

LEGISLATIVE COUNCIL
Question Without Notice

Tuesday, 21 February 2023


118. Hon Nick Goiran to the Leader of the House representing the Minister for Health

I refer to the Western Australian Vaccine Safety Surveillance (WAVSS) System which was established in 2011 and receives data on adverse events following immunisation that is then compiled in an annual report, and I ask:

1. Are you aware that the Standing Committee on Estimates & Financial Operations was informed that “the WAVSS Annual Report 2021 is due to be released by end of August 2022”?
2. What is the date of each of the last three annual reports?
3. Further to 2, will you table these three reports?
4. When is the WAVSS Annual Report 2022 scheduled to be released?

Answer

1. Yes.
 2. The last three WAVSS Annual Reports are for the years 2021, 2020 and 2019.
 3. I table the 2019 and 2020 reports. The 2021 report will be published in coming days.
 4. The anticipated schedule for release is July 2023.
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Western Australia Vaccine Safety Surveillance – Annual Report 2020

Produced by the Immunisation 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 (WAVSS) system for vaccinations received in 2020.

No safety signals were detected for any of the vaccines administered in 2020.

WAVSS received 270 individual reports of AEFI in 2020. The number of AEFIs reported for vaccinations administered in 2020 is similar to the average number of reports received per year for the 2016 - 2019 time period (mean = 267.5).

There were 2,170, 877 individual doses of vaccine recorded in the Australian Immunisation Register (AIR) in 2020, giving a total rate of 12.44 events per 100,000 doses. This is similar to the rate of 12.21/100,000 doses reported in 2019.

Minor injection site reactions and rashes remain the most commonly reported reactions following vaccination. Influenza vaccine (any brand) was the most commonly reported vaccine, with 124/270 (47%) reports receiving an influenza vaccine either alone, or in combination with another vaccine. This reflects influenza vaccine delivery, with influenza vaccine comprising 55% of all vaccines recorded as given in 2020 in the Australian Immunisation Register (AIR).

In children < 5 years of age, DTPa-IPV (Quadracel) had the highest rate of AEFI reported (5.88 per 10,000 doses), similar to reported rates in previous years. Meningococcal B (Bexsero) and DTPa-IPV (Infanrix-IPV) had similar rates of AEFI (4.26 and 4.20 per 10,000 doses administered, respectively). The highest proportion of reports for all other age groups were for those who received influenza vaccine either alone or in combination with other vaccines; this is reflective of influenza vaccine being the most commonly administered vaccine in each of these other age groups.

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 based 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. Passive AEFI surveillance in Australia relies on 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 outcome, 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 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 2019². In 2020 all AEFI reports received by the Department through passive surveillance were forwarded to the Therapeutic Goods Administration (TGA) each business day. In addition, the TGA received AEFI reports directly from clinicians, the public and pharmaceutical companies that manufacture vaccines. Once a month, the TGA provided the Department with data on all reports of 'suspected' AEFI that they had received for residents of WA and these were cross-checked with WAVSS reports and entered where missing.

In addition to receiving passive AEFI reports, WAVSS also received 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 AusVaxSafety³, which is an enhanced surveillance system of AEFI 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. Active surveillance data can be found at ausvaxsafety.org.au/.

¹Western Australian Vaccine Safety Surveillance (WAVSS) system. https://ww2.health.wa.gov.au/Articles/U_Z/Western-Australian-Vaccine-Safety-Surveillance-WAVSS

²SmartVax <http://www.smartvax.com.au/>

³AusVaxSafety <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. This includes reports where a determination is still pending, and
- the residential address of the individual was recorded as WA, and
- the vaccination occurred between 1 January 2020 and the 31 December 2020, and
- the suspected reaction was captured through the passive reporting system (WAVSS).

Important considerations when interpreting the AEFI summary data

1. Young children often receive multiple vaccines as part of the National Immunisation Program (NIP) schedule⁴ 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 2020 as of 9 November 2021 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 for persons vaccinated in 2020

There were 270 individual AEFI reports received for persons vaccinated in 2020 that were assessed as events possibly or certainly related to vaccination. This is similar to the average number of reports per year for the previous four years (2016 – 2019, mean = 267.5) (Figure 1).

The month with the highest number of AEFI reports in 2020 was April, which is in keeping with peaks seen following the rollout of influenza vaccines each year between April and June. The highest recorded influenza vaccination coverage rates were achieved in 2020, with over 1 million influenza doses recorded in the AIR. The average number of reports per month was 22.5, similar to the monthly average 2016 – 2019 (22.3).

The rate of AEFI per 100,000 doses is shown in Figure 2. Counts of reported AEFI by age group are shown in Figure 3 with rates per 100,000 doses for each age group shown in Figure 4- Figure 7. The monthly rates of AEFI in 2020 remained within +/- 2 standard deviations from the mean, based on the monthly reported events from the previous 4 years (2016 – 2019).

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

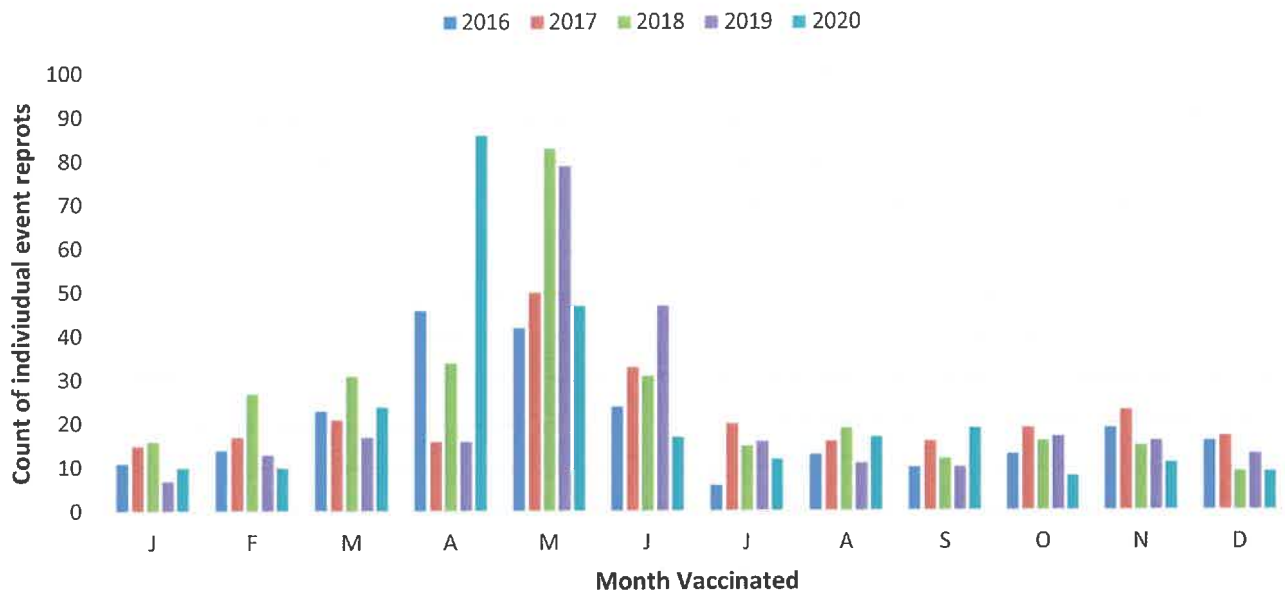


Figure 1 Reports of adverse events following immunisation, Western Australia 2016 to 2020, by month of vaccination.

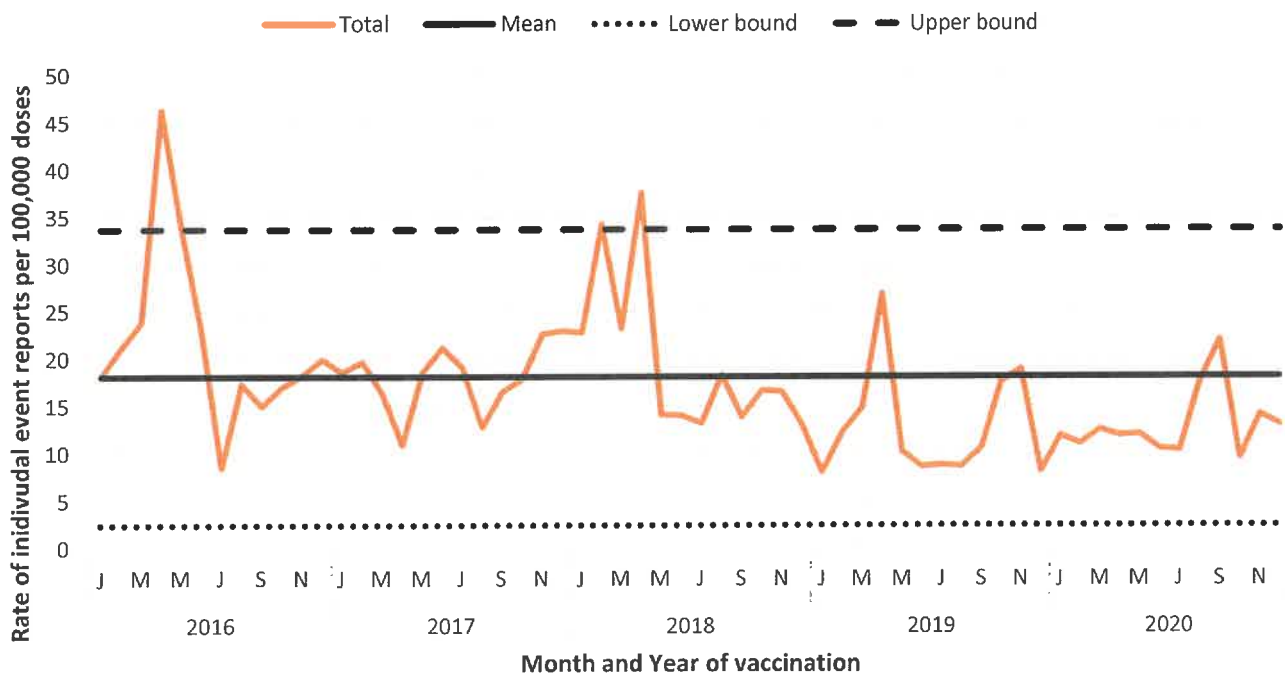


Figure 2 Rates of AEFI per 100,000 doses with statistical control limits (+/- 2σ), total cases 2016 – 2020.

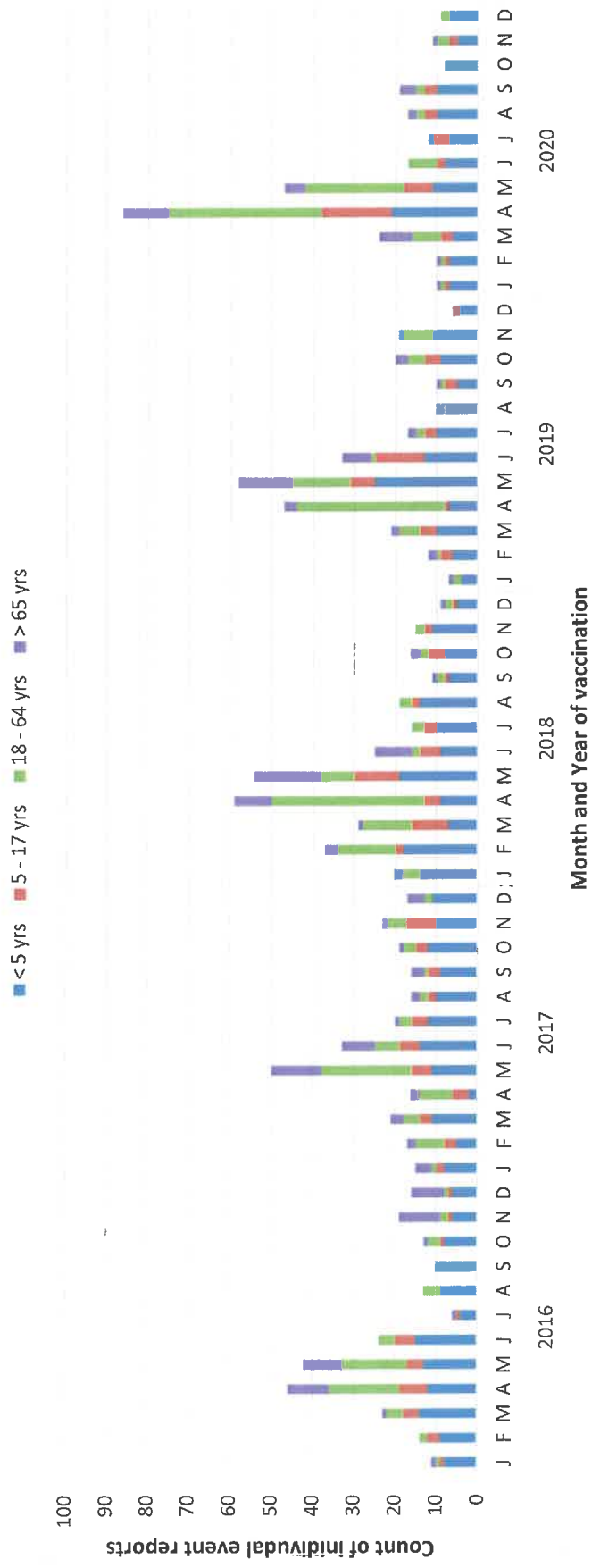


Figure 3 Reports of adverse events following immunisation, Western Australia, 2016 to 2020, by month of vaccination and age group in years.

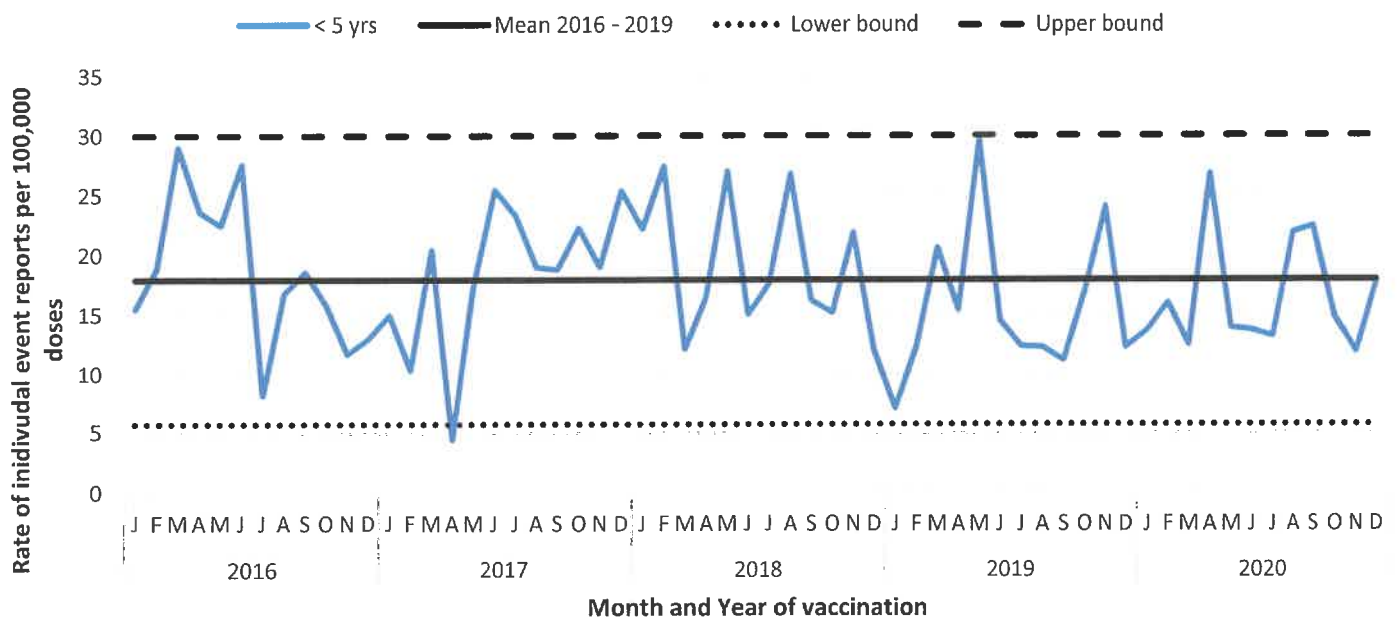


Figure 4 Rates of AEFI in <5 year olds per 100,000 doses with statistical control limits ($\pm 2\sigma$)

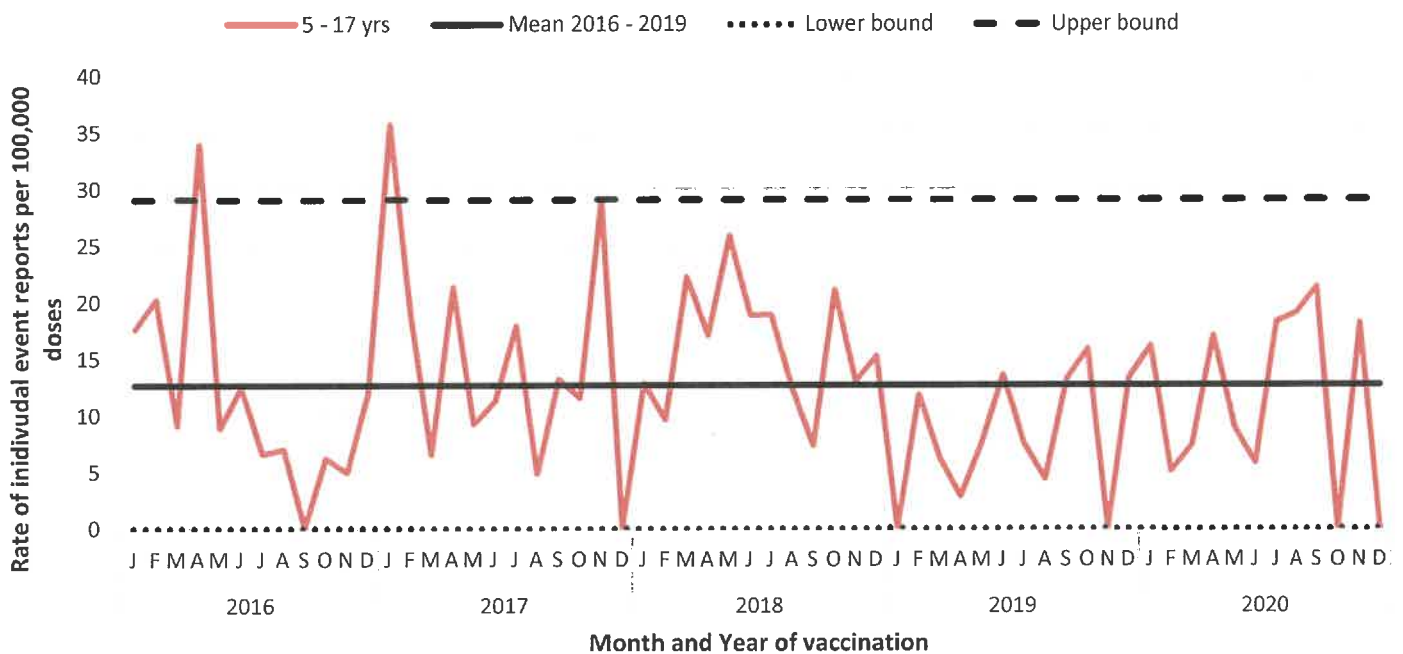


Figure 5 Rates of AEFI in 5-17 year olds per 100,000 doses with statistical control limits ($\pm 2\sigma$)

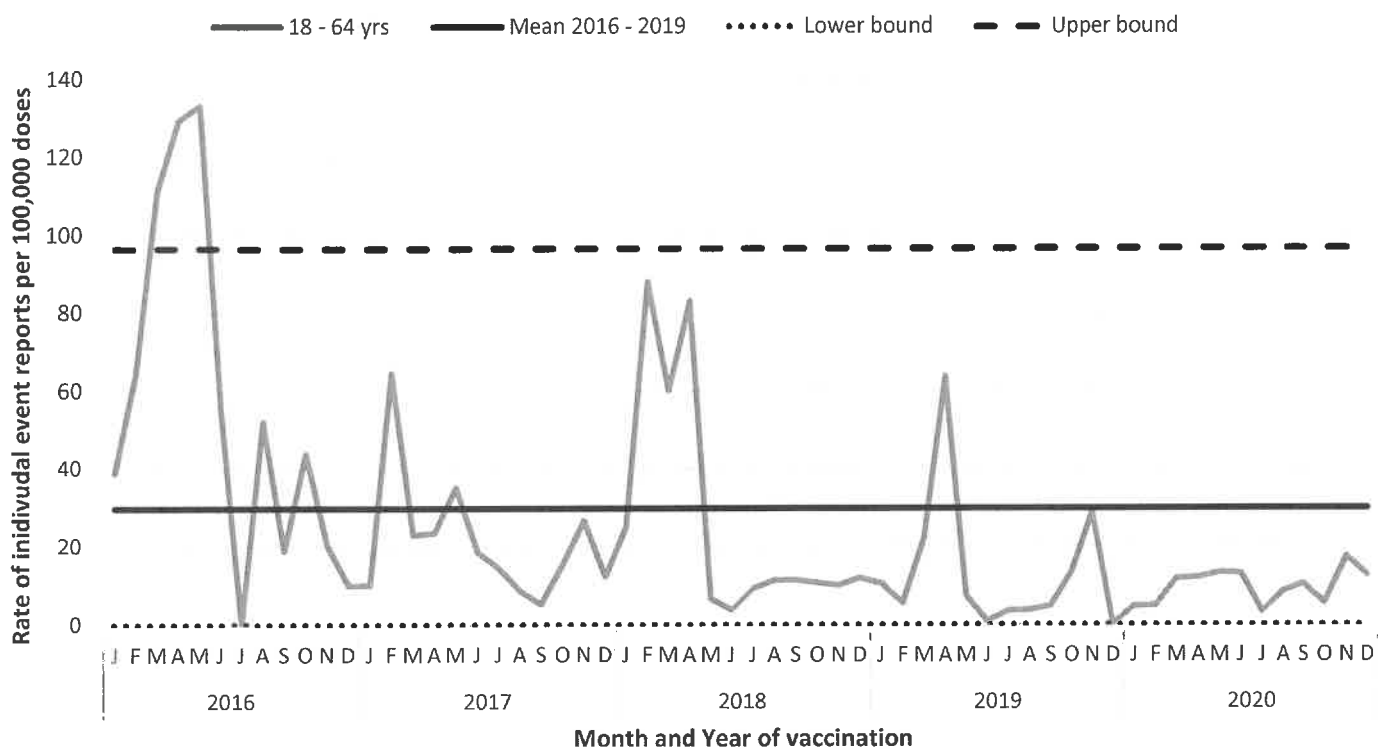


Figure 6 Rates of AEFI in 18-64 year olds per 100,000 doses with statistical control limits (+/- 2σ)

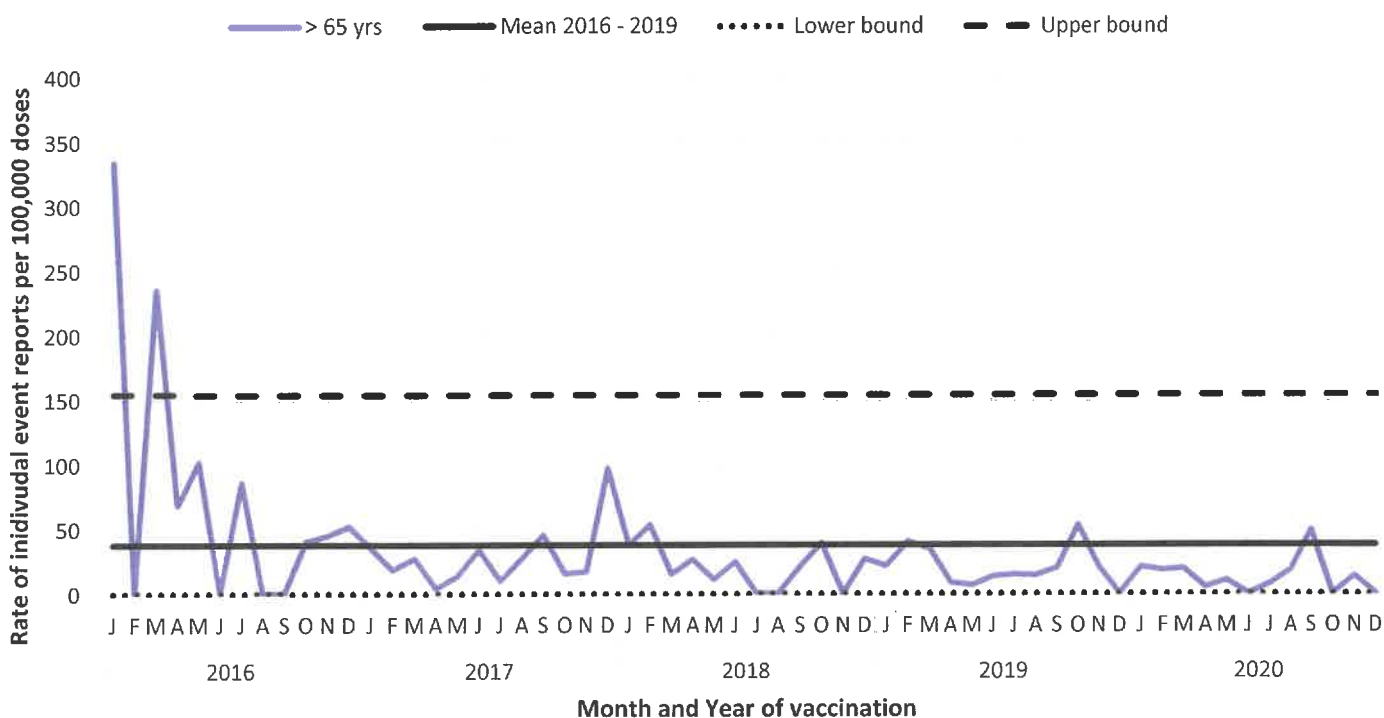


Figure 7 Rates of AEFI in >65 year olds per 100,000 doses with statistical control limits (+/- 2σ)

Characteristics of AEFI reports

Characteristics of AEFI reports 2016 - 2020 are summarised in Table 1. The majority (76%) of reports to WAVSS were received from healthcare providers, with 12% of reports being received directly from the public. Of the 270 vaccinees with AEFIs reported following a vaccination in 2020, 46% (124/270) were seen by a GP, 17% (46/270) were seen by a nurse, 23% (61/270) were seen at an emergency department, 7% (18/270) were admitted to hospital, and 4% (10/270) reported seeking help from HealthDirect. These proportions are in keeping with previous years.

In 2020, the number of AEFIs reported following immunisation at a pharmacy increased to 9% (25/270), which reflects the increasing uptake of vaccinations at community pharmacies. The vast majority of reports were submitted online (99%) via <https://www.safevac.org.au/>, reflecting a move away from mail, fax and phone-based reporting.

Reactions reported in 2020

In 2020, 318 adverse reactions that met established case definitions were described in the 270 reports (note that a vaccinee may describe multiple AEFI reactions).

A summary of the reactions that met established case definitions is shown in Table 2. The most commonly reported reactions in 2020 were minor injection site reactions (n=65), rash (n=51), and fever (≥ 38 - $<40^{\circ}\text{C}$) (n=25).

The number of reports of febrile seizures (n=6) was similar to the number reported for 2016-2019 (range = 4-11). There were no deaths or severe AEFI that caused long term sequelae related to vaccination reported to WAVSS in 2020.

Newly reported reactions in 2020

Brachial neuritis was added to the established reactions in 2020. However, no confirmed cases were reported in 2020.

Table 1 Characteristics of AEFIs reported to WAVSS for 2016 - 2020

	2016	2017	2018	2019	2020
Total	237	263	308	262	270
Sex					
Female	135 (57%)	156 (59%)	182 (59%)	158 (60%)	165 (61%)
Male	102 (43%)	107 (41%)	124 (40%)	103 (39%)	105 (39%)
Unknown	0 (0%)	0 (0%)	2 (1%)	1 (0%)	0 (0%)
Aboriginality					
Aboriginal	7 (3%)	4 (2%)	13 (4%)	16 (6%)	19 (7%)
Non-Aboriginal	132 (56%)	190 (72%)	214 (69%)	195 (74%)	226 (84%)
Unknown	98 (41%)	69 (26%)	81 (26%)	51 (19%)	25 (9%)
Age group					
≤ 5 years	113 (48%)	115 (44%)	130 (42%)	112 (43%)	106 (39%)
5 - 17 years	29 (12%)	41 (16%)	45 (15%)	38 (15%)	42 (16%)
18 - 64 years	54 (23%)	64 (24%)	89 (29%)	77 (29%)	88 (33%)
≥ 65 years	41 (17%)	43 (16%)	44 (14%)	35 (13%)	34 (13%)
Reporter Type					
Healthcare Provider	193 (81%)	213 (81%)	255 (83%)	217 (83%)	204 (76%)
Parent/Self	24 (10%)	41 (16%)	29 (9%)	31 (12%)	33 (12%)
Pharmacy	4 (2%)	3 (1%)	16 (5%)	10 (4%)	25 (9%)
Other	16 (7%)	6 (2%)	8 (3%)	4 (2%)	8 (3%)
Immunisation Provider Type					
Aboriginal Medical Service	0 (0%)	1 (0%)	3 (1%)	0 (0%)	2 (1%)
GP	138 (58%)	167 (63%)	185 (60%)	134 (51%)	136 (50%)
Nurse	0 (0%)	0 (0%)	0 (0%)	2 (1%)	0 (0%)
Pharmacy	3 (1%)	4 (2%)	9 (3%)	12 (5%)	29 (11%)
Workplace	2 (1%)	2 (1%)	1 (0%)	6 (2%)	9 (3%)
Hospital	21 (9%)	25 (10%)	38 (12%)	27 (10%)	22 (8%)
Community Clinic	0 (0%)	0 (0%)	2 (1%)	4 (2%)	2 (1%)
Other	46 (19%)	47 (18%)	51 (17%)	42 (16%)	27 (10%)
Missing data	27 (11%)	17 (6%)	19 (6%)	35 (13%)	43 (16%)
Managed by*					
Emergency department	40 (17%)	49 (19%)	63 (20%)	53 (20%)	61 (23%)
Admitted to hospital	13 (5%)	12 (5%)	16 (5%)	23 (9%)	18 (7%)
HealthDirect	9 (4%)	7 (3%)	6 (2%)	9 (3%)	10 (4%)
Central Immunisation Clinic	4 (2%)	1 (0%)	0 (0%)	0 (0%)	0 (0%)
Nurse assessment	56 (24%)	48 (18%)	70 (23%)	58 (22%)	46 (17%)
GP assessment	122 (51%)	124 (47%)	141 (46%)	119 (45%)	124 (46%)
Method of Report Submission					
Fax	89 (38%)	91 (35%)	114 (37%)	54 (21%)	0 (0%)
Online	140 (59%)	170 (65%)	191 (62%)	202 (77%)	266 (99%)
Post	4 (2%)	0 (0%)	2 (1%)	2 (1%)	0 (0%)
Telephone	0 (0%)	1 (0%)	0 (0%)	3 (1%)	1 (0%)
Missing data	4 (2%)	1 (0%)	1 (0%)	1 (0%)	3 (1%)

Table 2 Summary of AEFI reactions that met case definitions, 2016 to 2020.

Reaction	2016	2017	2018	2019	2020
Abdominal pain	0	0	0	6	6
Abscess	0	0	0	2	0
Allergic reaction (generalised)	2	3	1	5	4
Anaphylaxis	2	3	1	2	6
Angioedema	4	1	5	0	6
Apnoea (or Apnea)	0	0	1	2	0
Arthralgia	0	0	3	1	0
Brachial neuritis	0	0	0	0	1
Cellulitis at injection site	0	0	1	7	5
Complex Regional Pain	0	0	0	0	0
Crying (persistent)	0	0	0	4	0
Diarrhoea	6	5	3	7	9
Fever ($\geq 40^{\circ}\text{C}$)	0	0	0	3	0
Fever (≥ 38 - $<40^{\circ}\text{C}$)	5	11	9	16	25
Fever (unspecified)	20	33	33	16	17
Guillain-Barré Syndrome (GBS)	0	0	0	0	1
Headache (severe)	3	4	11	6	15
Hypotonic-hyporesponsive episode	2	2	4	2	3
Influenza-like-illness	0	0	0	1	13
Injection site reaction - minor/common/expected	74	67	91	58	65
Injection site reaction - severe	25	12	14	19	4
Intussusception	1	0	1	4	0
Lethargy	0	0	0	9	18
Lymphadenitis (includes suppurative lymphadenitis)	0	0	2	0	0
Lymphadenopathy	0	0	0	4	1
Nodule at injection site	0	0	6	3	0
Pain in limb	0	0	1	13	10
Paraesthesia	0	0	0	2	4
Parotitis	2	0	0	0	0
Rash	51	54	74	35	51
SIRVA	1	0	0	1	4
Seizure-afebrile	1	3	3	8	1
Seizure-febrile	4	6	11	8	6
Seizure-syncopal	0	0	5	2	1
Sepsis	0	0	1	0	0
Thrombocytopenia	0	0	1	1	0
Urticaria/hives/allergic rash	2	2	0	6	8
Vasovagal episode (syncope, faint)	8	16	14	19	20
Vomiting	9	11	10	15	14
Total	222	233	306	287	318

Reported AEFI by age group, vaccine

Children aged <5 years

For vaccines on the childhood immunisation schedule, the overall rate of AEFIs in children under five years recorded on the AIR is presented in Table 3. DTPa-IPV (Quadracel) had the highest rate of AEFI reported (5.88 per 10,000 doses), similar to reported rates in previous years. Meningococcal B (Bexsero) and DTPa-IPV (Infanrix-IPV) had similar rates of AEFI (4.26 and 4.20 per 10,000 doses administered, respectively). The reactogenicity of these vaccines has been well documented.^{5,6} The rate of AEFI for all other vaccines was ≤ 2 per 10,000 doses (Table 3).

Adolescents aged 5 – 17 years

Adverse events following seasonal influenza immunisation comprised the largest proportion of events reported by people aged 5 - 17 years (24/42, 57%). These also comprised the largest proportion of vaccines given in this age group (52%).

Adults aged 18 – 64 years

Adverse events following seasonal influenza immunisation comprised the largest proportion of events reported by people aged 18-64 years (68/88, 77%). These also comprised the largest proportion of vaccines given in this age group (75%).

Adults aged ≥ 65 years

The influenza vaccine was the most common vaccine associated with AEFI reported in people over 65 years of age (17/34, 50%) followed by Pneumovax 23 (9/34, 26%), and Prevenar 13 (6/34, 18%) vaccination. These reflect the proportion of doses of each vaccine given in this population group.

⁵National 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

⁶Pichichero, 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, 2016 to 2020

Vaccine Type	2016			2017			2018			2019			2020		
	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	6	20,596	2.91	11	24,448	4.50	11	29,993	3.67	2	26,257	0.76	3	23,925	1.25
DTPa - Triptacel	2	6,313	3.17	4	12,068	3.31	0	6,294	0.00	2	9,910	2.02	2	9,888	2.02
DTPa-IPV - Infanrix-IPV	1	5,016	1.99	2	5,565	3.59	5	17,454	2.86	6	19,284	3.11	9	21,436	4.20
DTPa-IPV - Quadracel	29	34,342	8.44	27	32,310	8.36	10	18,178	5.50	11	17,342	6.34	9	15,309	5.88
DTPa-hepB-IPV-Hib - Infanrix hexa	9	113,490	0.79	8	108,713	0.74	12	105,903	1.13	12	104,846	1.14	15	103,214	1.45
Hep A - Vaqta Paediatric	0	5,485	0.00	1	5,738	1.74	0	5,703	0.00	0	6,036	0.00	0	4,054	0.00
Hib - Act-Hib										3	19,425	1.54	3	32,885	0.91
Seasonal influenza - Fluarix Tetra	2	5,249	3.81	1	4,208	2.38	1	3,955	2.53	3	12,880	2.33	1	7,833	1.28
Seasonal influenza - FluQuadri				1	4,908	2.04	4	11,119	3.60	7	35,799	1.96	2	21,005	0.95
Seasonal influenza - Vaxigrip Tetra													9	49,578	1.82
Men ACWY - Nimenrix	0	1,715	0.00	3	4,481	6.69	16	62,001	2.58	8	58,640	1.36	5	43,967	1.14
Men B - Bexsero	1	3,857	2.59	18	20,038	8.98	5	21,571	2.32	6	17,149	3.50	8	18,789	4.26
MMR - MMR II	14	31,879	4.39	4	28,409	1.41	7	25,551	2.74	2	19,717	1.01	3	18,077	1.66
MMR - Priorix	3	11,413	2.63	2	11,805	1.69	9	12,113	7.43	4	17,884	2.24	1	16,875	0.59
MMRV - Priorix-Tetra	4	22,846	1.75	2	20,834	0.96	0	17,939	0.00	1	8,752	1.14	1	8,020	1.25
MMRV - ProQuad	5	15,204	3.29	6	16,620	3.61	1	18,771	0.53	3	27,762	1.08	4	26,053	1.54
Pneumococcal 13 - Prevenar 13	9	117,530	0.77	3	112,785	0.27	10	101,220	0.99	9	107,108	0.84	12	104,983	1.14
Rotavirus - Rotarix	0	4,704	0.00	2	28,407	0.70	6	66,096	0.91	8	65,877	1.21	9	65,302	1.38

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

Events that occur when multiple vaccines are given at a single encounter are ascribed to all vaccines, so there may be multiple vaccines listed for any individual report.

AEFIs associated with influenza vaccines

Seasonal influenza vaccines were the most commonly reported vaccines in individual reports of AEFIs in 2020. Administration of an influenza vaccine was recorded, either alone or in combination with other vaccines, in 128/270 (47%) of the AEFI reports in 2020. This reflects the proportion of influenza vaccines that comprised the total number of doses reported in AIR in 2020 (55%).

The majority of reports received associated with an influenza vaccination were for adults aged 18 to 64 years of age 68/128 (53%). This group also received the highest number of influenza vaccine doses (589,277). A total of 19 adverse event reports associated with influenza vaccines occurred in children less than five years of age (18%). Rates of AEFI per 10,000 doses, by brand, are shown in Table 4.

In 2020, the most commonly reported reaction following receipt of an influenza vaccine were injection site reactions, rash, fever, and vasovagal episodes. There was one febrile seizure and one afebrile seizure reported following influenza vaccination, both in children aged less than five following Vaxigrip Tetra vaccination.

Table 4 Rates of AEFI per 10,000 doses of influenza vaccine, by brand, Western Australia, 2020

Brand	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses
Afluria Quad	17	186,693	0.91
Fluad	1	64,240	0.16
Fluad Quad	25	99,080	2.52
Fluarix tetra	14	115,542	1.21
FluQuadri	34	316,529	1.07
Influvac Tetra	11	156,659	0.70
Vaxigrip Tetra	15	70,763	2.12
Brand unspecified	11	-	-

Clinic activity

In 2020 the Specialist Immunisation Clinic was operational on Thursday afternoons on a weekly basis. A total of 51 clinics were held throughout the year.

There were 107 children newly referred to the Specialist Immunisation Clinic from a variety of sources including General Practitioners, WAVSS, the Stan Perron Immunisation Centre and specialist paediatricians at PCH and privately.

Overall, 214 children attended the Specialist Immunisation Clinic and 41 did not attend their appointment. Of these clinic attendances 46 (21%) were due to possible AEFI, 53 (25%) for complex medically-at-risk immunisation requirements, 50 (23%) for vaccine hesitancy, 42 (20%) for needle phobia and 23 (11%) for other immunisation reasons.

Of the adults that attended the Specialist Immunisation Clinic, 3 were referred to the Immunology Clinic at Sir Charles Gardiner Hospital (SCGH).



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) system¹.

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.

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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 2019². 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 SmartVax². 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 AusVaxSafety³, 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.

¹Western Australian Vaccine Safety Surveillance (WAVSS) system. https://ww2.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI

²SmartVax <http://www.smartvax.com.au/>

³AusVaxSafety <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 were in children under five years (Figure 2). This is to be expected, as this cohort receives the largest proportion of vaccinations⁴.

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

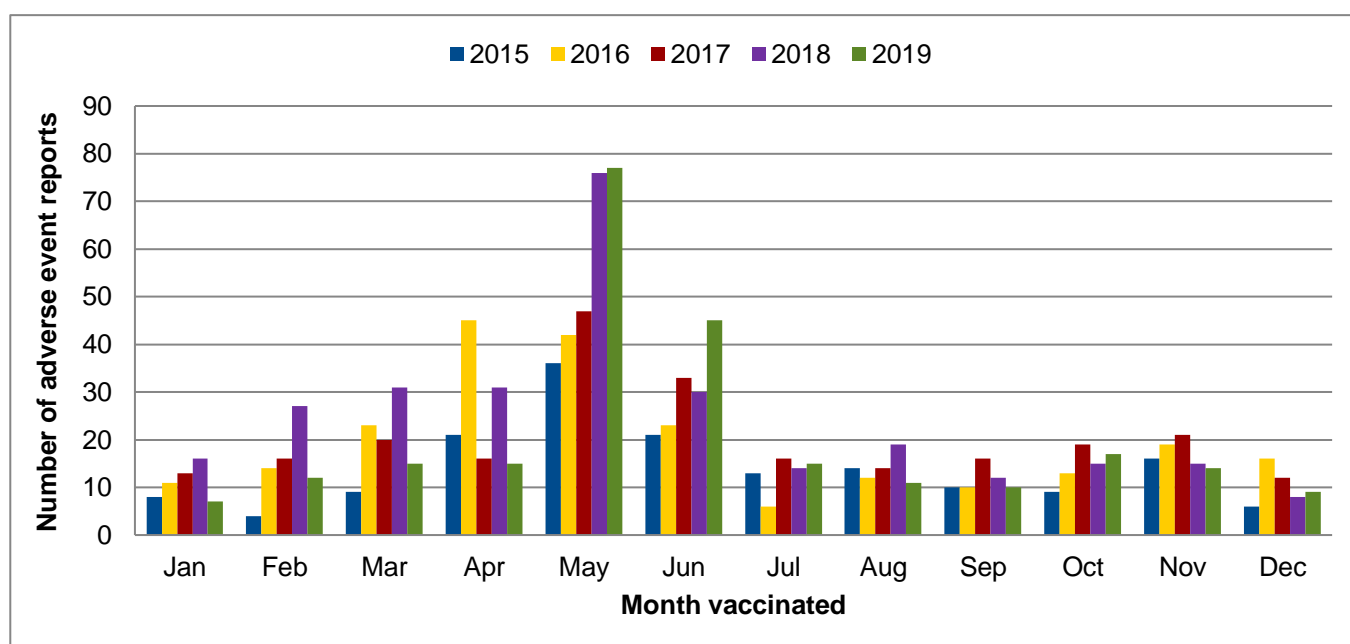


Figure 1 – Reports of adverse events following immunisation, Western Australia 2015 to 2019, by month of vaccination.

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.

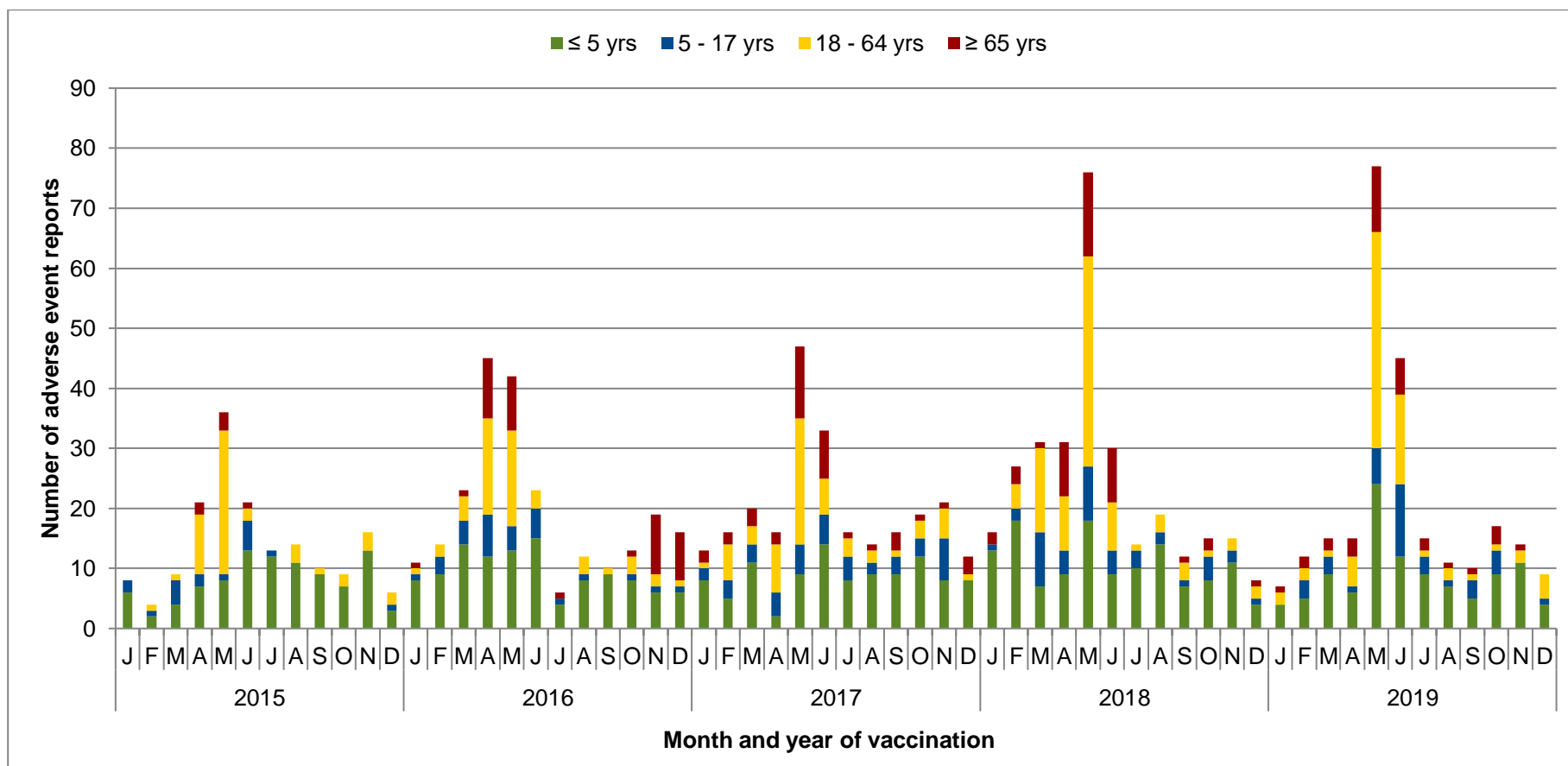


Figure 2 – Reports of adverse events following immunisation, Western Australia, 2015 to 2019, by month of vaccination and age group in years.

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 (≥40°C)					2	2
Fever (≥38-<40°C)	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% (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.

⁵National 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

⁶Pichichero, 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 -Tripace1	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).