Government of Western Australia
Department of Health

Western Australia Vaccine Safety Surveillance – Annual Report 2015

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

Executive Summary

The number of AEFI reports received in 2015 was similar to the number received in 2014, with a similar number of vaccines being distributed and reported as administered to children <7 in ACIR. A total of 216 individual reports were received in 2015, for which 228 adverse events which met established case definitions were reported.

In children under 5, who receive the majority of vaccinations and for whom denominator data from the Australian Childhood Immunisation Register is available, there were slight increases were noted between 2014 and 2015 for Quadracel, TIV and Menitorix; none of these increases were statistically significant ($p>0.05$). The rates of AEFI for other paediatric vaccines declined, or remained stable.

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.

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://ww2.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI 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 2015 and the 31 December 2015.

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 2015 as 1 February 2016. These data are subject to change.

Surveillance data analysis

AEFI reports

A total of 229 individual AEFI reports were received by WAVSS for persons vaccinated in 2015, compared with 227 in 2014, 335 in 2013, 312 in 2012 and 289 in 2011. Of the 229 reports, 13 were reviewed and determined to be unrelated to vaccination and were removed from further analysis.

From the remaining 216 reports, 326 adverse events were described (compared with 328 in 2014, 499 in 2013, 605 in 2012 and 496 in 2011); 228 met established case definitions and 94 were recorded verbatim (note that a vaccinee may describe multiple AEFI reactions).

A total of 338 vaccines had been administered (compared with 326 in 2014, 534 in 2013, 529 in 2012 and 475 in 2011), with a median number of 1 vaccine per person reporting (range 1-5 vaccines per person).

A comparison of the number of reports received by month vaccinated in 2011, 2012, 2013, 2014 and 2015 is shown in Figure 1. The month with the highest number of AEFI reports in 2015 was May which is reflective of the influenza vaccination program launch and roll-out. The reactions reported in this month are seen mainly in adults ≥18 years (Figure 2).

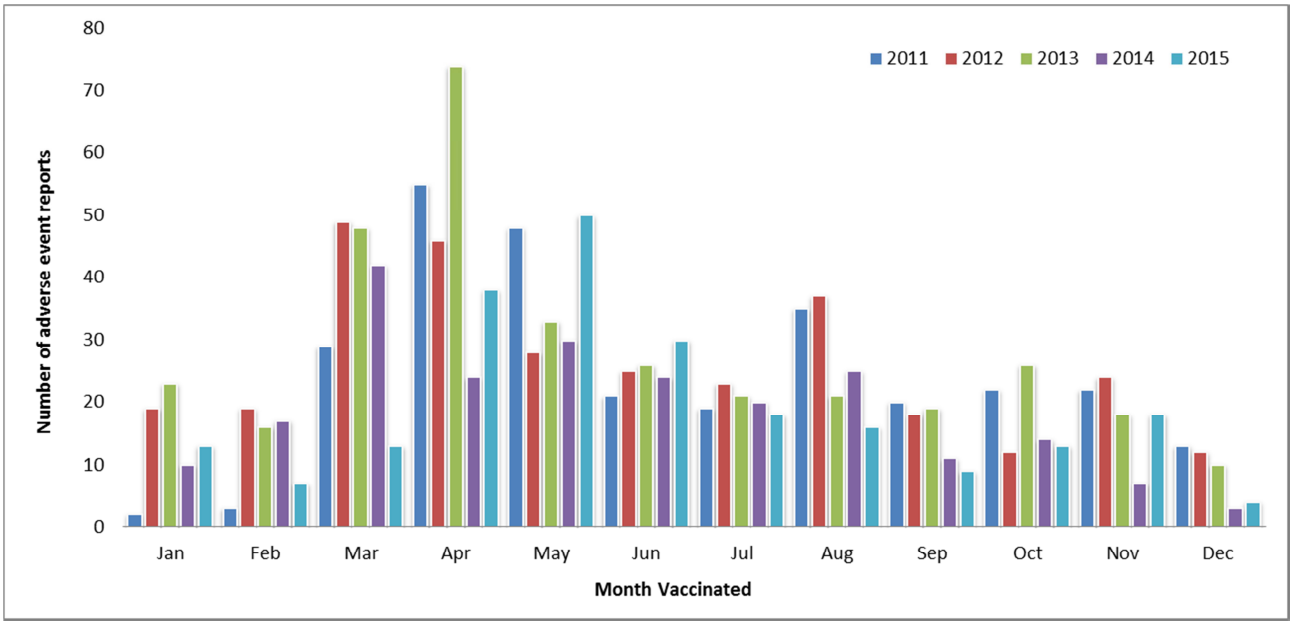

Figure 1 – Reports of adverse events following immunisation, Western Australia 2011-2014, by month of vaccination.

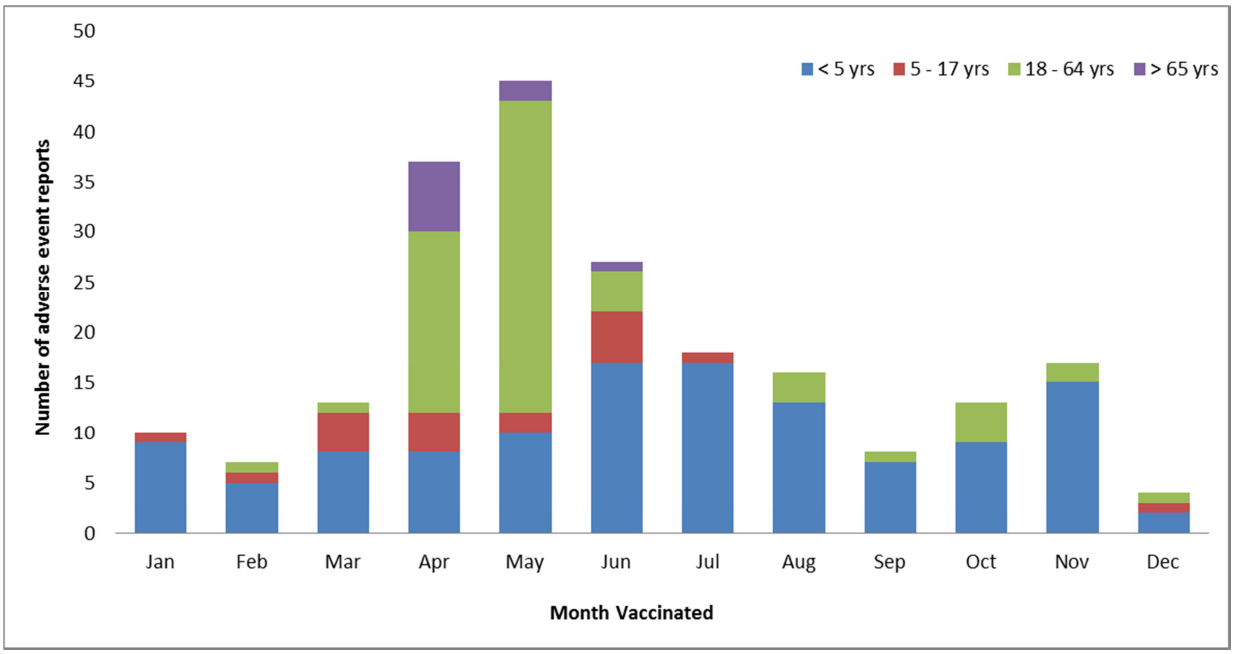

Figure 2 – Reports of adverse events following immunisation, Western Australia, 2014, by month of vaccination and age group in years.

Characteristics of AEFI reports received in 2015 are summarised in Table 1 and compared to those received in 2011, 2012, 2013 and 2014. The majority (82%) of reports to the system were received from healthcare providers, with 10% of reports from the public. Of the 216 reports, 79 were treated by a GP, 32 were seen by a nurse, 55 were seen at an Emergency Department, and 22 were reported as being hospitalised. The number of reports of patients being hospitalised (21, 10%) is similar to that in previous years (8% of cases in 2014, 6% of cases in 2013, 8% of cases in 2012 and 7% of cases in 2011), with a median length of stay of 2 days (range 1-5 days). Reports were most often received through the online system (58%) or by fax (38%).

A summary of the 228 reactions which met established case definitions is shown in Table 2. The most commonly reported reactions in 2015 were injection site (local) reaction (n=52), fever (n=42) and rash (n=39). The proportion of febrile reactions (with no seizure), febrile convulsions and afebrile convulsions were reported in 2015 were in keeping with previous years (Table 3).

Table 1 – Characteristics of AEFIs reported in 2011-2015

	2011	2012	2013	2014	2015
TOTAL	283	305	312	218	216
Gender:					
Female	163 (58%)	173 (57%)	167 (54%)	117 (54%)	119 (55%)
Male	120 (42%)	131 (43%)	145 (46%)	101 (46%)	96 (45%)
Aboriginal/Torres Strait Islander Status:					
ATSI	8 (3%)	12 (4%)	6 (2%)	11 (5%)	13 (6%)
Non-ATSI	200 (71%)	253 (83%)	231 (74%)	136 (62%)	138 (64%)
Unknown	75 (26%)	40 (13%)	75 (24%)	71 (33%)	65 (30%)
Age Group:					
<5 years	122 (43%)	141 (46%)	162 (52%)	122 (56%)	120 (56%)
5-17 years	55 (19%)	56 (18%)	36 (12%)	32 (15%)	19 (9%)
≥18 years	177 (63%)	197 (65%)	198 (63%)	154 (71%)	139 (64%)
Reporter Type:					
Health provider	225 (80%)	223 (73%)	249 (80%)	189 (87%)	178 (82%)
Parent/public	52 (18%)	72 (24%)	50 (16%)	23 (11%)	22 (10%)
Other	6 (2%)	10 (3%)	12 (4%)	6 (3%)	12 (6%)
Immunisation Provider					
GP	111 (39%)	84 (28%)	99 (32%)	52 (24%)	41 (19%)
Nurse	121 (43%)	163 (53%)	151 (48%)	108 (50%)	101 (47%)
Managed By:					
Healthdirect	12 (4%)	20 (7%)	21 (7%)	7 (3%)	8 (4%)
Nurse assessment	48 (17%)	70 (23%)	76 (24%)	69 (32%)	32 (15%)
GP assessment	134 (47%)	126 (41%)	142 (46%)	89 (41%)	79 (37%)
Central Immunisation Clinic	7 (2%)	11 (4%)	8 (3%)	5 (2%)	1 (0%)
Emergency Department	40 (14%)	66 (22%)	65 (21%)	42 (19%)	55 (25%)
Admitted to Hospital	20 (7%)	25 (8%)	19 (6%)	17 (8%)	22 (10%)
Reported By:					
Fax	129 (46%)	125 (41%)	119 (38%)	107 (49%)	83 (38%)
Online	120 (42%)	114 (37%)	132 (42%)	109 (50%)	125 (58%)
Post	14 (5%)	23 (8%)	16 (5%)	0 (0%)	1 (0%)
Telephone	18 (6%)	43 (14%)	39 (13%)	0 (0%)	2 (1%)

Table 2 – Summary of AEFI reaction(s) which met case definitions, 2011-2015

Reaction	2011	2012	2013	2014	2015	Total
Allergic reaction (generalised)	5	8	6	6	5	**30**
Anaphylaxis	0	2	2	4	5	**13**
Angioedema	1	0	0	0	1	**2**
Apnoea (or Apnea)	0	0	1	0	2	**3**
Apnoea (or Apnea) with bradycardia	1	2	3	0	0	**6**
Arthralgia	9	20	5	5	1	**40**
Arthritis	0	0	0	0	1	**1**
Brachial neuritis	2	0	0	0	0	**2**
Cellulitis at injection site	4	2	1	0	0	**7**
Complex Regional Pain	0	0	0	1	0	**1**
Crying (persistent)	9	9	4	4	2	**28**
Diarrhoea	4	16	8	5	6	**39**
Fever (>=38ºC to <39.5ºC)	16	18	26	9	16	**85**
Fever (≥39ºC)	8	8	18	7	2	**43**
Fever (unspecified)	48	47	39	33	24	**191**
Guillain-Barré Syndrome (GBS)	0	0	2	1	0	**3**
Headache (severe)	24	8	6	9	8	**55**
Hypotonic–hyporesponsive episode - HHE	6	6	3	6	2	**23**
Injection site reaction - large	69	73	57	27	14	**240**
Injection site reaction - minor/common/expected	22	23	34	29	35	**143**
Injection site reaction - severe	33	11	4	3	3	**54**
Intussusception	1	3	2	2	4	**12**
Lymphadenitis (includes suppurative lymphadenitis)	0	3	1	0	2	**6**
Nodule at injection site	1	2	1	1	0	**5**
Parotitis	0	1	1	0	0	**2**
Rash	44	54	39	27	39	**203**
Seizure-afebrile	1	5	3	2	5	**16**
Seizure-febrile	4	7	10	5	10	**36**
Seizure-syncopal	1	1	1	2	1	**6**
Sepsis	1	0	0	0	0	**1**
Thrombocytopenia	0	1	0	1	1	**3**
Urticaria/Hives/Allergic Rash	6	15	13	7	3	**44**
Vaccine error (Program error)	15	6	16	32	12	**81**
Vasovagal episode (syncope, faint)	8	8	15	10	13	**54**
Vomiting	26	23	16	18	11	**94**
Total	**369**	**382**	**337**	**256**	**228**	**1572**

Table 3 – Classification of the type of AEFI reaction(s), 2011-2015

	2011	2012	2013	2014	2015
Afebrile convulsions/seizures	2	6	4	4	6
Febrile convulsions	4	7	10	5	10
Local reaction	124	107	95	59	52
Other febrile reaction	72	73	83	49	42
Other reactions	167	189	145	139	118
Grand Total	**369**	**382**	**337**	**256**	**228**

Of all AEFI reports, 56% (120/216) were reported among children aged less than five years, compared with 56% in 2014, 52% in 2013, 46% in 2012 and 43% in 2011. In 2015, more than 490,000 doses of National Immunisation Program childhood vaccines were distributed in WA. The rate of AEFIs in children <5 years per 10,000 doses recorded on the Australian Childhood Immunisation Record (ACIR) is provided in Table 4. The highest rate of AEFI per 10,000 doses is seen with Quadracel (11.5 AEFI/10,000 doses) followed by TIV (8.1 AEFI/10,000 doses). The rate of AEFI for scheduled vaccinations in 2015 has remained relatively stable for the majority of vaccines. Increases were noted between 2014 and 2015 for Quadracel, TIV and Menitorix; none of these increases were statistically significant ($p>0.05$).

AEFIs associated with influenza vaccines

Administration of an influenza vaccine was recorded, either alone or in combination with other vaccines, in 32% (70/216) of the AEFI reports, compared with 24% (53/218) in 2014, 31% (97/312) in 2013, 24% (72/305) in 2012 and 19% (55/283) of reports in 2011.

Table 5 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 (66%). A total of 15 adverse reports to influenza vaccines occurred in children <5 years of age (Table 5).

In 2015, the most commonly reported type of adverse event following receipt of influenza vaccine, alone or in combination with other vaccines, was fever (n=14). There were 8 reports of rash, 7 vasovagal episodes and 6 reports of local reactions following receipt of influenza vaccine. Five reports of anaphylaxis following influenza vaccination were received in 2015, which is a higher number than reported in previous years. These cases are being reviewed by a clinical immunologist to determine if they all satisfy clinical case definitions.

Table 4 – Rate of AEFI in children <5 years per 10,000 doses administered as recorded on ACIR by vaccine, 2012-2015

	2012			2013			2014			2015		
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	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)	2,788	1	3.6	2,934	1	3.4	2,552	0	0.0	2,066	1	4.8
VAQTA Paediatric formulation (HepA)	3,547	1	2.8	3,792	0	0.0	3,944	1	2.5	4,216	0	0.0
Infanrix Hexa (DTP-HepB-Polio-HIB)	94,268	12	1.3	96,795	11	1.1	98,373	17	1.7	98,695	14	1.4
Prevenar (Pneumococcal)[a]	108,398	59	5.4	98,534	47	4.8	100,036	32	3.2	100,340	34	3.4
RotaTeq (Rotavirus)	82,861	50	6.0	86,404	41	4.7	88,886	34	3.8	90,034	33	3.7
TIV (Influenza)	9,405	10	10.6	18,732	13	6.9	15,240	8	5.2	18,594	15	8.1
QIV (Influenza)										35	0	0.0
Priorix (Measles, Mumps, Rubella)	61,270	41	6.7	49,000	61	12.4	10,356	7	6.8	10,658	6	5.6
Priorix Tetra (Measles, Mumps, Rubella, Varicella)				14,754	8	5.4	33,893	26	7.7	32,223	6	1.9
ProQuad (Measles, Mumps, Rubella, Varicella)										1,700	1	5.9
MMR – II (Measles, Mumps, Rubella)	1,270	0	0.0	14,933	19	12.7	51,009	25	4.9	49,933	0	0.0
Menitorix (Meningococcal C, HIB)				10,924	13	11.9	33,481	9	2.7	34,534	13	3.8
Varilrix (Varicella)	31,191	9	2.9	18,259	3	1.6	980	0	0.0	274	0	0.0
Varivax (Varicella)										328	0	0.0
Quadracel (DTPa-Polio)	28,829	45	15.6	28,198	56	19.9	26,102	24	9.2	30,505	35	11.5

[a]Includes both Prevenar7 and Prevenar13 figures

Table 5 – Age breakdown of all adverse reaction reports to influenza vaccines, by brand, Western Australia, 2015.

Row Labels	< 5 yrs	5 - 17 yrs	18 - 64 yrs	> 65 yrs	Total
Flu - Brand unspecified	0	0	1	0	**1**
Fluarix®	0	0	2	0	**2**
Fluarix Tetra®	0	0	15	0	**15**
Fluvax®	2	0	14	2	**19**
Influvac®	0	1	1	0	**2**
Vaxigrip®	8	3	12	3	**26**
Vaxigrip Junior®	5	0	0	0	**5**
Total	**15**	**4**	**45**	**5**	**69**

A total of 5 reports associated with influenza vaccines indicated the patient had been hospitalised for at least one night (compared to 6 in 2014, 6 in 2013, 6 in 2012 and 2 in 2011).

Non-influenza vaccines identified in AEFI reports

Influenza vaccines were the most commonly reported vaccine on an AEFI report in 2015 (n=70, 32% of all respondents). The other most frequently identified vaccines specified on AEFI reports were:

- Pneumococcal (n=44, 21%)
- dTpa-IPV (n=42, 20%)
- MMR (n=39, 19%)
- Rotavirus (n=37, 18%)
- DTPa-IPV-HepB-Hib (n=36, 17%)
- dTpa (n=18, 9%)

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 (all in children <5 years), 46 local reactions, 29 other febrile reactions, and 85 other reactions. There were no reports of anaphylaxis following administration of a non-influenza vaccine administered in 2015.

WAVSS clinical activity

There were ten monthly clinics run in 2015 (all months except March and December). Sixty children were booked in to attend these clinics, 43 new cases and 17 follow up cases with a total of 44 registered attendees. Twenty-six of these were GP/PMH referrals and 17 were WAVSS cases. A total of 13 children were vaccinated at the clinic, with the others referred to the Central Immunisation Clinic. Seven adults were referred to the adult immunology clinic at Sir Charles Gardiner Hospital (SCGH).

Publications

AusVaxSafety – 2015 Findings: http://www.ncirs.edu.au/surveillance/ausvaxsafety/index.php

Pillsbury A, Cashman P, Leeb A, Regan A, Westphal D, Snelling T, et al. Real-time safety surveillance of seasonal influenza vaccines in children, Australia, 2015. *Euro Surveill*. 2015 Oct 29;20(43). PubMed PMID: 26536867.