Government of Western Australia
Department of Health

Western Australia Vaccine Safety Surveillance – Annual Report 2019

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 following immunisation (AEFIs) passively reported to the Western Australian Vaccine Safety Surveillance System (WAVSS) for vaccinations received in 2019.

No safety signals were detected for any of the vaccines administered in 2019.

WAVSS received 247 individual reports of AEFI in 2019.

The number of AEFIs reported for vaccinations administered in 2019 is similar to the average number of reports received per year for the 2015 - 2018 time period (mean = 234.5).

The type and number of events reported was in keeping with data collected in previous years.

Minor injection site reactions and rashes remain the most commonly reported reactions following vaccination. These reactions were most commonly reported following influenza vaccination.

In children under five, rates of reported reactions were highest for the fifth dose of DTPa vaccine (Quadracel; 6.3 AEFI per 10,000 doses administered). The DTPa vaccine is known to be associated with increased local reactions, with reactogenicity increasing with the number of doses administered. Historical WAVSS data indicates that Quadracel is more reactogenic than Infanrix-IPV, and the number of reports associated with this vaccine in 2019 is within the observed range for the previous years.

Background

This annual report of adverse events following immunisation (AEFI) in Western Australia (WA) summarises passive surveillance data received by the Western Australia Vaccine Safety Surveillance (WAVSS) system[1].

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 directly from the public.

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.

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 2019[2]. 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[2]. SmartVax is an active surveillance tool that is installed in 87 sites (GPs and community health clinics) across Western Australia. De-identified active surveillance data from SmartVax is monitored by AusVaxSafety[3], 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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[1]Western Australian Vaccine Safety Surveillance (WAVSS) system. https://ww2.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI

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

[3]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 2019 and the 31 December 2019, and
- the suspected reaction was captured through passive reporting systems (WAVSS).

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 include all reports received by WAVSS for 2019 as of 29 May 2020 and are 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

AEFIs reported to WAVSS in 2019

There were 247 individual AEFI reports received for persons vaccinated in 2019 that were assessed as events possibly or certainly related to vaccination. This is 16% less than the number of reports received in 2018 (n = 294), but similar to the average number of reports per year for the previous four years (2015 – 2018, mean = 234.5).

The month with the highest number of AEFI reports in 2019 was May, with 77 reports. For the years 2015 to 2018, the number of reports was also highest in May (Figure 1). Increased reports of AEFI during this month are likely associated with the relatively high number of influenza vaccinations administered during this time-period.

The number of reports received for each age group was within the range of the previous four years. Majority of reports (43%, 105/247) received in 2019 where in children under five years (Figure 2). This is to be expected, as this cohort receives the largest proportion of vaccinations[4].

[4]National Immunisation Program https://www.health.gov.au/health-topics/immunisation/immunisation-throughout-life/national-immunisation-program-schedule

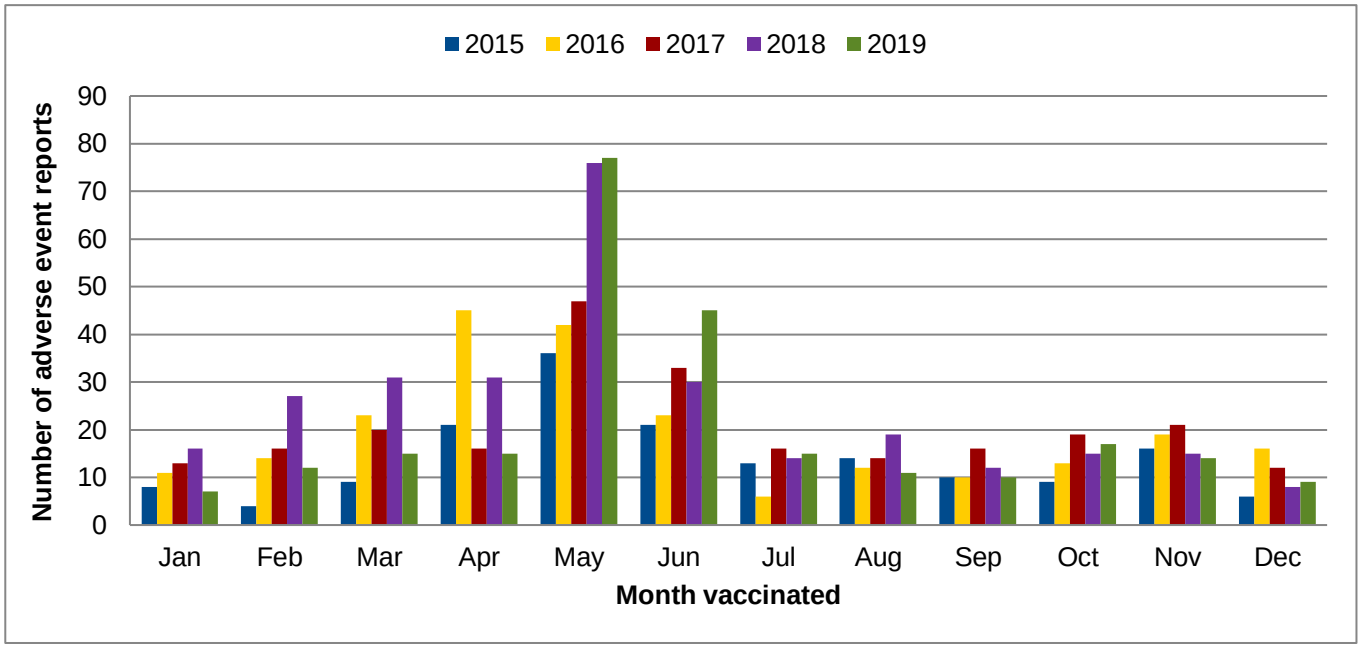

Figure 1 – Reports of adverse events following immunisation, Western Australia 2015 to 2019, by month of vaccination.

Characteristics of AEFI reports

Characteristics of AEFI reports in 2019, and 2015-2018 are summarised in Table 1. The majority (83%) of reports to WAVSS were received from healthcare providers, with 13% of reports being received directly from the public. Of the 247 vaccinees that reported AEFIs in 2019, 46% (115/247) were seen by a GP, 22% (55/247) were seen by a nurse, 20% (50/247) were seen at an emergency department, 9% (22/247) were hospitalised, and 3% (8/247) reported seeking help from HealthDirect. The number of reports of both emergency department presentations and hospital admissions are within expected ranges. In 2019, the number of AEFIs reported following immunisation at a pharmacy has increased to 6% (12/247), which reflects the increased uptake of vaccinations at community pharmacies in 2019. Reports were most often received online (77%).

Reactions reported in 2019

In 2019, 417 adverse reactions were described in the 247 reports (note that a vaccinee may describe multiple AEFI reactions). 273 of these reactions met established case definitions, and 144 were classified as other reactions.

A summary of the 273 reactions that met established case definitions is shown in Table 2. The most commonly reported reactions in 2019 were minor injection site reactions (n=53), rash (n=32), and vasovagal episodes (n=19). Minor injection site reactions and rash are within the expected range, however, the number of vasovagal episodes in 2019 are higher than the reported range for 2015-2018 (Table 2). Vasovagal episodes were reported across all age groups except those over 65 in 2019 and were not associated with any vaccine type. Injection site reactions and rash were most commonly reported AEFI following influenza vaccination (18/53, and 6/32, respectively).

The number of reports of febrile seizures (n=8) was within the range reported for 2015-2018 (range = 4 - 11). Two of these reports were following vaccination with FluQuadri, the other reports were across various vaccine types. There were no deaths or severe AEFI that caused long term sequelae related to vaccination reported to WAVSS in 2019.

Newly reported reactions in 2019

There was one case of shoulder injury related to vaccine administration (SIRVA) reported to WAVSS, following the addition of SIRVA to the established reactions to AEFI-CAN in November 2019. SIRVA was reported following vaccination with ADT Booster. Also, newly reported to WAVSS in 2019 was: abscess (n=2), and abdominal pain (n=6). Two of the six reports of abdominal pain were following rotavirus vaccination, the others were across various vaccines.

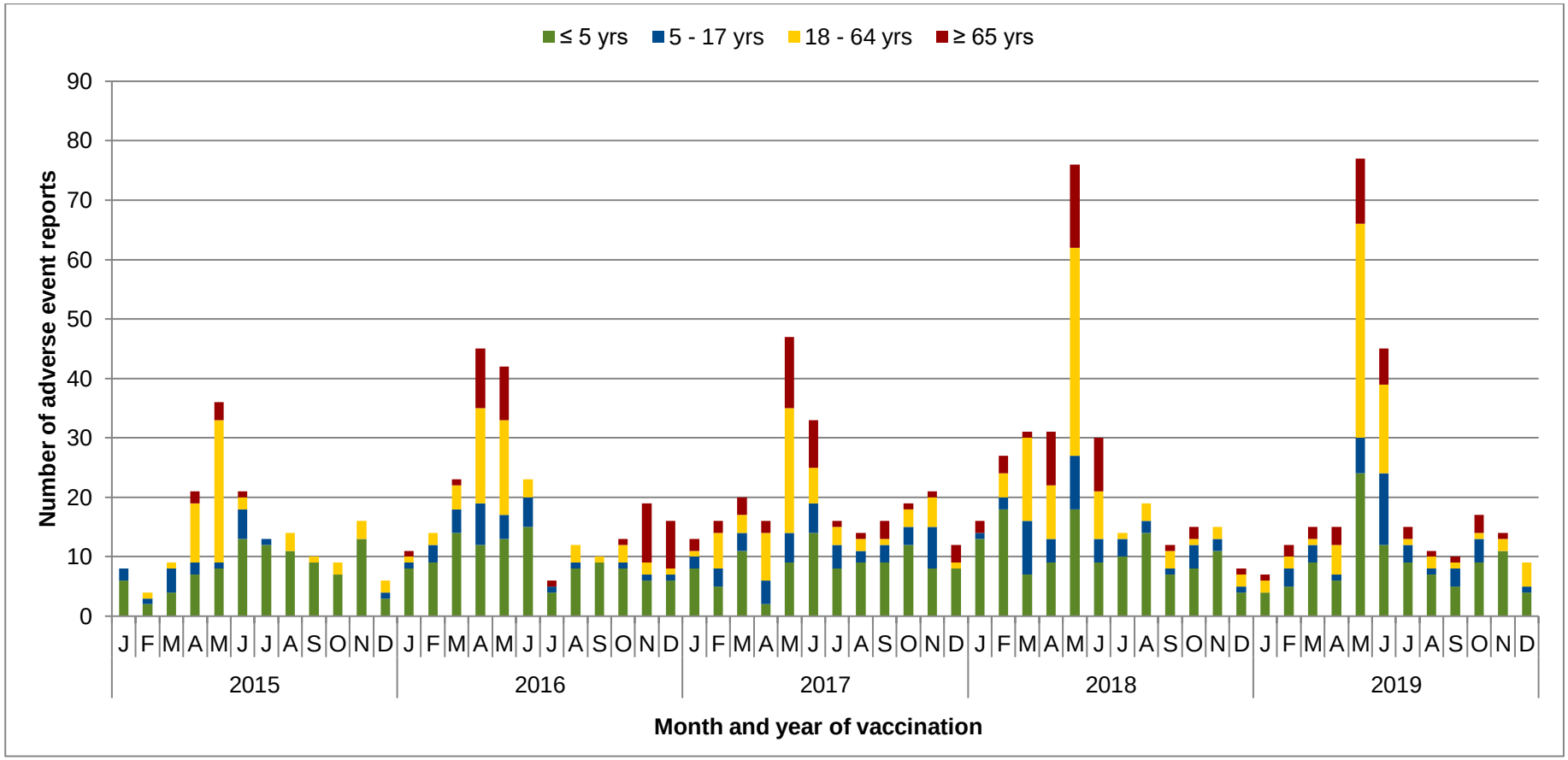

Figure 2 – Reports of adverse events following immunisation, Western Australia, 2015 to 2019, by month of vaccination and age group in years.

Table 1 – Characteristics of AEFIs reported to WAVSS for 2015 - 2019.

	2015	2016	2017	2018	2019
Total	167	233	242	293	247
Sex					
Female	92 (55%)	134 (58%)	147 (61%)	170 (58%)	146 (59%)
Male	75 (45%)	99 (42%)	95 (39%)	121 (41%)	100 (40%)
Unknown	0 (0%)	0 (0%)	0 (0%)	2 (1%)	1 (0%)
Aboriginality					
Aboriginal	10 (6%)	7 (3%)	4 (2%)	12 (4%)	14 (6%)
Non-Aboriginal	117 (70%)	128 (55%)	185 (76%)	208 (71%)	185 (75%)
Unknown	40 (24%)	98 (42%)	53 (22%)	73 (25%)	48 (19%)
Age group					
≤ 5 years	95 (57%)	112 (48%)	102 (42%)	128 (44%)	105 (43%)
5 - 17 years	17 (10%)	29 (12%)	41 (17%)	42 (14%)	37 (15%)
18 - 64 years	49 (29%)	51 (22%)	60 (25%)	81 (28%)	72 (29%)
≥ 65 years	6 (4%)	41 (18%)	39 (16%)	42 (14%)	33 (13%)
Reporter Type					
Healthcare Provider	135 (81%)	189 (81%)	199 (82%)	247 (84%)	205 (83%)
Parent/Self	21 (13%)	23 (10%)	36 (15%)	25 (9%)	28 (11%)
Pharmacy	1 (1%)	3 (1%)	0 (0%)	1 (0%)	10 (4%)
Other	10 (6%)	18 (8%)	7 (3%)	20 (7%)	4 (2%)
Immunisation Provider Type					
GP	89 (56%)	136 (66%)	156 (67%)	179 (64%)	125 (58%)
Nurse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)
Pharmacy	3 (2%)	3 (1%)	3 (1%)	9 (3%)	12 (6%)
Workplace	2 (1%)	2 (1%)	2 (1%)	0 (0%)	6 (3%)
Hospital	22 (14%)	20 (10%)	25 (11%)	38 (14%)	26 (12%)
Community Clinic	38 (24%)	38 (18%)	41 (18%)	43 (15%)	35 (16%)
Other	44 (28%)	8 (4%)	7 (3%)	11 (4%)	8 (4%)
Managed by					
Emergency department	38 (24%)	39 (16%)	46 (20%)	62 (22%)	50 (20%)
Admitted to hospital	12 (8%)	13 (5%)	11 (5%)	15 (5%)	22 (9%)
HealthDirect	7 (4%)	9 (4%)	7 (3%)	6 (2%)	8 (3%)
Central Immunisation Clinic	1 (1%)	4 (2%)	1 (0%)	0 (0%)	0 (0%)
Nurse assessment	31 (20%)	55 (23%)	46 (20%)	67 (24%)	55 (22%)
GP assessment	69 (44%)	121 (50%)	116 (51%)	135 (47%)	115 (46%)
Method of Report Submission					
Fax	60 (37%)	88 (38%)	86 (36%)	112 (38%)	51 (21%)
Online	99 (61%)	137 (60%)	154 (64%)	178 (61%)	190 (77%)
Post	1 (1%)	4 (2%)	0 (0%)	2 (1%)	2 (1%)
Telephone	2 (1%)	0 (0%)	1 (0%)	0 (0%)	3 (1%)

Table 2 – Summary of AEFI reactions that met case definitions, 2015 to 2019.

Reaction	2015	2016	2017	2018	2019	Total
Abdominal pain					6	**6**
Abscess					2	**2**
Allergic reaction (generalised)	5	2	3	1	5	**16**
Anaphylaxis	2	2	3	1	2	**10**
Angioedema	1	4	1	5		**11**
Apnoea (or Apnea)	1			1	2	**4**
Arthralgia	1			3	1	**5**
Cellulitis at injection site				1	7	**8**
Complex Regional Pain						**0**
Crying (persistent)	1				4	**5**
Diarrhoea	5	6	5	3	7	**26**
Drug error (Program error)	6	5	12	18	2	**43**
Fever (≥40ºC)					2	**2**
Fever (≥38-<40ºC)	14	5	10	9	16	**54**
Fever (unspecified)	24	20	29	31	13	**117**
Guillain-Barré Syndrome (GBS)						**0**
Headache (severe)	7	3	4	11	6	**31**
Hypotonic-hyporesponsive episode	2	2	2	4	2	**12**
Influenza-like-illness					1	**1**
Injection site reaction - minor/common/expected	29	73	62	89	53	**306**
Injection site reaction - severe	15	25	10	14	18	**82**
Intussusception	4	1		1	4	**10**
Lethargy					8	**8**
Lymphadenitis (includes suppurative lymphadenitis)	1			2		**3**
Lymphadenopathy					4	**4**
Nodule at injection site				6	3	**9**
Not related to vaccine	4	2	4	16	4	**30**
Pain in limb				1	12	**13**
Paraesthesia					1	**1**
Parotitis		2				**2**
Rash	37	51	52	70	32	**242**
SIRVA		1			1	**2**
Seizure-afebrile			3	3	6	**12**
Seizure-febrile	5	4	5	11	8	**33**
Seizure-syncopal				3	1	**4**
Sepsis				1		**1**
Thrombocytopenia				1	1	**2**
Urticaria/hives/allergic rash	2	2	1		6	**11**
Vasovagal episode (syncope, faint)	8	8	14	12	19	**61**
Vomiting	7	9	11	10	14	**51**
Total	**181**	**227**	**231**	**328**	**273**	**1240**

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 2019 was DTPa-IPV (Quadracel), with 6.3 AEFI per 10,000 doses recorded in AIR. Additionally, Meningococcal B (Bexsero), also demonstrated a relatively high rate of AEFI (4.5 per 10,000 doses administered). Historical data (Table 3) indicates high rates for both vaccines over the last five years.The reactogenicity of both vaccines have been well documented.[5,6]

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

Adverse events following seasonal influenza immunisation comprised the largest proportion of events reported by people aged 18-64 years (50/97 reports, Table 1).

The influenza vaccine was the most common vaccine associated with AEFI reported in people over 65 years of age (11/33), followed closely by Pneumovax 23 (10/33), and Zostavax (7/33). This is to be expected given the relatively high uptake of these vaccines in persons over 65 in 2019.

Vaccines identified in AEFI reports

Thirty-nine individual vaccines were named in AEFI reports where reactions met case definitions. Seasonal influenza vaccines (as a group) accounted for majority 35.9% (98/273) of all vaccines listed on AEFI reports where reactions met case definitions. Of these, FluQuadri was most commonly identified (40/273), followed by Fluarix Tetra (30/273). Influenza vaccines were followed by:

- Pneumovax 23 (23vPPV) – 7.7% (21/273)
- Infanrix *hexa* (DTPa-hepB-IPV-Hib) – 5.9% (16/273)
- Bexsero (Men B) – 5.1%1 (4/273)

AEFIs associated with influenza vaccines

Seasonal influenza vaccines were the most commonly reported vaccines in individual reports of AEFIs in 2019. Administration of an influenza vaccine was recorded, either alone or in combination with other vaccines, in 39.2% (97/247) of the AEFI reports in 2019. This is slightly higher compared to previous years; 30.3% (89/294) in 2018, 21.8% (53/243) in 2017, 23.5% (55/234) in 2016, 26.9% in 2015 (45/167). This is expected, given the relatively high uptake of seasonal influenza vaccines in 2019.

Table 4 shows the influenza vaccine brand and age breakdown of AEFI reports in 2019. Majority of reports received associated with an influenza vaccination were for adults aged 18 to 64 years of age (51.5%, 50/97). A total of 22 adverse event reports associated with influenza vaccines occurred in children less than five years of age (22.6%).

In 2019, the most commonly reported reaction following receipt of an influenza vaccine were local reactions (n=25), pain in limb (n=9), and vasovagal episode (n=8). There were two reports of febrile seizures following influenza vaccination, both in children aged less than five following FluQuadri vaccination.

[5]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

[6]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

Table 3 – Rate of AEFI in children under five years per 10,000 doses administered (as recorded on AIR*) by vaccine type, 2015 to 2019.

Vaccine Type	2015			2016			2017			2018			2019		
	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses
DTPa - Infanrix	0	317	0.00	8	18,480	4.33	12	22,369	5.36	9	27,592	3.26	3	24,343	1.23
DTPa -Tripacel	0	35	0.00	1	5,813	1.72	1	11,087	0.90	0	5,761	0.00	3	9,297	3.23
DTPa-IPV - Infanrix-IPV	0	2,815	0.00	2	3,635	5.50	1	4,298	2.33	5	15,452	3.24	5	17,453	2.86
DTPa-IPV - Quadracel	22	30,675	7.17	28	30,534	9.17	24	29,123	8.24	10	16,466	6.07	10	15,801	6.33
DTPa-hepB-IPV-Hib - Infanrix *hexa*	7	100,361	0.70	10	102,442	0.98	6	98,814	0.61	15	97,464	1.54	9	97,180	0.93
Hep A - Vaqta Paediatric	0	4,428	0.00	0	4,483	0.00	1	4,732	2.11	0	4,756	0.00	0	5,214	0.00
Hep B - H-B-Vax II	1	4,536	2.20	0	4,927	0.00	0	3,585	0.00	0	2,438	0.00	0	1,487	0.00
Hib – Act-Hib	0	65	0.00	0	80	0.00	0	72	0.00	0	206	0.00	2	17871	1.12
Seasonal influenza - Fluarix Tetra	0	11	0.00	2	4,672	4.28	2	3,769	5.31	2	3,542	5.65	3	11,757	2.55
Seasonal influenza - FluQuadri Jnr	0	26	0.00	7	10,856	6.45	6	17,052	3.52	4	30,226	1.32	11	75,427	1.46
Seasonal influenza - FluQuadri	0	40	0.00	1	713	14.03	1	4,416	2.26	4	10,018	3.99	8	33,245	2.41
Men ACWY - Menitorix	3	34,747	0.86	10	34,523	2.90	5	35,028	1.43	6	19,661	3.05	1	13,440	0.74
Men ACWY - Menveo	0	9	0.00	0	535	0.00	1	4,831	2.07	21	44,655	4.70	0	856	0.00
Men ACWY - Nimenrix	0	23	0.00	0	1,530	0.00	2	4,169	4.80	18	57,554	3.13	6	54,325	1.10
Men B - Bexsero	1	711	14.06	1	3,212	3.11	16	18,667	8.57	4	20,061	1.99	7	15,629	4.48
MMR - MMR II	13	51,258	2.54	10	28,521	3.51	0	25,844	0.00	6	23,503	2.55	4	18,267	2.19
MMR - Priorix	5	11,198	4.47	0	9,898	0.00	1	10,398	0.96	3	10,910	2.75	5	16,445	3.04
MMRV - Priorix-Tetra	3	32,880	0.91	2	20,495	0.98	3	18,933	1.58	4	16,421	2.44	0	8,116	0.00
MMRV - ProQuad	1	1,758	5.69	4	13,783	2.90	2	15,359	1.30	1	17,352	0.58	3	25,884	1.16
Pneumococcal 13 - Prevenar 13	9	102,350	0.88	6	104,860	0.57	8	101,418	0.79	9	92,389	0.97	8	98,884	0.81
Rotavirus - Rotarix	1	3,016	3.32	0	2,955	0.00	2	25,244	0.79	3	61,248	0.49	9	61,278	1.47
Rotavirus - RotaTeq	12	89,048	1.35	8	91,976	0.87	7	64,029	1.09	0	1,020	0.00	0	292	0.00

**AIR: the Australian Immunisation Register, which is a national register that records all vaccines given to all people in Australia.*

Table 4 – Age breakdown of all adverse reaction reports to influenza vaccines, by brand, Western Australia, 2019.

Vaccine brand	Age group				Total
	< 5 yrs	5 - 17 yrs	18 - 64 yrs	≥ 65 yrs	
Afluria Quad	0	2	6	1	**9**
Fluad	0	0	1	8	**9**
Fluarix Tetra	3	1	20	0	**24**
FluQuadri	8	10	20	1	**39**
FluQuadri Jnr	11	0	0	0	**11**
Influvac Tetra	0	0	1	0	**1**
Brand unspecified	0	1	2	1	**4**
Total	**22**	**14**	**50**	**11**	**97**

Clinic activity

In 2019 the Specialist Immunisation Clinic was operational on Thursday afternoons on a weekly basis. A total of 45 clinics were held in 2019.

There were 215 children booked in to attend the clinic. Of these, 118 were new cases and 34 were follow-up cases; 26 of these were WAVSS reported cases. Other referrals to the Specialist Immunisation Clinic were received from Perth Children's Hospital, General Practice, and Specialist Clinics. These referrals are comprised of children who are considered high risk and may need extra vaccinations, or those requiring revaccination due to other medical conditions.

There were 176 individuals who attended their clinic appointments, whilst 39 failed to attend.

A total of 64 children were vaccinated at the clinic, and their vaccinations were reported to the Australian Immunisation register (AIR).

Of the adults that attended the Specialist Immunisation Clinic, 7 were referred to the Immunology Clinic at Sir Charles Gardiner Hospital (SCGH).