Government of Western Australia
Department of Health

Western Australia Vaccine Safety Surveillance – Annual Report 2016

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

Executive Summary

This report describes adverse events passively reported to the Western Australian Vaccine Safety Surveillance System for vaccinations received in 2016.

The overall number of adverse events following immunisation reported for 2016 (240 reports) was similar to the average number of reports per year received for the previous four years (average of 243).

In 2016 there was an increase in reports received for ages 65 and over. One reason for the increase was that a new funded shingles vaccination program commenced in October 2016, and reports were received following administration of Zostavax. In addition, AEFI reports following Pneumovax 23 vaccination increased in 2016.

The percentage of reports where patients presented to an emergency department (17%) or were admitted to hospital (5%) was lower in 2016 than in previous years.

The number of reports for minor injection site reactions and rashes was higher in 2016 than in recent years. The vaccine for which minor injection site reactions was most commonly reported was Quadracel, and Zostavax was the vaccine with the most reports of rash.

In children under five, who receive the majority of vaccinations and for whom denominator data from the Australian Childhood Immunisation Register is available, there were relatively high rates of reactions reported for some of the vaccines introduced in 2016. These included the new 18 month DTPa vaccines that commenced in April 2016 and new QIV vaccines introduced in 2016. Reporting rates were also relatively high compared to previous years for the four year old DTPa vaccines. Increased local reactions following a fourth dose of acellular pertussis vaccine have been previously reported[1], and the number of reports was not considered to be outside of expected ranges.

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.

[1] Gold MS, Noonan S, Osbourn M, Precepa S, Kempe AE. Local reactions after the fourth dose of acellular pertussis vaccine in South Australia. *The Medical Journal of Australia*. 2003;179(4):191-4.

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 of Health 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 'possible or certain' 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 2016 and the 31 December 2016, and
- the vaccination was passively reported.

In addition to receiving passive AEFI reports, WAVSS also receives AEFI reports from active surveillance. These are primarily reports of medically attended AEFIs from AusVaxSafety. These are not included in this report.

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 2016 as 27 March 2017. These data are subject to change.

Surveillance data analysis

AEFI reports

There were 240 individual AEFI reports received for persons vaccinated in 2016 that were assessed as events possibly related to vaccination, which was more than for the previous year (165 reports) but similar to the average number of reports per year for the previous four years (243 reports).

In 2016, 324 adverse events were described; 231 met established case definitions and 93 were other reactions (note that a vaccinee may describe multiple AEFI reactions).

Reported adverse events for 2016 occurred following administration of 460 vaccines (compared to 278 in 2015, 281 in 2014, 593 in 2013 and 526 in 2012).

The month with the highest number of AEFI reports in 2016 was April, with 47 reports. For the years 2012 to 2016, the number of reports was higher for March to June, which related to increased reports following influenza vaccinations during these months (Figure 1).

In 2016, the number of reports received for each age group was within the range of the previous four years, with the exception of the 65 year and older age group, for which there were more reports in 2016 than in previous years (Figure 2). Funded shingles vaccination for 70 – 79 year olds was introduced in October 2016, and 16 of the 42 reports for people aged 65 and over for 2016 followed administration of Zostavax. In 2016 there was also an increase in reports following administration of Pneumovax 23, with 14 reports for 2016 compared to a range of 2 to 8 for the previous four years.

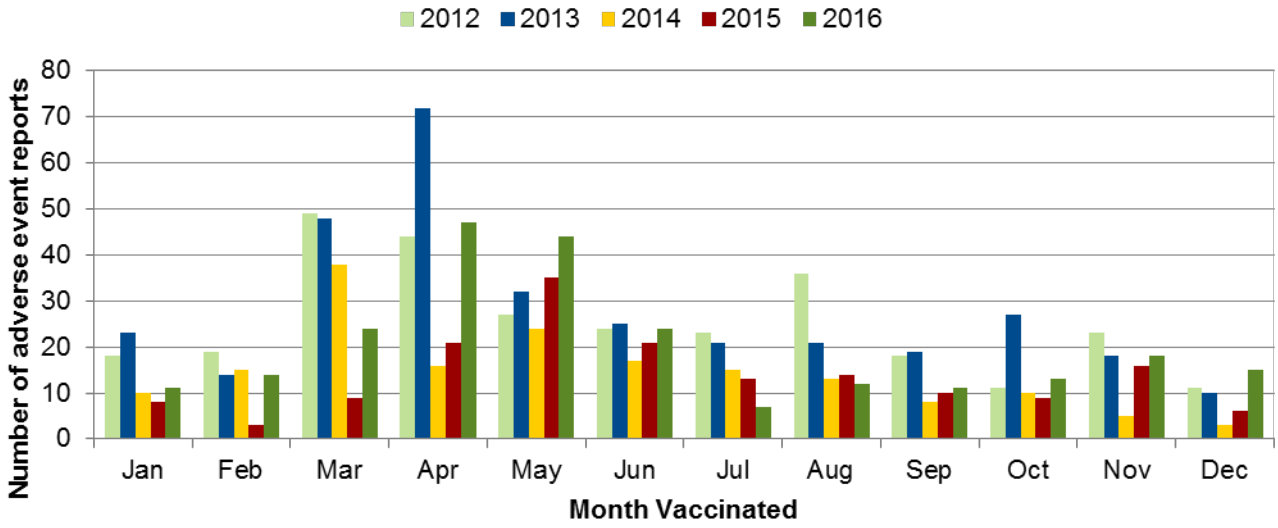

Figure 1 – Reports of adverse events following immunisation, Western Australia 2012 to 2016, by month of vaccination.

Characteristics of AEFI reports received in 2016 and previous years are summarised in Table 1. The majority (83%) of reports to WAVSS were received from healthcare providers, with 10% of reports from the public. Of the 240 patients, 120 were treated by a GP, 54 were seen by a nurse, 40 were seen at an emergency department and 12 were hospitalised. The number of reports of both emergency department presentations and hospital admissions were lower than for previous years. In 2016, 17% (40/240) of patients presented to an emergency department, compared to a range of 21% to 23% for the previous four years. The proportion of patients hospitalised (5%, 12/240) was lower than in previous years (7% in 2012, 9% in 2013, 7% in 2014 and 8% in 2015). Reports were most often received through the online system (59%) or by fax (38%).

A summary of the 231 reactions that met established case definitions is shown in Table 2. The most commonly reported reactions in 2016 were minor injection site reactions (n=71), rash (n=50) and fever (n=27). These were also the three most commonly reported reactions over the five years period from 2012 to 2016 (five year totals of 311 reports of fever, 209 reports of rash and 192 reports of minor injection site reactions). The number of minor injection site reactions reported in 2016 (71) was higher than in previous years (23 in 2012, 34 in 2013, 29 in 2014, 35 in 2015). Quadracel was the vaccine for which minor local reactions were most commonly reported in 2016 (23 reports). The number of rashes reported in 2016 (50) was also high compared to recent years (39 in 2013, 27 in 2014 and 39 in 2015). The vaccine most commonly associated with rash in 2016 was Zostavax (9 reports). The number of febrile reactions (including febrile seizure) reported in 2016 (32) was lower than in previous years (80, 93, 54 and 52, for 2012, 2013, 2014 and 2015, respectively).

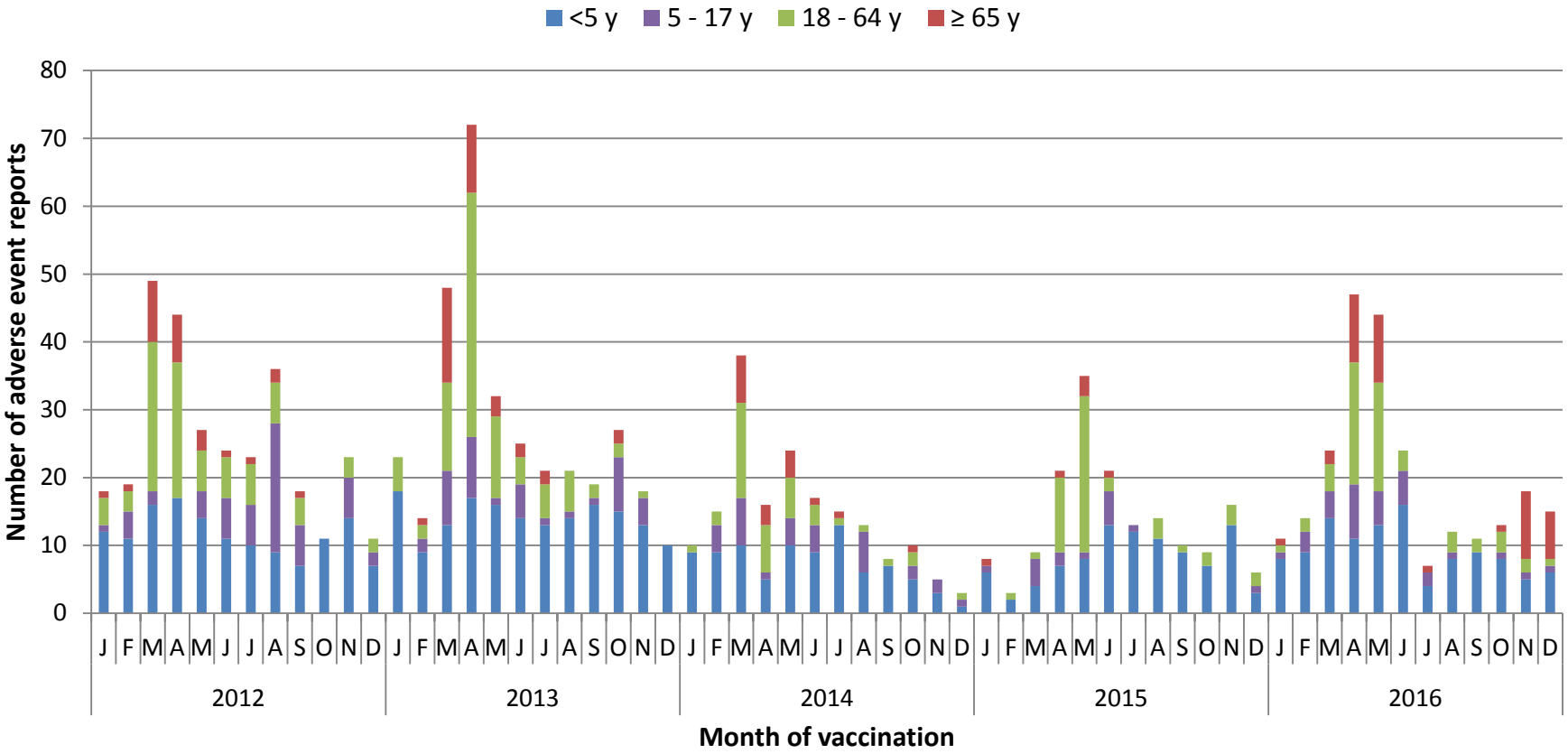

Figure 2 – Reports of adverse events following immunisation, Western Australia, 2012 to 2016, by month of vaccination and age group in years.

Table 1 – Characteristics of AEFIs reported in 2012 to 2016

	2012		2013		2014		2015		2016	
	Number	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Total	**303**		**330**		**174**		**165**		**240**	
Gender										
Female	172	57%	175	53%	96	55%	91	55%	139	58%
Male	130	43%	155	47%	78	45%	74	45%	101	42%
Aboriginal Status										
Aboriginal	11	4%	7	2%	9	5%	10	6%	8	3%
Non-Aboriginal	251	83%	248	75%	113	65%	115	70%	130	54%
Unknown	40	13%	75	23%	52	30%	40	24%	102	43%
Age Group										
< 5 years	139	46%	168	51%	87	50%	95	58%	111	46%
5-17 years	56	18%	40	12%	31	18%	15	9%	32	13%
18-64 years	82	27%	88	27%	39	22%	49	30%	55	23%
≥ 65 years	26	9%	34	10%	17	10%	6	4%	42	18%
Reporter Type										
Health provider	225	74%	260	79%	150	86%	137	83%	199	83%
Parent/Public	72	24%	58	18%	19	11%	20	12%	23	10%
Other	6	2%	12	4%	5	3%	8	5%	18	8%
Immunisation Provider										
GP	82	27%	103	31%	44	25%	35	21%	61	25%
Nurse	165	54%	163	49%	82	47%	73	44%	83	35%
Pharmacist	0	0%	0	0%	0	0%	3	2%	1	0%
Unknown	56	18%	64	19%	47	27%	54	33%	95	40%
Managed By:										
Healthdirect	20	7%	23	7%	7	4%	6	4%	10	4%
Nurse assessment	70	23%	80	24%	53	30%	31	19%	54	23%
GP assessment	124	41%	151	46%	80	46%	67	41%	120	50%
Central Immunisation Clinic	11	4%	8	2%	2	1%	0	0%	5	2%
Emergency Department	65	21%	72	22%	37	21%	38	23%	40	17%
Admitted to hospital	24	8%	23	7%	16	9%	12	7%	12	5%
Reported by:										
Fax	124	41%	123	37%	82	47%	58	35%	91	38%
Online	113	37%	144	44%	91	52%	99	60%	142	59%
Post	23	8%	16	5%	0	0%	1	1%	4	2%
Telephone	43	14%	40	12%	0	0%	2	1%	0	0%

Table 2 – Summary of AEFI reaction(s) that met case definitions, 2012 to 2016

Reaction	2012	2013	2014	2015	2016	Total
Allergic reaction (generalised)	8	6	6	5	2	**27**
Anaphylaxis	2	2	4	5	2	**15**
Angioedema	0	0	0	1	4	**5**
Apnoea (or Apnea)	0	1	0	2	0	**3**
Apnoea (or Apnea) with bradycardia	2	3	0	0	0	**5**
Arthralgia	20	5	5	1	0	**31**
Arthritis	0	0	0	1	0	**1**
Brachial neuritis	0	0	0	0	0	**0**
Cellulitis at injection site	2	1	0	0	0	**3**
Complex Regional Pain	0	0	1	0	0	**1**
Crying (persistent)	9	4	4	2	0	**19**
Diarrhoea	16	8	5	6	6	**41**
Fever (>=38ºC to <39.5ºC)	18	26	9	16	5	**74**
Fever (≥39ºC)	8	18	7	2	2	**37**
Fever (unspecified)	47	39	33	24	20	**163**
Guillain-Barré Syndrome (GBS)	0	2	1	0	0	**3**
Headache (severe)	8	6	9	8	4	**35**
Hypotonic–hyporesponsive episode - HHE	6	3	6	2	2	**19**
Injection site reaction - large	73	57	27	14	25	**196**
Injection site reaction - minor/common/expected	23	34	29	35	71	**192**
Injection site reaction - severe	11	4	3	3	2	**23**
Intussusception	3	2	2	4	1	**12**
Lymphadenitis (includes suppurative lymphadenitis)	3	1	0	2	0	**6**
Nodule at injection site	2	1	1	0	0	**4**
Parotitis	1	1	0	0	2	**4**
Rash	54	39	27	39	50	**209**
Seizure-afebrile	5	3	2	5	1	**16**
Seizure-febrile	7	10	5	10	5	**37**
Seizure-syncopal	1	1	2	1	0	**5**
Sepsis	0	0	0	0	0	**0**
Thrombocytopenia	1	0	1	1	0	**3**
Urticaria/Hives/Allergic Rash	15	13	7	3	2	**40**
Vaccine error (Program error)	6	16	32	12	5	**71**
Vasovagal episode (syncope, faint)	8	15	10	13	8	**54**
Vomiting	23	16	18	11	12	**80**
Total	**382**	**337**	**256**	**228**	**231**	**1434**

Of all AEFI reports for 2016, 46% (111/240) were for children aged less than five years, compared with 58% in 2015, 50% in 2014, 51% in 2013 and 46% in 2012. In 2016, for vaccines on the childhood immunisation schedule, the overall rate of AEFIs in children <5 years was 6.1 per 10,000 doses recorded on the Australian Immunisation Register (AIR) (Table 3). This was within the range of overall rates for the previous four years, which ranged from 5.1 to 8.3 per 10,000 doses. The highest rate of AEFI per 10,000 doses for any vaccine in 2016 was for Infanrix IPV (31.1 AEFI/10,000 doses) followed by quadrivalent influenza vaccine (QIV) (23.6 AEFI/10,000 doses).

In 2016 the rate of reactions increased with the age point of vaccination. For the vaccines administered at 2, 4 and 6 months the AEFI reporting rate was 2.2, 2.5 and 2.7 reports per 10,000 doses, for Prevenar 13, Rotateq and Infanrix hexa, respectively. The AEFI reporting rate was 4.9, 6.1 and 7.1 for the 12 months vaccines (Menitorix, Priorix and MMR II, respectively). For the 18 month vaccines the AEFI reporting rates were 10.9, 12.1, 12.6 and 20.3 per 10,000 doses administered, for Proquad, Infanrix, Priorix Tetra and Tripacel, respectively. The rates of AEFI reporting for the 4 year vaccines were 18.9 and 31.1 per 10,000 doses administered for Quadracel and Infanrix IPV, respectively.

AEFIs associated with influenza vaccines

Influenza vaccines were the most commonly reported vaccines in AEFI reports for 2016. Administration of an influenza vaccine was recorded, either alone or in combination with other vaccines, in 36% (86/240) of the AEFI reports in 2016, compared with 32% (53/165) in 2015, 26% (46/174) in 2014, 33% (108/330) in 2013 and 24% (74/303) in 2012.

Table 4 shows the brand and age breakdown of the reports. The majority of reports received associated with an influenza vaccination were for adults aged 18 to 64 years of age (43%, 37/86). A total of 31 (36%) adverse event reports to influenza vaccines occurred in children less than 5 years of age.

In 2016, the most commonly reported type of adverse event following receipt of influenza vaccine was fever (n=25). There were 17 reports of local reactions and 15 reports of rash following receipt of influenza vaccines. There were two reports of febrile convulsions and there was one report of anaphylaxis.

Three people with reported adverse reactions to influenza vaccines were admitted to hospital (compared to 4 in 2015, 4 in 2014, 6 in 2013 and 6 in 2012).

Table 3 – Rate of AEFI in children <5 years per 10,000 doses administered as recorded on ACIR by vaccine, 2012 to 2016

Vaccine	2012			2013			2014			2015			2016		
	Doses administered*	AEFI reports to WAVSS	AEFI rate/ 10,000 doses	Doses administered	AEFI reports to WAVSS	AEFI rate/ 10,000 doses	Doses administered	AEFI reports to WAVSS	AEFI rate/ 10,000 doses	Doses administered	AEFI reports to WAVSS	AEFI rate/ 10,000 doses	Doses administered	AEFI reports to WAVSS	AEFI rate/ 10,000 doses
DTPa - Infanrix													18,202	22	12.1
DTPa - Tripacel													5,921	12	20.3
DTPa-HepB-IPV-Hib - Infanrix hexa	94,268	56	5.9	96,795	54	5.6	98,373	39	4.0	98,695	47	4.8	101,418	27	2.7
DTPa-IPV - Infanrix-IPV													2,573	8	31.1
DTPa-IPV - Quadracel	28,829	45	15.6	28,198	58	20.6	26,102	24	9.2	30,505	38	12.5	30,740	58	18.9
Flu - QIV										35	0	0.0	16,524	39	23.6
Flu - TIV	9,405	10	10.6	18,732	16	8.5	15,240	11	7.2	18,594	16	8.6	158	0	0.0
HepA - Vaqta Paediatric formulation	3,547	1	2.8	3,792	0	0.0	3,944	1	2.5	4,216	0	0.0	4,450	0	0.0
HepB - H-B-Vax II Paediatric formulation	2,788	1	3.6	2,934	1	3.4	2,552	0	0.0	2,066	1	4.8	4,493	0	0.0
HIB-Men C - Menitorix				10,924	19	17.4	33,481	15	4.5	34,534	15	4.3	34,589	17	4.9
MMR - MMR II	1,270		0.0	14,933	23	15.4	51,009	31	6.1	49,933	31	6.2	28,187	20	7.1
MMR - Priorix	61,270	41	6.7	49,000	70	14.3	10,356	9	8.7	10,658	8	7.5	9,788	6	6.1
MMRV - Priorix Tetra				14,754	15	10.2	33,893	29	8.6	32,223	6	1.9	20,577	26	12.6
MMRV - Proquad										1,700	1	5.9	13,752	15	10.9
Pneumococcal - Prevenar13	108,398	62	5.7	98,534	50	5.1	100,036	36	3.6	100,340	44	4.4	103,049	23	2.2
Rotavirus - RotaTeq	82,861	52	6.3	86,404	45	5.2	88,886	41	4.6	90,034	44	4.9	92,954	23	2.5

*As reported in the Australian Immunisation Register

Table 4 – Age breakdown of all adverse reaction reports to influenza vaccines, by brand, Western Australia, 2016

Brand	Age group				Total
	<5 y	5 - 17 y	18 - 64 y	≥ 65 y	
Flu - Brand unspecified	1	1	2	4	**8**
Flu - Flu Quadri	1	1	17	0	**19**
Flu - Flu Quadri Junior	20	0	0	0	**20**
Flu - Fluarix	0	1	0	0	**1**
Flu - Fluarix Tetra	9	2	14	9	**34**
Flu - Fluvax	0	0	4	0	**4**
Total	**31**	**5**	**37**	**13**	**86**

Vaccines most commonly identified in AEFI reports

After influenza, the other most frequently identified vaccines specified on AEFI reports were:

- DTPa-IPV (n=69, 15%)
- Pneumococcal (n=46, 10%)
- MMRV (n=37, 8%)
- MMR (n=27, 6%)

For the 374 adverse events reported following receipt of all vaccines other than influenza, that met case definitions (alone or in combination with other vaccines), there were 7 febrile convulsions (all in children <5 years), two afebrile convulsions (in children aged 5 to 17 years), 150 local reactions, 67 other febrile reactions, and 148 other reactions. There was one report of anaphylaxis following administration of a non-influenza vaccine, Gardasil, in 2016.

WAVSS clinical activity

In 2016 there was a change in the WAVSS clinical activity due to the introduction of a ”High Risk Clinic” to run with the current Adverse Events Clinic at Princess Margaret Hospital (PMH). In 2016 the clinic changed to run from monthly to fortnightly.

There were 18 fortnightly clinics in 2016 (all months except January and September).

There were 124 children booked in to attend these clinics; 69 new cases and 64 follow up cases (some children required more follow up appointments as they were on a “catch up program”), with a total of 61 registered attendees. Fifty-five of these were GP/PMH referrals (which was more than double the number in 2015, due to the “No Jab No Pay” policy) and six were WAVSS cases. A total of 31 children were vaccinated at the clinic, with the others referred to the Central Immunisation Clinic. Sixty-three children failed to attend or cancelled appointments.

Two adults were referred to the adult immunology clinic at Sir Charles Gardiner Hospital (SCGH).

Publications

Regan AK, Tracey LE, Blyth CC, Richmond PC, Effler PV. A prospective cohort study assessing the reactogenicity of pertussis and influenza vaccines administered during pregnancy. Vaccine. 2016;34(20):2299-304.