Government of Western Australia
Department of Health

Western Australia Vaccine Safety Surveillance – Annual Report 2018

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

Executive Summary

The post-licensure surveillance of adverse events following immunisation (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.

This report describes adverse events passively reported to the Western Australian Vaccine Safety Surveillance System (WAVSS) for vaccinations received in 2018.

WAVSS received 293 individual reports of AEFI in 2018, which is higher than the average number of reports received per year for the previous four years (mean = 204). The percentage of reports where patients presented to an emergency department (22%) or were admitted to hospital (5%) was similar to that from previous years. Minor injection site reactions and rashes remain the most commonly reported reactions following vaccination. These reactions were most commonly reported following Meningococcal ACWY vaccine (Menveo) vaccination.

In children under five, rates of reported reactions were highest for the fifth dose of DTPa vaccine (Infanrix-IPV and Quadracel) (3.2–7.9 AEFI per 10,000 doses administered). The DTPa vaccine is known to be associated with increased local reactions[1], and the number of reports associated with this vaccine in WA in 2018 is within the expected range. In this age group there were also relatively high rates of AEFI (3.0-6.4 AEFI per 10,000 doses administered), following administration of MMR vaccine (MMR II and Priorix). Rash was most commonly reported following MMR vaccination, which is a reaction known to be associated with this vaccine[2].

No safety signals were detected for any of the vaccines administered in 2018 which warranted further investigation by WAVSS. The type and number of events reported was in keeping with data collected in previous years.

[1] Pichichero, M., Edwards, K., Anderson, E., Rennels, M., Englund, J., Yerg, D., Blackwelder, W., Jansen, D., Meade, B. (2000). Safety and immunogenicity of six acellular pertussis vaccines and one whole-cell pertussis vaccine given as a fifth dose in four- to six-year-old children. *Pediatrics*, *105(1)*, 1-8. doi: 10.1542/peds.105.1.e11

[2] Di Pietrantonj, C., Rivetti, A., Marchione, P., Debalini, M., Demicheli, V. (2020). Vaccines for measles, mumps, rubella, and varicella in children. *Cochrane Database of Systematic Reviews*; *4 (CD004407):* 1-419. doi: 10.1002/14651858.CD004407.pub4.

Background

This annual report of adverse events following immunisation (AEFI) in Western Australia (WA) summarises passive surveillance data received by the Western Australian Vaccine Safety Surveillance (WAVSS) system[3].

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 and 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 testing, and other medication given near the time of vaccination must be examined to help to determine the likely cause of an adverse event.

In 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 2018[3]. All AEFI reports received by the Department are forwarded to the Therapeutic Goods Administration (TGA) daily each working day. In addition, the TGA may receive AEFI reports directly from clinicians, the public and pharmaceutical companies that manufacture vaccines. Once a month, 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 reports 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.

In addition to receiving passive AEFI reports, WAVSS also receives AEFI reports from active surveillance, primarily reports of medically attended AEFIs received from SmartVax[4]. SmartVax is an active surveillance tool that is installed in 90 sites (GPs and community health clinics) across Western Australia. De-identified active surveillance data from SmartVax is monitored by AusVaxSafety[5], which is an enhanced surveillance system of adverse events following immunisation led by the National Centre for Immunisation Research and Surveillance (NCIRS). Actively identified adverse events are not included in this report, as the addition of these events may skew the reported numbers.

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[3]Western Australian Vaccine Safety Surveillance (WAVSS) system. https://ww2.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI

[4]SmartVax. http://www.smartvax.com.au/

[5]AusVaxSafety http://ausvaxsafety.org.au/

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 the cause or contributing to the reported adverse event
- the residential address of the individual was recorded as WA, and
- the vaccination occurred between 1 January 2018 and the 31 December 2018, and
- the suspected reaction was captured through passive reporting systems.

Important considerations when interpreting the AEFI 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 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 includes all reports received by WAVSS for 2018 as of 8 October 2019. This data is subject to change.
4. Limited information available in the AEFI reports received via the TGA may preclude determination of whether an event was likely to be causally related to vaccination. Any events for which a 'Possible' or 'Certain' determination could not be made are excluded from this report.

Vaccine safety surveillance data analysis

AEFI reports

There were 293 individual AEFI reports received for persons vaccinated in 2018 that were assessed as events possibly or certainly related to vaccination, which is similar to the number of reports in 2017 (242 reports) and the average number of reports per year for the previous four years (mean = 222).

In 2018, 336 adverse reactions were described in the 246 reports (note that a vaccinee may describe multiple AEFI reactions); 230 reactions met established case definitions and 106 were other reactions.

The month with the highest number of AEFI reports in 2018 was May, with 76 reports. For the years 2013 to 2017, the number of reports was higher for March to June, which related to increased reports associated with the high number of influenza vaccinations occurring 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 (42%) received in children under five years, i.e. the age group who receives the largest proportion of vaccinations (Figure 2).

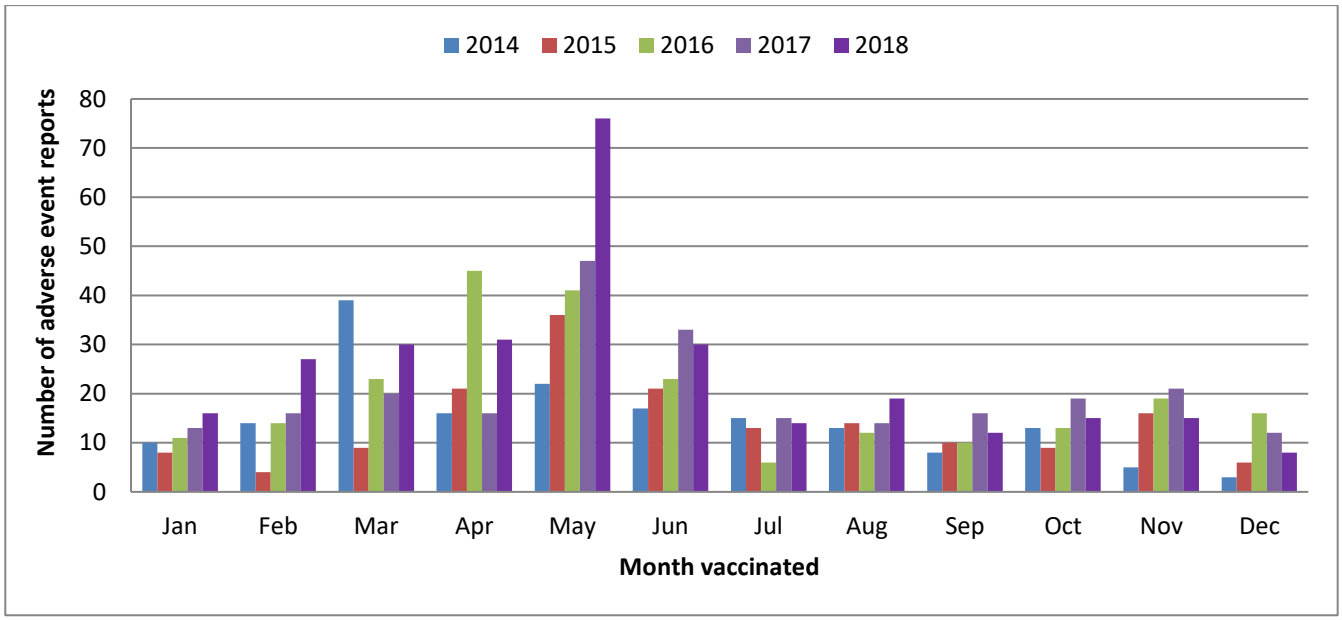

Figure 1 – Reports of adverse events following immunisation, Western Australia 2012 to 2018, by month of vaccination.

Characteristics of AEFI reports in 2018 and previous years are summarised in Table 1. The majority (85%) of reports to WAVSS were received from healthcare providers, with 16% of reports received directly from the public. Of the 293 vaccinees in the reports, 135 were seen by a GP, 67 were seen by a nurse, 62 were seen at an emergency department and 15 were hospitalised, the others were not assessed. The number of reports of both emergency department presentations and hospital admissions are within expected ranges. In 2018, 22% of reports indicated that the vaccinee presented to an emergency department, compared to a range of 19% to 24% for the previous four years. The proportion of reports indicating the vaccinee had been hospitalised (5%) was consistent with previous years (range = 5% - 8%).

A summary of the 328 reactions that met established case definitions is shown in Table 2. The most commonly reported reactions in 2018 were minor injection site reactions (n=89), rash (n=70) and fever (n=31), which is in keeping with previous years. Injection site reactions were the most commonly reported AEFI following Menveo (18/89) and Pneumovax (14/89), and rash the most commonly reported AEFI following Menveo (10/69). The number of reports of febrile seizures (11 reports) was higher than the previous four years (range = 4 – 5). Two of these were reported following vaccination with Nimenrix.

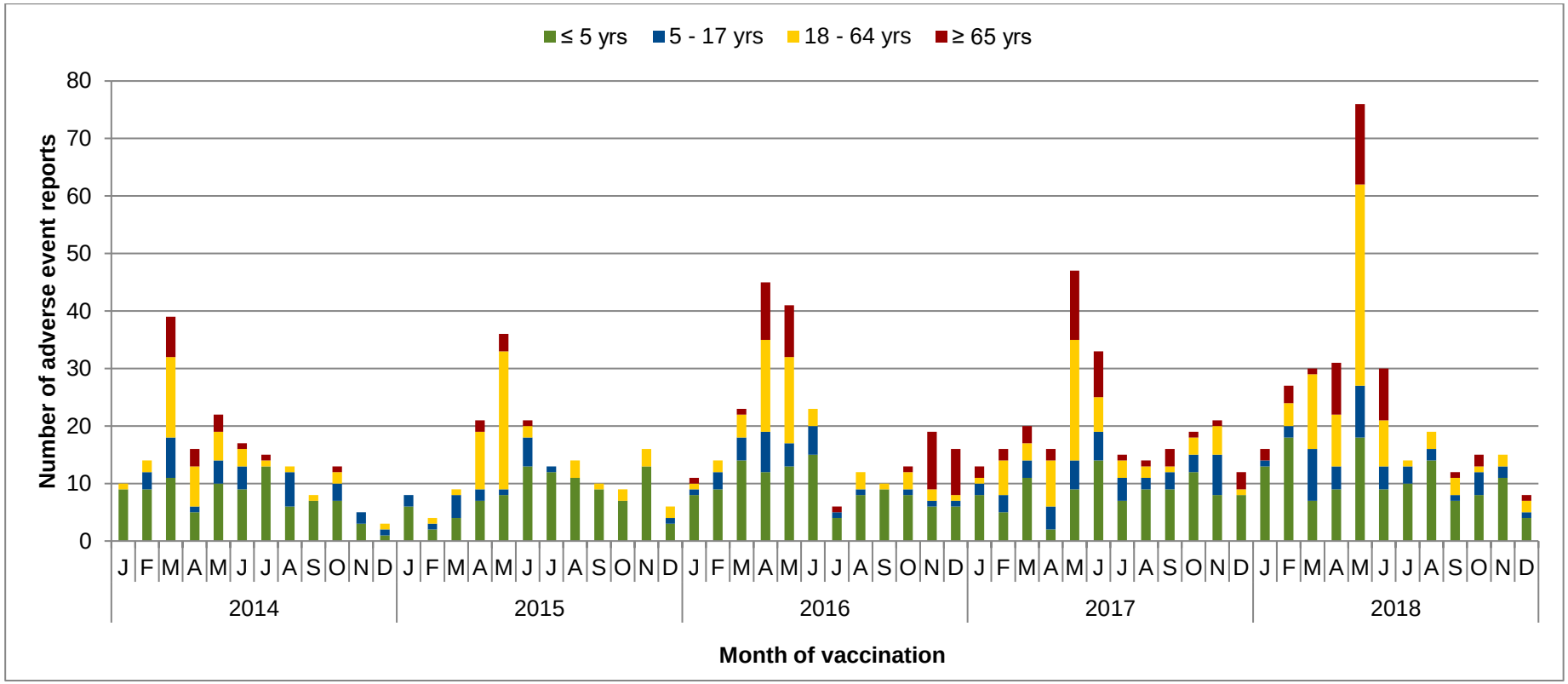

Figure 2 – Reports of adverse events following immunisation, Western Australia, 2013 to 2018, by month of vaccination and age group in years.

Table 1 – Characteristics of AEFIs reported in 2014 to 2018.

	2014		2015		2016		2017		2018	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Total reports	175	100%	167	100%	233	100%	242	100%	293	100%
Sex										
Female	95	54%	92	55%	134	58%	147	61%	170	58%
Male	80	46%	75	45%	99	42%	95	39%	121	41%
Unknown	0	0%	0	0%	0	0%	0	0%	2	1%
ATSI Status										
Aboriginal and Not TSI	11	6%	10	6%	6	3%	3	1%	11	4%
Aboriginal and TSI	0	0%	0	0%	0	0%	0	0%	1	0%
Not Aboriginal or TSI	113	65%	117	70%	128	55%	185	76%	208	71%
Torres Strait Islander	0	0%	0	0%	1	0%	1	0%	0	0%
Unknown	51	29%	40	24%	98	42%	53	22%	73	25%
Age group										
≤ 5 yrs	90	51%	95	57%	112	48%	102	42%	128	44%
5 - 17 yrs	31	18%	17	10%	29	12%	41	17%	42	14%
18 - 64 yrs	38	22%	49	29%	51	22%	60	25%	81	28%
≥ 65 yrs	16	9%	6	4%	41	18%	39	16%	42	14%
Reporter Type										
Health Provider	150	86%	135	81%	189	81%	199	82%	247	84%
Parent/Self	17	10%	21	13%	23	10%	36	15%	25	9%
Pharmacy	0	0%	1	1%	3	1%	0	0%	1	0%
Other	8	5%	10	6%	18	8%	7	3%	20	7%
Immunisation Provider Type										
GP	91	55%	89	56%	135	66%	156	67%	179	64%
Nurse	1	1%	0	0%	0	0%	0	0%	0	0%
Pharmacy	0	0%	3	2%	3	1%	3	1%	9	3%
Workplace	4	2%	2	1%	5	2%	4	2%	0	0%
Hospital	18	11%	22	14%	19	9%	25	11%	38	14%
Other	50	30%	44	28%	44	21%	45	19%	55	20%
Managed By										
Emergency department	37	19%	38	24%	39	16%	46	20%	62	22%
Admitted to hospital	16	8%	12	8%	13	5%	11	5%	15	5%
Health direct	7	4%	7	4%	9	4%	7	3%	6	2%
Central Immunisation Clinic	2	1%	1	1%	4	2%	1	0%	0	0%
Nurse assessment	53	27%	31	20%	55	23%	46	20%	67	24%
GP assessment	81	41%	69	44%	121	50%	116	51%	135	47%
Report Type										
Fax	83	47%	60	37%	88	38%	86	36%	112	38%
Online	92	53%	99	61%	137	60%	154	64%	178	61%
Post	0	0%	1	1%	4	2%	0	0%	2	1%
Telephone	0	0%	2	1%	0	0%	1	0%	0	0%

Table 2 – Summary of AEFI reaction(s) that met case definitions, 2014 to 2018.

Reaction	2014	2015	2016	2017	2018	Total
Allergic reaction (generalised)	5	5	2	3	1	16
Anaphylaxis	4	2	2	3	1	12
Angioedema		1	4	1	5	11
Apnoea (or Apnea)		1			1	2
Apnoea (or Apnea) with bradycardia						0
Arthralgia	4	1			3	8
Cellulitis at injection site					1	1
Complex Regional Pain	1					1
Crying (persistent)	3	1				4
Diarrhoea	5	5	6	4	3	23
Fever (≥38 ≤40ºC)	9	14	5	10	9	47
Fever (unspecified)	36	24	20	29	31	140
Guillain-Barre Syndrome (GBS)	1					1
Headache (severe)	7	7	3	4	11	32
Hypotonic-hyporesponsive episode	5	2	2	2	4	15
Injection site reaction - minor/common/expected	26	29	73	62	89	279
Injection site reaction - severe	29	15	25	10	14	93
Intussusception	2	4	1		1	8
Lymphadenitis (includes suppurative lymphadenitis)		1			2	3
Nodule at injection site					6	6
Not related to vaccine	2	4	2	4	16	28
Pain in limb					1	1
Parotitis			2			2
Rash	26	37	51	52	70	236
Seizure-afebrile	1			3	3	7
Seizure-febrile	4	5	4	5	11	29
Seizure-syncopal	2				3	5
Sepsis					1	1
Thrombocytopenia	1				1	2
Urticaria/hives/allergic rash	7	2	2	1		12
Vaccine error (program error)	10	6	5	12	18	51
Vasovagal episode (syncope, faint)	8	8	8	14	12	50
Vomiting	14	7	9	11	10	51
Total	**212**	**181**	**226**	**230**	**328**	**1177**

Reported AEFI by age group

For vaccines on the childhood immunisation schedule, the overall rate of AEFIs in children under five 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 2018 was DTPa-IPV (Quadracel), with 7.9 AEFI per 10,000 doses recorded in AIR. Additionally, MMR vaccine (Priorix), also demonstrated a relatively high rate of AEFI (6.42 per 10,000 doses administered). The reactogenicity of both vaccines have been well documented.

Ongoing monitoring of the impact 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 (50/79 reports). This is expected, given the relatively low uptake of other vaccines for people in this age group.

Similarly, the influenza vaccine was the most common vaccine associated with AEFI reported in people over 65 years of age (17/41 reports).

Vaccines most commonly identified in AEFI reports

Thirty-seven 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:

- Meningococcal ACWY vaccine – Menveo (n=70, 11%)
- Meningococcal ACWY vaccine – Nimenrix (n=45, 7%)
- Pnuemococcal vaccine – Pneumovax (n=37, 6%)

AEFIs associated with influenza vaccines

Influenza vaccines were the most commonly reported vaccines in AEFI reports for 2018. Administration of an influenza vaccine was recorded, either alone or in combination with other vaccines, in 30% (88/290) of the AEFI reports in 2018, compared with 23% in 2017, 36% in 2016, 32% in 2015, and 26% in 2014.

Table 4 shows the influenza vaccine 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 (56%, 50/88). A total of 10 (11%) adverse event reports to influenza vaccines occurred in children less than five years of age.

In 2018, the most commonly reported type of adverse events following receipt of an influenza vaccine were local reactions (n=22), rash (n=14) and fever (n=13). There was one report of febrile convulsions following influenza vaccination.

Table 3 – Rate of AEFI in children under five years per 10,000 doses administered as recorded on AIR by vaccine, 2014 to 2018.

Vaccine	2014			2015			2016			2017			2018		
	Doses admin. (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses admin. (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses admin. (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses admin. (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses	Doses admin. (AIR)	AEFI reported to WAVSS	AEFI rate per 10,000 doses
DTPa - Infanrix	371	0	0.00	317	0	0.00	18,480	8	4.33	22,369	13	5.81	27,592	9	3.26
DTPa - Tripacel	21	0	0.00	35	0	0.00	5,813	2	3.44	11,087	3	2.71	5,761	0	0.00
DTPa-HepB-IPV-Hib - Infanrix hexa	99,298	10	1.01	100,361	12	1.20	102,442	5	0.49	98,814	8	0.81	97,464	15	1.54
DTPa-IPV - Infanrix-IPV	4,962	2	4.03	2,815	0	0.00	3,635	1	2.75	4,298	1	2.33	15,452	5	3.24
DTPa-IPV - Quadracel	16,375	18	10.99	30,675	26	8.48	30,534	26	8.52	29,123	25	8.58	16,466	13	7.90
Hep A - VAQTA Paed/Adolescent formulation	4,100	0	0.00	4,428	0	0.00	4,483	0	0.00	4,732	1	2.11	4,756	1	2.10
Hep B - H-B-Vax II Paed formulation	3,640	0	0.00	4,536	0	0.00	4,927	0	0.00	3,585	0	0.00	2,438	0	0.00
HIB-MenC - Menitorix	33,544	5	1.49	34,747	8	2.30	34,523	2	0.58	35,028	2	0.57	19,661	5	2.54
Influenza - FluQuadri	6	0	0.00	40	0	0.00	713	1	14.03	4,416	1	2.26	10,018	4	3.99
Influenza - FluQuadri Jnr	10	0	0.00	26	0	0.00	10,856	8	7.37	17,052	4	2.35	30,226	3	0.99
Influenza - Fluarix Tetra	1	0	0.00	11	0	0.00	4,672	3	6.42	3,769	2	5.31	3,542	2	5.65
Men B - Bexsero	220	0	0.00	711	1	14.06	3,212	1	3.11	18,667	16	8.57	20,061	4	1.99
MenACWY - Menveo	7	0	0.00	9	0	0.00	535	0	0.00	4,831	1	2.07	44,655	19	4.25
MenACWY - Nimenrix	21	0	0.00	23	0	0.00	1,530	0	0.00	4,169	2	4.80	57,554	16	2.78
MMR - M-M-R II	42,745	14	3.28	51,258	10	1.95	28,521	15	5.26	25,844	1	0.39	23,503	7	2.98
MMR - Priorix	9,289	1	1.08	11,198	3	2.68	9,898	3	3.03	10,398	3	2.89	10,910	7	6.42
MMRV - Priorix-Tetra	33,705	12	3.56	32,880	3	0.91	20,495	6	2.93	18,933	2	1.06	16,421	3	1.83
MMRV- ProQuad	30	0	0.00	1,758	1	5.69	13,783	2	1.45	15,359	3	1.95	17,352	1	0.58
Pneumococcal - Prevenar 13	100,847	6	0.59	102,350	12	1.17	104,860	12	1.14	101,418	4	0.39	92,389	8	0.87
Rotavirus - RotaTeq	87,683	15	1.71	89,048	6	0.67	91,976	8	0.87	64,029	6	0.94	1,020	0	0.00

Table 4 – Age breakdown of all adverse reaction reports to influenza vaccines, by brand, Western Australia, 2018.

Vaccine brand	Age group				Total
	< 5 yrs	5 - 17 yrs	18 - 64 yrs	≥ 65 yrs	
Afluria Quad	1	3	7	1	12
FluQuadri	4	4	14	3	25
FluQuadri Jnr	3	0	0	0	3
Fluarix Tetra	2	3	21	1	27
Brand unspecified	0	1	8	12	21
Total	**10**	**11**	**50**	**17**	**88**

WAVSS vaccine safety surveillance summary for 2018

There were 293 individual AEFI reports received for persons vaccinated in 2018 that were assessed as events possibly or certainly related to vaccination, which is 22% greater than the number of reports in 2017 (242 reports), and 43% greater the average number of reports per year for the four years prior (205 reports).

No safety signals were detected for any of the vaccines administered in 2018 which warranted further investigation by WAVSS. The type of events reported was in keeping with data collected in previous years, with minor injection site reactions and rashes remaining the most commonly reported reactions following vaccination.