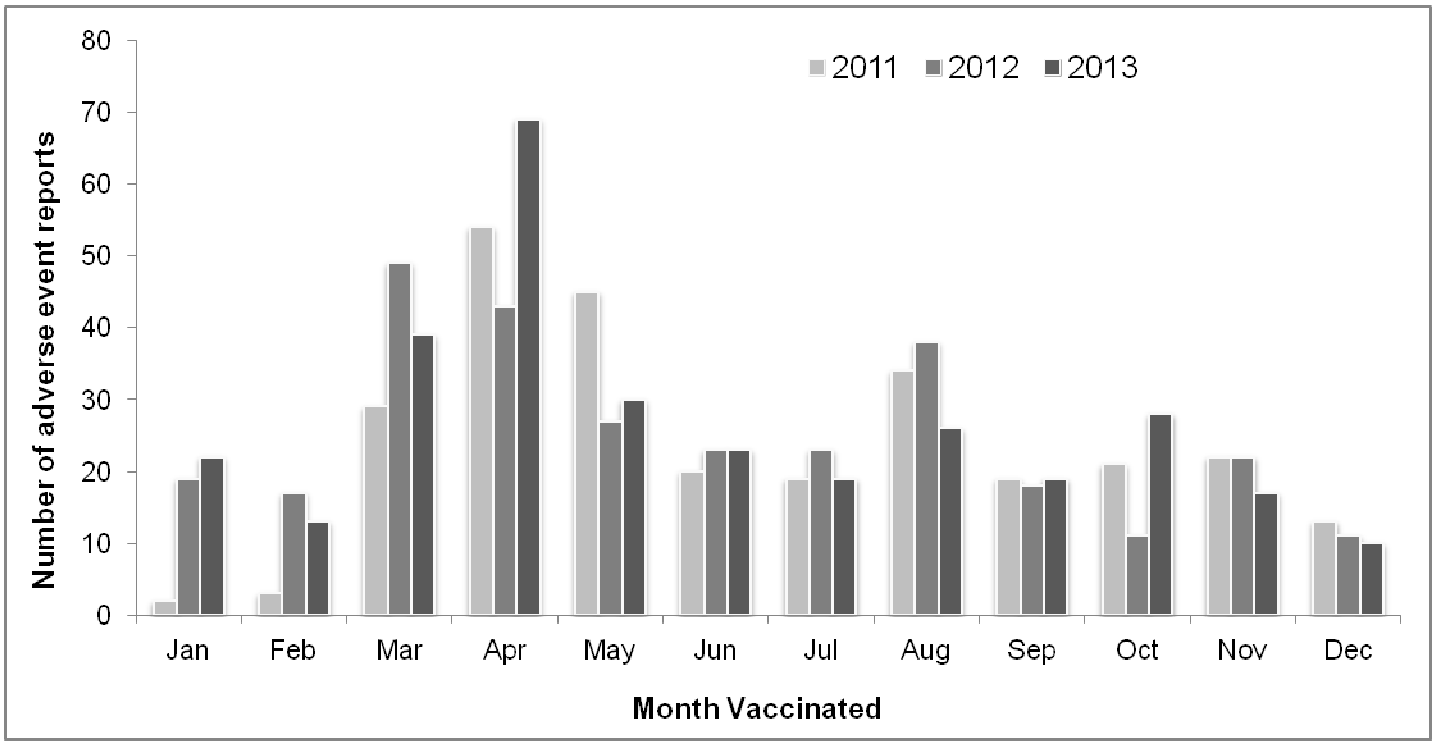


**Figure 1 – Reports of adverse events following immunisation, Western Australia 2011-2013, by month of vaccination.**

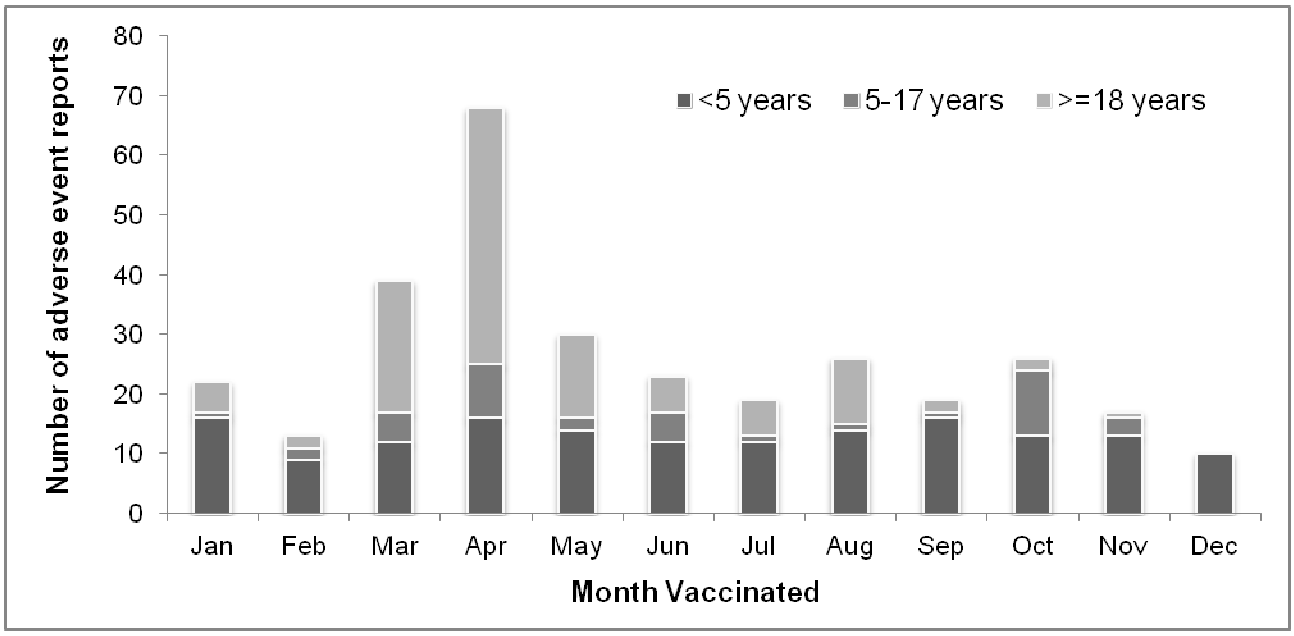


**Figure 2 – Reports of adverse events following immunisation, Western Australia, 2013, by month of vaccination and age group in years.**

Characteristics of AEFI reports received in 2013 are summarised in Table 1 and compared to those received in 2011 and 2012. The majority (78%) of reports to the system were received from healthcare providers, with 16% of reports from the public. Of the 315 reports, 139 were treated by a GP, 75 were seen by a nurse, 66 were seen at an Emergency Department, and 20 were reported as being hospitalised. The number of reports of patients being hospitalised is similar to that in previous years (23 in 2012 and 20 in 2011), with a median length of stay of 1 day (range 1-8 days). Reports were most often received through the online system (41%) or by fax (37%).

Of the 336 events which met established case definitions, 96 were attributed to a local reaction and 85 to a febrile reaction (with no seizure). A small number of febrile convulsions (9/336) and afebrile convulsions (4/336) were reported in 2013. The remaining 142 event were other reactions.

**Table 1 – Characteristics of AEFIs reported in 2011-2013**

| | 2011 | 2012 | 2013 |
|---|---|---|---|
| **TOTAL** | 281 | 301 | 315 |
| **Gender:** | | | |
| Male | 119 (42%) | 130 (43%) | 146 (46%) |
| Female | 162 (58%) | 170 (57%) | 169 (54%) |
| **Aboriginal/Torres Strait Islander Status:** | | | |
| ATSI | 8 (3%) | 12 (4%) | 6 (2%) |
| Non-ATSI | 197 (70%) | 249 (83%) | 228 (72%) |
| Unknown | 76 (27%) | 40 (13%) | 81 (26%) |
| **Age Group:** | | | |
| <5 years | 117 (42%) | 135 (45%) | 157 (50%) |
| 5-17 years | 56 (20%) | 57 (19%) | 41 (13%) |
| ≥18 years | 108 (38%) | 108 (36%) | 114 (36%) |
| **Reporter Type:** | | | |
| Health provider | 224 (80%) | 226 (75%) | 247 (78%) |
| Parent/public | 52 (18%) | 69 (23%) | 51 (16%) |
| Other | 5 (2%) | 6 (2%) | 16 (5%) |
| **Immunisation Provider** | | | |
| GP | 111 (40%) | 81 (27%) | 97 (31%) |
| Nurse | 118 (42%) | 154 (51%) | 139 (44%) |
| **Managed By:** | | | |
| Healthdirect | 12 (4%) | 20 (7%) | 21 (7%) |
| Nurse assessment | 48 (17%) | 70 (23%) | 75 (24%) |
| GP assessment | 135 (48%) | 123 (41%) | 139 (44%) |
| Central Immunisation Clinic | 7 (2%) | 11 (4%) | 8 (3%) |
| Emergency Department | 40 (14%) | 64 (21%) | 66 (21%) |
| Admitted to Hospital | 20 (7%) | 23 (8%) | 20 (6%) |
| **Reported By:** | | | |
| Fax | 129 (46%) | 125 (41%) | 118 (37%) |
| Online | 119 (42%) | 111 (37%) | 129 (41%) |
| Post | 13 (5%) | 23 (8%) | 17 (5%) |
| Telephone | 18 (6%) | 42 (14%) | 39 (12%) |

**Table 2 – Classification of the type of AEFI reaction(s), 2011-2013**

| | 2011 | 2012 | 2013 |
|---|---|---|---|
| **Afebrile convulsions/seizures** | 2 | 5 | 4 |
| **Febrile convulsions** | 4 | 6 | 9 |
| **Local reaction** | 124 | 109 | 96 |
| **Other febrile reaction** | 71 | 72 | 85 |
| **Other reactions** | 166 | 185 | 142 |
| **Grand Total** | **367** | **377** | **336** |

Of all AEFI reports, 50% (157/315) were reported among children aged less than five years, compared with 45% (135/301) in 2012 and 42% (117/281) in 2011. In 2013, more than 750,000 doses of National Immunisation Program childhood vaccines were distributed in WA. The rate of AEFIs in children <7 years per 10,000 doses recorded on the Australian Childhood Immunisation Record (ACIR) is provided in Table 3. The highest rate of AEFI per 10,000 doses is seen with Quadracel (19.2 AEFI/10,000 doses) followed by MMR-II (13.5 AEFI/10,000 doses). With the exception of Quadracel, the rate of AEFI in 2013 for scheduled vaccinations is comparable to 2012 and 2011.

### *AEFIs associated with influenza vaccines*

Administration of an influenza vaccine (inactivated trivalent influenza vaccine [TIV]) was recorded, either alone or in combination with other vaccines, in 25% (85/336) of the AEFI reports, compared with 19% (71/377) in 2012 and 19% (69/367) of reports in 2011.

Table 4 shows the brand and age breakdown of the reports. The majority of reports received associated with an influenza vaccination were from adults 18 to 64 years of age (75%). A total of 13 adverse reports to influenza vaccines occurred in children <5 years of age (Table 1)

In 2013, the most commonly reported type of adverse event following receipt of influenza vaccine, alone or in combination with other vaccines, was an ‘other reaction’ (n=34). There were 24 fevers and 26 local reactions reported following receipt of influenza vaccine. One report of anaphylaxis and 1 report of Guillan-Barré Syndrome were received in 2013.

**Table 3 – Rate of AEFI in children <7 years per 10,000 doses administered as recorded on ACIR by vaccine, 2011-2013**

| | 2011 | | | 2012 | | | 2013 | | |
|---|---|---|---|---|---|---|---|---|---|
| VACCINE (DISEASE(S)) | Doses administered in <5 yrs | AEFIs Reported to WAVSS in <5 yrs | Rate of AEFI per 10,000 doses | Doses administered in <5 yrs | AEFIs Reported to WAVSS in <5 yrs | Rate of AEFI per 10,000 doses | Doses administered in <5 yrs | AEFIs Reported to WAVSS in <5 yrs | Rate of AEFI per 10,000 doses |
| H-B-Vax II Paediatric formulation (HepB) | 3,130 | 1 | 3.2 | 4,155 | 0 | 0 | 3,732 | 1 | 2.7 |
| VAQTA Paediatric formulation (HepA) | 3,273 | 2 | 6.1 | 3,589 | 1 | 2.8 | 3,754 | 0 | 0 |
| Infanrix Hexa (DTP-HepB-Polio-HIB) | 91,839 | 46 | 5.0 | 94,005 | 52 | 5.5 | 95,882 | 48 | 5.0 |
| Prevenar (Pneumococcal)[a] | 100,215 | 53 | 5.3 | 108,304 | 57 | 5.3 | 97,848 | 47 | 4.8 |
| RotaTeq (Rotavirus) | 80,934 | 36 | 4.4 | 83,852 | 49 | 5.8 | 86,961 | 41 | 4.7 |
| TIV (Influenza) | 8,645 | 7 | 8.1 | 9,416 | 9 | 9.6 | 18,711 | 13 | 6.9 |
| Priorix (Measles, Mumps, Rubella) | 53,864 | 42 | 7.8 | 61,719 | 41 | 6.6 | 48,496 | 59 | 12.2 |
| Priorix Tetra (Measles, Mumps, Rubella, Varicella) | | | | | | | 14,006 | 7 | 5.0 |
| MMR – II (Measles, Mumps, Rubella) | 1,080 | 0 | 0 | 752 | 0 | 0 | 14,035 | 19 | 13.5 |
| Hiberix (Haemophilus influenza B) | 29,993 | 14 | 4.7 | 31,019 | 16 | 5.2 | 21,692 | 12 | 5.5 |
| NeisVac-C (Meningococcal C) | 31,055 | 14 | 4.5 | 32,432 | 14 | 4.3 | 23,102 | 12 | 5.2 |
| Menitorix (Meningococcal C, HIB) | | | | | | | 10,618 | 13 | 12.2 |
| Varilrix (Varicella) | 29,720 | 9 | 3.0 | 30,901 | 8 | 2.6 | 17,840 | 4 | 2.2 |
| Quadracel (DTPa-Polio) | 22,275 | 32 | 14.4 | 29,287 | 45 | 15.4 | 28,087 | 54 | 19.2 |

[a]Includes both Prevenar7 and Prevenar13 figures

**Table 4 – Age breakdown of all adverse reaction reports to 2013 influenza vaccines, by brand, Western Australia, 2013.**

| | <5 years | 5-17 years | 18-64 years | ≥65 years | TOTAL |
|---|---|---|---|---|---|
| **Brand unspecified** | | 1 | 5 | 3 | **9** |
| **Agrippal®** | | | 1 | | **1** |
| **Fluarix®** | | | | 1 | **1** |
| **Fluvax®** | | | 13 | 7 | **21*** |
| **Influvac®** | | 1 | 4 | 1 | **6** |
| **Intanza®** | | | 13 | | **13** |
| **Vaxigrip®** | 4 | 5 | 17 | 15 | **41** |
| **Vaxigrip Junior®** | 9 | | | | **9** |
| **Grand Total** | **13** | **7** | **53** | **27** | **71** |

*One reaction associated with Fluvax® was recorded with an unknown age.

A total of 4 reports associated with influenza vaccines indicated the patient had been hospitalised for at least one night (compared to 5 in 2012 and 1 in 2011).

### *Non-influenza vaccines identified in AEFI reports*

Influenza vaccines were the most commonly reported vaccine on an AEFI report in 2013. The other most frequently identified vaccines specified on AEFI reports were:

- MMR (n=67, 12% of all reports)
- Pneumococcal (n=66, 12% of all reports)
- dTpa-IPV (67, 12%)
- Rotavirus vaccine (46, 16%)
- DTPa-IPV-HepB-Hib (49, 16%)
- HPV (24, 4%)

Of the adverse events following receipt of all vaccines other than influenza (alone or in combination with other vaccines), there were 9 febrile convulsions (all in children <5 years), 4 afebrile convulsions (2 in children <5 years, 1 aged 5-17 years, and 1 aged ≥18 years), 70 local reactions, 61 other febrile reactions, and 108 other reactions. There was one report of anaphylaxis following administration of a non-influenza vaccine administered in 2013.

## WAVSS clinical activity

Of the 315 reports of AEFI in 2013, a total of 27 children were invited to and attended a WAVSS clinic at either the Central Immunisation Clinic or Princess Margaret Hospital for Children. 48% (13/27) were vaccinated at the clinic.

Also seen in clinics in 2013 were 15 children who previously experienced an AEFI following vaccination or were referred by their GP or parent for allergy or concerns related to vaccination, bringing the total number of children seen to 42. Three adults were seen by the adult immunology clinic at Sir Charles Gairdner Hospital (SCGH).

## Publications

Carcione D, Blyth CC, Mak DB, Effler PV. User satisfaction with the Western Australian Vaccine Safety Surveillance (WAVSS) system. Aust N Z J Public Health 2013; 37(3): 296.

Regan AK, Blyth CC, Effler PV. Using SMS technology to verify the safety of seasonal trivalent influenza vaccine for pregnant women in real time. Med J Aust 2013; 199(11): 744-6.

Leeb A, Regan AK, Peters I, Leeb C, Effler PV. Using automated text messages to monitor adverse events following immunisation in general practice: results of prototype testing. Med J Aust, in press.

## Discussion

WAVSS was a recommendation as a result 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 Department was able to launch WAVSS to health providers and the public in 2011. This report summarised the AEFIs experienced following vaccination in the third year of WAVSS in 2013.

The numbers of reports received following vaccination given in 2013 were similar to that reported in 2012 and 2011. A slightly higher proportion of events following influenza immunisation were reported in 2013 compared to 2012 and 2011; however, because the rate of AEFI is similar to previous years, this is likely reflective of the greater distribution of influenza vaccine in 2013. The highest rate of AEFI in children <5 years continues to be reported among children receiving Quadracel (DTPa-Polio). A low level of hospitalisation associated with an AEFI was reported in 2013, consistent with previous years and supporting the safety of vaccinations.

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.