Western Australia Vaccine Safety Surveillance – Annual Report 2017

Produced by the Immunisation, Surveillance and Disease 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 2017. The overall number of adverse events following immunisation reported for 2017 (246 reports) was similar to the average number of reports per year received for the previous four years (mean = 230). The percentage of reports where patients presented to an emergency department (18%) or were admitted to hospital (4%) was in keeping with in previous years. Minor injection site reactions and rashes remain the most commonly reported reactions. 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 Immunisation Register is available, the reported rates of reactions were highest for DTPa vaccines given as a fourth dose (2.7 – 9.3 AEFI per 10,000 doses administered), which are known to be associated with increased local reactions [1]. The number of reports associated with these vaccines were within expected ranges. Relatively high rates of AEFI following vaccination with the meningococcal B vaccine were also reported (9.3 AEFI per 10,000 doses administered). The rates of AEFI, particularly fever, following this vaccine are known to be higher than for others, especially when given concomitantly with other vaccines[2].

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.

There were no safety signals detected for any of the vaccines administered in 2017 that warrant changes to current vaccination recommendations. The type and number of events reported was in keeping with data collected in previous years. The uptake of vaccination, particularly seasonal influenza vaccination, the introduction of new vaccines to the schedule, and the coverage of vaccinations on the National Immunisation Program are all used to inform surveillance of AEFI and any fluctuations in report numbers.

[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.

[2] National Centre for Immunisation Research and Surveillance (NCIRS). Meningococcal vaccines for Australians. NCIRS Fact sheet: August 2018. Available from http://www.ncirs.edu.au/assets/provider_resources/fact-sheets/meningococcal-vaccines-fact-sheet.pdf

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), per the requirements of the Public Health Act 2016 and the Public Health Regulations 2017 (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 reports.

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. 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 2017 and the 31 December 2017, and
- the AEFI 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 collected through an active surveillance system managed by AusVaxSafety. AEFIs reported through active surveillance are not included in this WAVSS 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 2017 as of 20 Sep 2018. These data are subject to change.
4. Limited information available for reports received via the TGA often precludes determination of whether an event was likely to be related to vaccination. As a result, any events for which a 'Possible' or 'Certain' determination cannot be made were excluded from this report.

Surveillance data analysis

AEFI reports

There were 246 individual AEFI reports received for persons vaccinated in 2017 that were assessed as events possibly or certainly related to vaccination, which is similar to the number of reports in 2016 (242 reports) and the average number of reports per year for the previous four years (230 reports).

In 2017, 336 adverse events were described; 230 met established case definitions and 106 were other reactions (note that a vaccinee may describe multiple AEFI reactions).

The month with the highest number of AEFI reports in 2017 was May, 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).

The number of reports received for each age group was within the range of the previous four years, with the majority of reports (41%) received in children <5, with this cohort receiving the largest proportion of vaccinations (Figure 2).

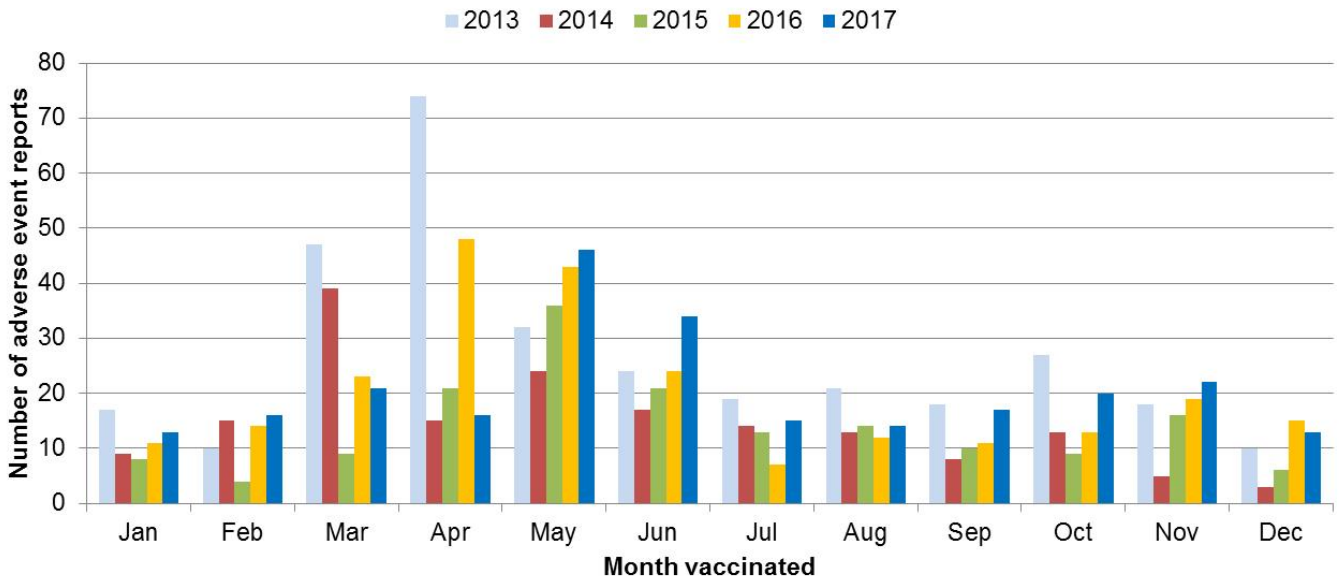

Figure 1 – Reports of adverse events following immunisation, Western Australia 2012 to 2017, by month of vaccination.

Characteristics of AEFI reports received in 2017 and previous years are summarised in Table 1. The majority (83%) of reports to WAVSS were received from healthcare providers, with 15% of reports from the public. Of the 246 cases, 117 were seen by a GP, 47 were seen by a nurse, 45 were received at an emergency department and 10 were hospitalised. The number of reports of both emergency department presentations and hospital admissions are within expected ranges. In 2017, 18% of cases presented to an emergency department, compared to a range of 16% to 23% for the previous four years. The proportion of patients hospitalised (4%) was lower than in previous years (range 5% - 7%).

A summary of the 230 reactions that met established case definitions is shown in Table 2. The most commonly reported reactions in 2017 were minor injection site reactions (n=64), rash (n=50) and fever (n=41), which is in keeping with previous years. Injection site reactions were the most commonly reported AEFI following Quadracel (18/34 events) and Bexsero (8/22), and rash was the most commonly reported AEFI following Zostavax (11/22). The number of reports of febrile seizures (5 reports) was within expected ranges.

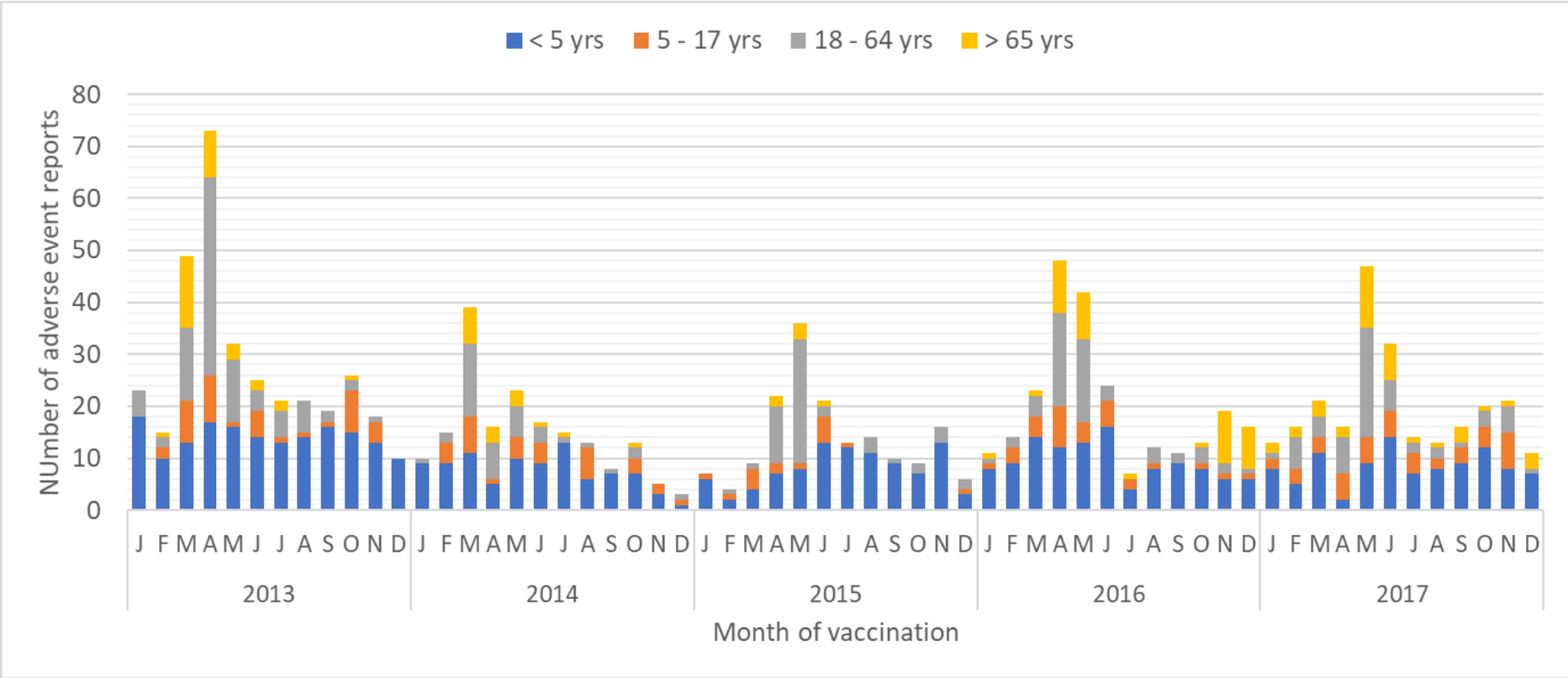

Figure 2 – Reports of adverse events following immunisation, Western Australia, 2013 to 2017, by month of vaccination and age group in years.

Table 1 – Characteristics of AEFIs reported in 2013 to 2017

Year	2013		2014		2015		2016		2017	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Total	334	100%	178	100%	168	100%	242	100%	246	100%
Sex										
Female	178	53%	98	55%	93	55%	139	57%	151	61%
Male	156	47%	80	45%	75	45%	103	43%	95	39%
Aboriginal Status										
Aboriginal and TSI	1	0%	0	0%	0	0%	1	0%	1	0%
Aboriginal and not TSI	7	2%	11	6%	10	6%	7	3%	3	1%
Not Aboriginal or TSI	248	74%	114	64%	116	69%	129	53%	184	75%
Unknown	78	23%	53	30%	42	25%	105	43%	58	24%
Age group										
< 5 yrs	169	51%	90	51%	95	57%	113	47%	100	41%
5 - 17 yrs	40	12%	32	18%	16	10%	31	13%	43	17%
18 - 64 yrs	91	27%	39	22%	50	30%	55	23%	59	24%
> 65 yrs	32	10%	16	9%	6	4%	41	17%	38	15%
unknown	2	1%	1	1%	1	1%	2	1%	6	2%
Reporter Type										
Health Provider	263	79%	152	85%	136	81%	191	79%	203	83%
Other	8	2%	4	2%	7	4%	18	7%	3	1%
Parent/Self	60	18%	20	11%	21	13%	25	10%	38	15%
Pharmacy	3	1%	2	1%	4	2%	8	3%	2	1%
Immunisation Provider										
GP	199	60%	92	52%	91	54%	139	57%	163	66%
Nurse	110	33%	68	38%	62	37%	60	25%	65	26%
Pharmacy	1	0%	0	0%	3	2%	5	2%	3	1%
Unknown/Other	17	5%	13	7%	10	6%	30	12%	12	5%
Workplace	7	2%	5	3%	2	1%	8	3%	3	1%
Managed by										
Healthdirect	23	7%	7	4%	7	4%	10	4%	7	3%
Nurse assessment	82	25%	53	30%	31	18%	55	23%	47	19%
GP assessment	154	46%	81	46%	68	40%	121	50%	117	48%
Central Immunisation Clinic	8	2%	2	1%	1	1%	5	2%	1	0%
Emergency Department	73	22%	37	21%	38	23%	39	16%	45	18%
Admitted to Hospital	24	7%	16	9%	12	7%	13	5%	10	4%
Reported by										
Fax	125	37%	83	47%	60	36%	89	37%	85	35%
Online	146	44%	94	53%	100	60%	145	60%	159	65%
Post	16	5%	0	0%	1	1%	4	2%	0	0%
Telephone	40	12%	0	0%	2	1%	0	0%	1	0%

Table 2 – Summary of AEFI reaction(s) that met case definitions, 2013 to 2017

Reaction	2013	2014	2015	2016	2017	Total
Allergic reaction (generalised)	6	5	5	2	3	**21**
Anaphylaxis	2	4	2	2	3	**13**
Angioedema	0	0	1	4	1	**6**
Apnoea (or Apnea)	1	0	1	0	0	**2**
Apnoea (or Apnea) with bradycardia	3	0	0	0	0	**3**
Arthralgia	5	4	1	0	0	**10**
Cellulitis at injection site	1	0	0	0	0	**1**
Complex Regional Pain	0	1	0	0	0	**1**
Crying (persistent)	4	3	1	0	0	**8**
Diarrhoea	8	5	5	6	4	**28**
Fever (>=38ºC to <39.5ºC)	26	9	13	5	11	**64**
Fever (unspecified)	38	31	21	21	22	**133**
Fever (≥39ºC)	18	6	3	2	8	**37**
Guillain-Barré Syndrome (GBS)	2	1	0	0	0	**3**
Headache (severe)	6	7	7	4	4	**28**
Hypotonic–hyporesponsive episode - HHE	3	5	2	2	2	**14**
Injection site reaction - large	57	26	12	25	11	**131**
Injection site reaction - minor/common/expected	35	27	29	73	64	**228**
Injection site reaction - severe	4	3	3	2	0	**12**
Intussusception	2	2	4	1	0	**9**
Lymphadenitis (includes suppurative lymphadenitis)	1	0	1	0	0	**2**
Nodule at injection site	1	0	0	0	0	**1**
Parotitis	1	0	0	2	0	**3**
Rash	38	26	37	52	50	**203**
Seizure-afebrile	3	1	0	1	3	**8**
Seizure-febrile	10	4	5	4	5	**28**
Seizure-syncopal	1	2	1	0	0	**4**
Thrombocytopenia	0	1	0	0	0	**1**
Urticaria/Hives/Allergic Rash	13	7	2	2	2	**26**
Vaccine error (Program error)	17	10	6	5	12	**50**
Vasovagal episode (syncope, faint)	15	9	8	8	14	**54**
Vomiting	16	14	7	12	11	**60**
Total	**337**	**213**	**177**	**235**	**230**	**1192**

AEFI by age group

Of all AEFI reports for 2017, 41% (100/246) were for children aged less than five years. For vaccines on the childhood immunisation schedule, the overall rate of AEFIs in children <5 years recorded on the Australian Immunisation Register (AIR) is presented in Table 3. The highest rate of AEFI per 10,000 doses for any vaccine in 2017 was DTPa-IPV – Quadracel, with 9.32 AEFI per 10,000 doses recorded in AIR. The reaction rate for Bexsero was 9.30 per 10,000 doses. The reactogencity of both a fourth dose of acellular pertussis-containing vaccine, and the meningococcal B vaccine Bexsero, have been well documented.

In 2017, two meningococcal ACWY vaccines were introduced to the paediatric vaccine schedule. Reported AEFI rates for Menveo and Nimenrix vaccines were 2.07 and 4.85 cases per 10,000 doses, respectively (1 AEFI reported following Menveo and 2 following Nimenrix vaccination). Ongoing

monitoring of changes to the vaccine schedule is an important component of post-licensure vaccine safety surveillance.

Adverse events following influenza immunisation comprised the largest proportion of events reported by people aged 18-64 years (30/43 reports). This is expected, given the relatively low uptake of other vaccines in people of this age. Zostavax was the most common vaccine associated with AEFI reported in people over 65 years of age (22/38 reports).

Vaccines most commonly identified in AEFI reports

Thirty-six individual vaccines were named in AEFI reports that met case definitions. Influenza vaccines as a group accounted for 17% (57/327) of all vaccines listed on AEFI reports. After influenza, the other most frequently identified vaccines specified on AEFI reports were:

- DTPa-IPV - Quadracel (n=34, 10%)
- Bexsero (n=25, 8%)
- Zostavax (n=22, 7%)

AEFIs associated with influenza vaccines

Influenza vaccines were the most commonly reported vaccines in AEFI reports for 2017. Administration of an influenza vaccine was recorded, either alone or in combination with other vaccines, in 23% (57/246) of the AEFI reports in 2017, compared with 36% in 2016, 32% in 2015, 26% in 2014, and 33% in 2013.

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 (53%, 30/57). A total of 12 (21%) adverse event reports to influenza vaccines occurred in children less than 5 years of age.

In 2017, the most commonly reported type of adverse events following receipt of an influenza vaccine were local reactions (n=11), fever (n=8) and rash (n=8). There were two reports of febrile convulsions and there were three reports of anaphylaxis.

Two people with reported adverse reactions to influenza vaccines (anaphylaxis) were admitted to hospital (compared to 3 in 2016, 4 in 2015, 4 in 2014 and 6 in 2013).

AEFIs leading to hospitalisation

In 2017, there were 9 individuals (4%) who were reported as having an AEFI and were subsequently hospitalised. This included seven females and two males with six people aged <5 years old and three adults (ages 49, 79 and 97 years). Eight of the nine people were hospitalised from one to two days with one person hospitalised for 10 days. The AEI events in children followed scheduled vaccinations at two, four and 12 months. Adults had either influenza vaccines or the shingles vaccine. The children's symptoms included seizures (febrile and afebrile), hypotonic-hyporesponsive episode, vomiting and minor injection reaction. Symptoms in adults included anaphylaxis (had influenza vaccines), and possible encephalopathy (had shingles vaccine). Eight individuals were discharged from hospital once symptoms resolved and in many instances attended specialist immunisation clinic for further followup. One adult who was discharged from hospital after 10 days continued to be under the care of hospital specialists.

Table 3 – Rate of AEFI in children <5 years per 10,000 doses administered as recorded on AIR by vaccine, 2013 to 2017

Vaccine	2013			2014			2015			2016			2017		
	Doses administered (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses administered (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses administered (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses administered (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses administered (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses
DTPa - Infanrix										18,411	2	1.09	22,084	15	6.79
DTPa - Tripacel										5,900	2	3.39	11,073	3	2.71
DTPa-HepB-IPV-Hib - Infanrix hexa	96,961	41	4.23	98,013	14	1.43	99,986	17	1.70	101,182	14	1.38	98,199	16	1.63
DTPa-IPV - Infanrix-IPV	3654	5	13.68	1542	2	12.97	2224	0	0.00	3,048	1	3.28	3,695	1	2.71
DTPa-IPV - Quadracel							29,944	28	9.35	30,503	32	10.49	28,976	27	9.32
Flu - Flu Quadri										692	1	14.45	4,403	1	2.27
Flu - Flu Quadri Junior										10,990	10	9.10	17,111	8	4.68
Flu - Fluarix Tetra										4,676	3	6.42	3,719	3	8.07
HepA - VAQTA Paediatric/Adolescent formulation	3,698	0	0.00	3,890	1	2.57	4,293	0	0.00	4,450	0	0.00	4,639	1	2.16
HepB - H-B-Vax II Paediatric formulation	3,539	1	2.83	3,242	0	0.00	4,181	1	2.39	4,625	0	0.00	3,298	0	0.00
HIB-Men C - Menitorix	10878	13	11.95	32997	8	2.42	34484	9	2.61	34,458	14	4.06	34,808	5	1.44
MenACWY - Menveo													4,827	1	2.07
MenACWY - Nimenrix													4,120	2	4.85
MenB - Bexsero													18,289	17	9.30
MMR - II	10,954	19	17.35	32,591	22	6.75	50,231	23	4.58	28,218	18	6.38	25,454	2	0.79
MMR - Priorix	46,200	63	13.64	7,028	7	9.96	10,916	6	5.50	9,768	3	3.07	10,240	5	4.88
MMRV - Priorix Tetra	14566	8	5.49	33075	12	3.63	32315	3	0.93	20,408	9	4.41	18,793	5	2.66
MMRV - Proquad							1729		0.00	13,728	7	5.10	15,188	6	3.95
Pneumococcal - Prevenar13	97,695	48	4.91	99,511	27	2.71	101,817	25	2.46	103,408	18	1.74	100,373	13	1.30
Rotavirus - Rotarix													24,447	5	2.05
Rotavirus - RotaTeq	85,667	43	5.02	87,568	27	3.08	90,022	25	2.78	92,263	18	1.95	64,547	14	2.17

*As reported in the Australian Immunisation Register

Table 4 – Age breakdown of all adverse reaction reports to influenza vaccines, by brand, Western Australia, 2017

Brand	Age group				Total
	< 5 yrs	5 - 17 yrs	18 - 64 yrs	> 65 yrs	
Flu - Afluria Quad	0	0	4	1	5
Flu - Brand unspecified	0	1	1	1	3
Flu - Flu Quadri	1	2	7	2	12
Flu - Flu Quadri Junior	8	0	0	0	8
Flu - Fluarix Tetra	3	1	18	6	29
Total	**12**	**4**	**30**	**10**	**57**

WAVSS clinical activity

In 2017, the WAVSS "High Risk" Clinic continued to run on a fortnightly basis, with a move in June 2018 to the new Perth Children Hospital, where the clinics will run every week in conjunction with the Stan Perron Immunisation Service. The Clinic name will change to "The Specialist Immunisation Clinic".

There were 19 fortnightly clinics in 2017 (all months except April and December). One hundred and three children booked to attend the clinic; 77 new cases and 26 follow up cases. Thirteen were WAVSS reported cases; others were referrals from PMH, GPs and Specialist Clinics. These were children considered high risk, who might need extra vaccinations or revaccinations due to other medical conditions.

A total of 79 attended their clinic appointments; 34 children were vaccinated at the clinic and their vaccination reported to the Australian Immunisation register (AIR). There were 24 children who failed to attend. The number of children who Did Not Attend (DNA) decreased from the previous year, as parents received an SMS reminder text message from PMH or the Central Immunisation Clinic.

Five adults were referred to the Immunology Clinic at Sir Charles Gardiner Hospital.