Government of Western Australia
Department of Health

Western Australia Vaccine Safety Surveillance – Annual Report, 2014

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 2014 declined, despite a similar number of vaccines being distributed and reported as administered to children <7 in ACIR. When given alone or in combination with other vaccines, there were 36 fewer adverse events reported in persons who received Quadracel, 35 fewer adverse events reported in persons who received an MMR containing vaccine, 26 fewer adverse events reported in persons who received Vaxigrip, and 21 fewer adverse events reported in persons who received Infanrix hexa and/or Pneumococcal vaccines.

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 statistically significant reductions in reported rates of AEFI associated with receiving vaccines as a single dose, or in combination with other vaccines, for Infanrix hexa ($P < 0.001$), MMR-containing vaccines (includes Priorix, Priorix Tetra and MMR-II, $P < 0.001$), Menitorix ($P < 0.001$) and Quadracel ($P = 0.001$) (Table 3).

As shown in Table 4, the greatest reduction in AEFI between 2013 and 2014 occurred in reports of local reactions and other febrile reactions, which could be considered more mild events. This reduction may indicate a trend toward reduced reporting of mild events. In contrast, reports of more serious adverse events, such as anaphylaxis and febrile seizures, have remained stable between 2013 and 2014, suggesting the passive system continues to capture more serious events, which is the primary intention.

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://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 2014 and the 31 December 2014; 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 2014 as at 21 January 2015. These data are subject to change.

Surveillance data analysis

AEFI reports

A total of 220 individual AEFI reports were received by WAVSS for persons vaccinated in 2014, compared with 333 in 2013, 311 in 2012 and 289 in 2011. Of the 220 reports, 10 were reviewed and determined to be unrelated to vaccination and were removed from further analysis.

From the remaining 210 reports, 320 adverse events were described (compared with 520 in 2013, 609 in 2012 and 496 in 2011); 249 met established case definitions and 71 were recorded verbatim (note that a vaccinee may describe multiple AEFI reactions).

A total of 317 vaccines had been administered (compared with 532 in 2013, 528 in 2012 and 476 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, 2013 and 2014 is shown in Figure 1. The month with the highest number of AEFI reports in 2014 was March and , 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).

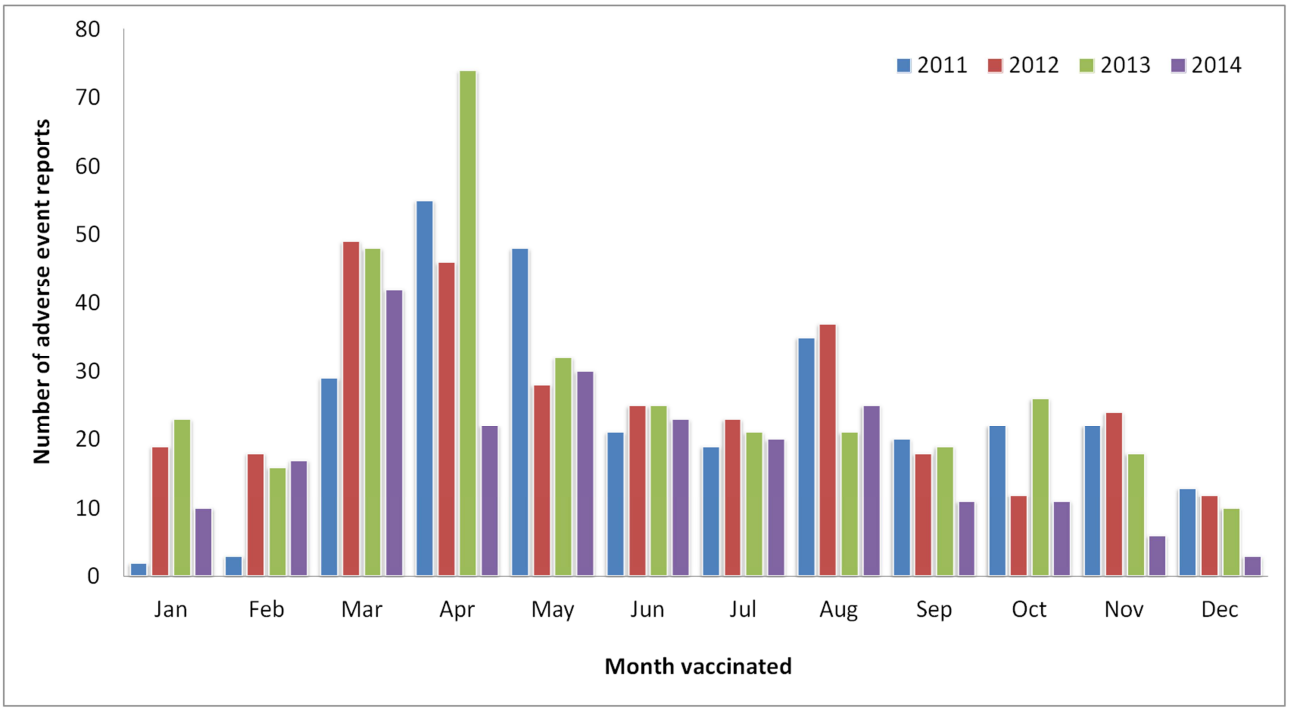

Figure 1 – Reports of adverse events following immunisation, Western Australia 2011-2014, by month of vaccination.

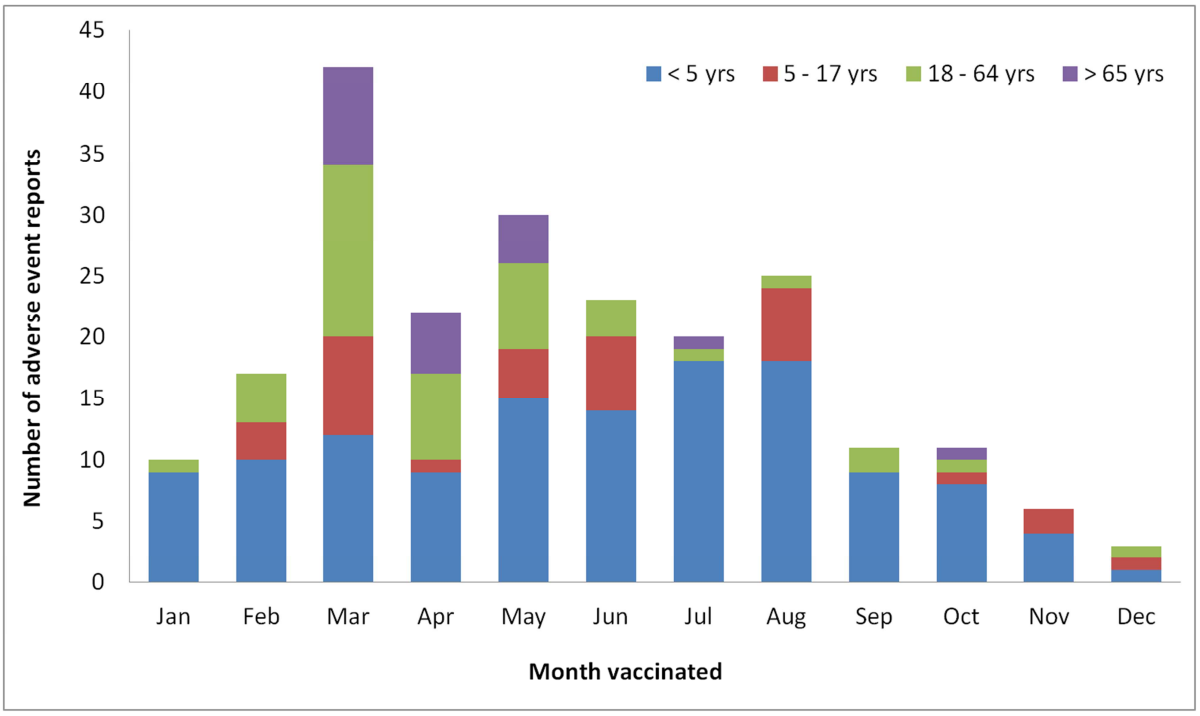

Figure 2 – Reports of adverse events following immunisation, Western Australia, 2014, by month of vaccination and age group in years.

Characteristics of AEFI reports received in 2014 are summarised in Table 1 and compared to those received in 2011, 2012 and 2013. The majority (87%) of reports to the system were received from healthcare providers, with 10% of reports from the public. Of the 210 reports, 87 were treated by a GP, 69 were seen by a nurse, 42 were seen at an Emergency Department, and 17 were reported as being hospitalised. The number of reports of patients being hospitalised (17, 8%) is similar to that in previous years (6% of cases in 2013, 8% of cases in 2012 and 7% of cases in 2013), with a median length of stay of 1 day (range 1-4 days). Reports were most often received through the online system (50%) or by fax (50%).

Of the 249 events which met established case definitions, 58 (23%) were attributed to a local reaction and 48 (19%) to a febrile reaction (with no seizure). A small number of febrile convulsions (5, 2%) and afebrile convulsions (4, 2%) were reported in 2014. The remaining 134 event were other reactions (Table 2).

Table 1 – Characteristics of AEFIs reported in 2011-2014

	2011	2012	2013	2014
TOTAL	283	304	310	210
Gender:				
Female	163 (58%)	173 (57%)	166 (54%)	111 (53%)
Male	120 (42%)	130 (43%)	144 (46%)	99 (47%)
Aboriginal/Torres Strait Islander Status:				
ATSI	8 (3%)	12 (4%)	6 (2%)	11 (5%)
Non-ATSI	200 (71%)	252 (83%)	230 (74%)	133 (63%)
Unknown	75 (26%)	40 (13%)	74 (24%)	66 (31%)
Age Group:				
<5 years	121 (43%)	140 (46%)	163 (52%)	121 (58%)
5-17 years	56 (20%)	56 (18%)	36 (12%)	30 (14%)
≥18 years	106 (37%)	108 (36%)	111 (36%)	59 (28%)
Reporter Type:				
Health provider	225 (80%)	222 (73%)	245 (79%)	182 (87%)
Parent/public	52 (18%)	72 (24%)	50 (16%)	21 (10%)
Other	6 (2%)	10 (3%)	14 (5%)	7 (3%)
Immunisation Provider				
GP	111 (39%)	84 (28%)	99 (32%)	51 (24%)
Nurse	121 (43%)	163 (54%)	152 (49%)	106 (50%)
Managed By:				
Healthdirect	12 (4%)	20 (7%)	21 (7%)	7 (3%)
Nurse assessment	48 (17%)	70 (23%)	76 (25%)	69 (33%)
GP assessment	134 (46%)	126 (41%)	141 (45%)	87 (41%)
Central Immunisation Clinic	7 (2%)	11 (21%)	8 (3%)	5 (2%)
Emergency Department	40 (14%)	66 (22%)	65 (11%)	42 (20%)
Admitted to Hospital	20 (7%)	25 (8%)	19 (6%)	17 (8%)
Reported By:				
Fax	129 (46%)	125 (41%)	119 (38%)	105 (50%)
Online	120 (42%)	113 (37%)	130 (42%)	104 (50%)
Post	14 (5)	23 (8%)	16 (5%)	0 (0%)
Telephone	18 (6%)	43 (14%)	39 (13%)	0 (0%)

Table 2 – Classification of the type of AEFI reaction(s), 2011-2014

	2011	2012	2013	2014
Afebrile convulsions/seizures	2	6	4	4
Febrile convulsions	4	6	9	5
Local reaction	124	107	95	58
Other febrile reaction	72	73	82	48
Other reactions	167	188	145	134
Grand Total	**369**	**380**	**335**	**249**

Of all AEFI reports, 58% (121/210) were reported among children aged less than five years, compared with 53% in 2013, 46% in 2012 and 43% in 2011. In 2014, more than 480,000 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 3. The highest rate of AEFI per 10,000 doses is seen with Quadracel (9.4 AEFI/10,000 doses) followed by Priorix Tetra (7.5 AEFI/10,000 doses). The rate of AEFI for scheduled vaccinations in 2014 has decreased for the majority of vaccines, with the exception of VAQTA and Priorix Tetra which showed modest increases.

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% (52/210) of the AEFI reports, compared with 25% (85/336) in 2013, 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 4)

In 2014, 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=32). There were 16 local reactions and 12 fevers reported following receipt of influenza vaccine. Two reports of anaphylaxis and 1 report of Guillan-Barré Syndrome following influenza vaccination were received in 2014.

Table 3 – Rate of AEFI in children <5 years per 10,000 doses administered as recorded on ACIR by vaccine, 2011-2014

	2011			2012			2013			2014		
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)	3,130	1	3.2	4,155	1	2.4	3,732	1	2.7	3,077	0	0.0
VAQTA Paediatric formulation (HepA)	3,273	2	6.1	3,589	1	2.8	3,754	0	0.0	3,870	1	2.6
Infanrix Hexa (DTP-HepB-Polio-HIB)	91,839	36	3.9	94,005	42	4.5	95,882	49	5.1	97,787	18	1.8
Prevenar (Pneumococcal)[a]	100,215	53	5.3	108,304	59	5.4	97,848	47	4.8	99,565	32	3.2
RotaTeq (Rotavirus)	80,934	36	4.4	83,852	50	6.0	86,961	41	4.7	89,081	34	3.8
TIV (Influenza)	8,645	7	8.1	9,416	10	10.6	18,711	14	7.5	15,159	8	5.3
Priorix (Measles, Mumps, Rubella)	53,864	45	8.4	61,719	41	6.6	48,496	62	12.8	10,038	7	7.0
Priorix Tetra (Measles, Mumps, Rubella, Varicella)							14,006	8	5.7	33,302	25	7.5
MMR – II (Measles, Mumps, Rubella)	1,080	0	0.0	752	0	0.0	14,035	19	13.5	50,198	25	5.0
Hiberix (Haemophilus influenza B)	29,993	16	5.3	31,019	16	5.2	21,692	12	5.5	560	0	0.0
NeisVac-C (Meningococcal C)	31,055	16	5.2	32,432	14	4.3	23,102	12	5.2	768	0	0.0
Menitorix (Meningococcal C, HIB)							10,618	13	12.2	33,310	9	2.7
Varilrix (Varicella)	29,720	9	3.0	30,901	9	2.9	17,840	4	2.2	853	0	0.0
Quadracel (DTPa-Polio)	22,275	34	15.3	29,287	45	15.4	28,087	57	20.3	25,656	24	9.4

[a]Includes both Prevenar7 and Prevenar13 figures

Table 4 – Age breakdown of all adverse reaction reports to influenza vaccines, by brand, Western Australia, 2014.

	<5 years	5-17 years	18-64 years	≥65 years	TOTAL
Brand unspecified	0	1	3	2	**6**
Fluarix®	0	1	0	1	**2**
Fluvax®	2[†]	0	6	9	**17**
Influvac®	0	0	1	0	**1**
Intanza®	0	0	7	0	**7**
Vaxigrip®	3	3	6	4	**16**
Vaxigrip Junior®	3	0	0	0	**3**
Grand Total	**13**	**7**	**53**	**27**	**71**

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

[†]Both reactions to Fluvax in children under 5 were 'vaccine error' only with no associated AEFI

A total of 6 reports associated with influenza vaccines indicated the patient had been hospitalised for at least one night (compared to 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 2014 (n=54, 16% of all respondents). The other most frequently identified vaccines specified on AEFI reports were:

- Pneumococcal (n=44, 13%)
- Rotavirus (n=38, 11%)
- MMR (n=37, 11%)
- dTpa-IPV (n=28, 8%)
- MMRV (n=26, 8%)
- DTPa-IPV-HepB-Hib (n=19, 6%)
- HPV (n=18, 5%)

Of the adverse events following receipt of all vaccines other than influenza (alone or in combination with other vaccines), there were 4 febrile convulsions (all in children <5 years), 3 afebrile convulsions (all in children <5 years), 42 local reactions, 36 other febrile reactions, and 101 other reactions. There were 2 reports of anaphylaxis following administration of a non-influenza vaccine administered in 2014.

WAVSS clinical activity

There were ten monthly clinics run in 2014 (all months except September and December). Fifty-six children were booked in to attend these clinics, with a total of 41 registered attendees. Twenty-nine of these were GP/PMH referrals and 26 were WAVSS cases. A total of 12 children were vaccinated at the clinic, with the others referred to the Central Immunisation Clinic. Five adults were seen by the adult immunology clinic at Sir Charles Gairdner Hospital (SCGH).

Publications

Regan AK, Blyth CC, Mak DB, Richmond PC, Effler PV. Using SMS to monitor adverse events following trivalent influenza vaccination in pregnant women. The Australian & New Zealand journal of obstetrics & gynaecology. 2014 Dec;54(6):522-8. PubMed PMID: 25306915. Epub 2014/10/14. eng.

Tracey LE, Regan AK, Mak DB and Effler PV. Adverse Events Following Influenza Immunization Reported by Healthcare Personnel Using Active Surveillance Based on Text Messages. Infection Control & Hospital Epidemiology, Available on CJO 2015 doi:10.1017/ice.2015.16

AusVaxSafety – 2014 Findings: http://www.ncirs.edu.au/surveillance/ausvaxsafety/index.php