Government of **Western Australia**
Department of **Health**

Western Australian Vaccine Safety Surveillance –

Annual Report 2023

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

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Contents

Executive Summary

This report describes adverse events following immunisation (AEFI) reported to the Western Australian Vaccine Safety Surveillance (WAVSS) system for vaccinations received in 2023 and describes reporting trends over the 5-year period from 1 January 2019 to 31 December 2023.

In 2023, a total of 2,283,782 vaccinations were administered by Western Australian (WA) immunisation providers, as recorded in the Australian Immunisation Register (AIR). Of this total, 484,000 (21.2%) were doses of a COVID-19 vaccine.

WAVSS received 850 distinct AEFI reports encompassing 1,267 vaccine doses. Of the 1,267 vaccine doses included in the AEFI reports, 307 (24.2%) were COVID-19 vaccines, 259 (20.4%) were influenza vaccines, 650 (51.3%) were vaccines on the National Immunisation Program (NIP) (excluding influenza vaccines), and 51 (4.0%) were 'Other' vaccines.

The proportion of AEFI reports following COVID-19 vaccines decreased substantially from 83.3% in 2022 to 36.1% in 2023, and the AEFI report rate per 100,000 COVID-19 doses decreased by 24.3%, from 83.8 per 100,000 doses in 2022 to 63.4 per 100,000 doses in 2023.

The AEFI reporting numbers for vaccines on the NIP and influenza vaccines increased in 2023. The increase can be attributed to reports solicited via active surveillance, particularly SmartVax. Most adverse reactions identified via SmartVax were common, minor and expected reactions.

The 2023 annual report provides an overview of the adverse events of special interest specifically monitored by the WA Department of Health and reviewed by WAVSS, including: anaphylaxis, immune thrombocytopenic purpura, Guillain-Barré syndrome, myocarditis, myopericarditis, pericarditis, menstrual disturbance, thrombosis with thrombocytopenia syndrome, and febrile convulsions.

1. Background

1.1. Western Australian Vaccine Safety Surveillance system

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

WAVSS was established in March 2011 and is a public health partnership between the WA Department of Health (the department) and Child and Adolescent Health Services (CAHS) which monitor vaccine safety. WAVSS has an important role in post-licensure surveillance of AEFI, essential for detecting rare, late onset or unexpected events that may not have been identified in clinical trials undertaken for licensure of vaccines. All AEFI reports received by WAVSS are submitted via the online reporting portal 'SAFEVAC' (www.safevac.org.au) which is an Australian reporting hub created by Victoria's SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community). The system accepts passive or spontaneous surveillance reports of suspected AEFI from health care providers and the public and actively identified AEFI reports.

1.2. Adverse event following immunisation

An AEFI is defined as any unwanted or unexpected event following the administration of a vaccine or vaccines, which could be mild, such as a sore arm, or serious, such as anaphylaxis.[2] Adverse events may also include conditions that occur following the incorrect handling or administration of a vaccine. The fact that an adverse event occurred following immunisation is not conclusive evidence that the event was caused by the vaccine or vaccination. 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.

1.3. Adverse events of special interest

Adverse events of special interest (AESI) are medically significant events that have the potential to be causally associated with a vaccine. The Expert Clinical Review Group (ECRG), a sub-group of the WA Vaccine Safety Advisory Committee (WAVSAC), determine potential AESI based on international and national medicines regulatory agency information and published literature. These AESI are then monitored by WAVSS. AESI for COVID-19 vaccines, influenza vaccines, and the Shingrix shingles vaccine were monitored throughout 2023. Where possible, assessment of causality for AESI was also undertaken by the ECRG using World Health Organization (WHO) criteria.[3]

1.4. Passive surveillance

Passive surveillance refers to spontaneous reporting of AEFI to WAVSS. Passive surveillance includes AEFI reports submitted by the person who received the vaccine (the vaccinee), AEFI reports made on behalf of a vaccinee by a family member or by a health professional (including their immunisation provider), or AEFI reports entered by the WAVSS team following patient review at a Specialist Immunisation Clinic (SIC). In WA, there is a statutory requirement for medical and nurse

[1] "Adverse event following immunisation", WA Department of Health, https://www.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI

[2] "Vaccination for people who have had an adverse event following immunisation", Australian Government Department of Health and Aged Care, https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-people-who-have-had-an-adverse-event-following-immunisation

[3] World Health Organization, *Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update* (2021), https://www.who.int/publications/i/item/9789241516990

practitioners to report AEFI to the department, per the requirements of the *Public Health Act 2016*[4] and the *Public Health Regulations 2017*.[5] Pharmacists, nurses and midwives administering vaccines are required to report AEFI to the WAVSS system and the patient's nominated healthcare provider under their respective Structured Administration and Supply Arrangements (SASAs). All AEFI reports received by the department are forwarded to the Therapeutic Goods Administration (TGA) within 48 hours of receipt for inclusion in national reporting. In addition, the TGA may receive AEFI reports directly from clinicians, the public, and pharmaceutical companies. The TGA provides the department with fortnightly data on all reports of 'suspected' AEFI that they receive for WA residents. These AEFI reports are cross-checked against existing WAVSS AEFI reports and where missing entered into the WAVSS system. The TGA also notifies the department within 24 hours of a serious adverse event following immunisation (SAEFI) report. Spontaneous AEFI reporting enables early detection of safety signals which can then be investigated more rigorously.

1.5. Active surveillance

Active surveillance refers to active monitoring of post-vaccination clinical manifestations. The two active surveillance systems contributing to WAVSS in 2023 are SmartVax and the WA Health Vaccination Linked Data Repository (VLDR).

1.5.1. SmartVax

SmartVax[6] is an application installed in sentinel immunisation providers' patient management software which sends a post-vaccination survey directly to the person, or the parent/guardian of the person, who received the vaccine. Survey responses are reported back to either the immunisation provider or the department, depending on the location where a person received their vaccination. SmartVax is installed in 130 sites (General Practitioners (GP), pharmacies, and community health and State-run clinics) across WA. Surveys following vaccination at state-run clinics, school-based immunisations, pharmacy-based immunisations, and some community health clinics are reported directly to the department. Surveys following vaccination at GP clinics are reported directly to the GP, who can review the AEFI and report to WAVSS. SmartVax survey responses for vaccines administered at sites other than GP clinics are entered into WAVSS if the vaccinee reported any medical attendance or the response was flagged by SmartVax as anaphylaxis-like symptoms.

In 2023, following vaccination with a COVID-19 vaccine, surveys were sent on day 3, 8 and 42 until July 2023, then on day 3 only. For all other scheduled vaccines, surveys were sent on day 3 only.

De-identified, aggregated, national active surveillance data from SmartVax is contributed to AusVaxSafety[7], an enhanced active AEFI surveillance system led by the National Centre for Immunisation Research and Surveillance (NCIRS). National active surveillance data can be found at https://ausvaxsafety.org.au.

1.5.2. Vaccination Linked Data Repository

The department conducts data linkage to identify potential AEFI signals. The VLDR was established in April 2021 and links an individual's vaccination information captured in the Australian Immunisation Register (AIR) to emergency department (ED) presentation, hospital admission and death records. Within the context of the 2023 annual report, routine scheduled data linkage was conducted to identify potential AESI associated with COVID-19 vaccines, influenza vaccines and the shingles

[4] "Public Health Act 2016", Government of Western Australia, https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13791_homepage.html
[5] "Public Health Regulations 2017:, Government of Western Australia, https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_s49088.html
[6] "SmartVax", https://www.smartvax.com.au/
[7] "AusVaxSafety", http://ausvaxsafety.org.au/

vaccine, Shingrix. The data linkage process searches for specific conditions of interest within a pre-defined window following vaccination.

Utilising data linkage mitigates the risk that a healthcare provider or vaccine recipient does not report a potential SAEFI or AESI which resulted in ED presentation, hospital admission or death. Therefore, data linkage enhances the completeness of the vaccine safety surveillance system. The search criteria for specific medical conditions were modified throughout 2023 based on findings from local, national, and international vaccine safety surveillance reports. Potential AEFIs identified through data linkage were reviewed by clinicians, and if identified as a possible SAEFI entered into WAVSS when appropriate.

1.5.3. Changes to vaccine recommendations in 2023

Reports summarising WA AEFI surveillance data have been published regularly since 2011.[8] Changes to the State and National Immunisation Programs have influenced trends in reported AEFI over time. Recent changes (2023) to the immunisation schedule that impact AEFI data presented in this report are listed below.

- *February 2023:* COVID-19 vaccine booster dose recommended for specific groups[9] if their last vaccine dose or confirmed infection was ≥6 months ago.
- *February 2023:* Recommended schedule of 9vHPV for immunocompetent adolescents and young adults aged 9–25 years becomes a single dose.
- *May-June 2023:* WA Government provided state-funded influenza vaccination program for all residents from 1 May to 30 June 2023.
- *July 2023:* Vaxelis funded under the NIP as an alternative vaccine to Infanrix hexa.
- *November 2023:* The shingles vaccine Shingrix replaced Zostavax on the NIP schedule. Two doses of Shingrix, six months apart, are recommended and funded for adults 65 years and older and all Aboriginal adults 50 years and older.

[8] "Adverse event following immunisation: Reports & Publications", https://www.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI
[9] "Significant events in COVID-19 vaccination practice in Australia", https://ncirs.org.au/sites/default/files/2024-05/COVID-19_May%202024.pdf

2. Methodology

2.1. Inclusion and exclusion criteria

For this annual report, AEFI reports were eligible for inclusion in the analysis if:

- the vaccination was recorded as 'possibly' being the cause of, or contributing to, the reported adverse event including AEFI reports where a determination is still pending;
- the address of the vaccination provider or the AEFI reporter was recorded as Western Australia;
- the vaccination occurred between 1 January 2023 and 31 December 2023; and
- the suspected reaction was captured in the state reporting system (WAVSS).

AEFI reports were excluded if:

- no vaccination date could be determined;
- the reaction included in the report was classified in the WAVSS system as 'not related';
- no reaction was reported; or
- the only reported 'reaction' was a vaccine administration error.

Data included in this annual report were captured in the WAVSS system as at 31 March 2024. This date was chosen as a cut-off to enable data validation and timely reporting, and to capture AEFI which may have developed over a longer period. AEFI data reported from 2019 to 2022 in this report may differ slightly from previous annual reports due to delayed reporting.

2.2. Data analysis

AEFI report rates are calculated as the count of AEFI reports recorded against a particular vaccine/vaccine group divided by the total number of doses of that vaccine/vaccine group administered by WA-based immunisation providers in the vaccination year(s) of interest. Rates are presented per 100,000 doses of vaccines administered. Total counts of doses administered by WA-based immunisation providers were derived from the AIR as at 10 April 2024.

Analyses of AEFI reports are categorised by the following vaccine groups:

- National Immunisation Program (NIP) vaccines; comprising all vaccines available on the 2023 WA Immunisation Schedule, excluding influenza vaccines
- Influenza vaccines
- COVID-19 vaccines
- Other vaccines; comprising all vaccines not included in the above groups.

2.3. Interpretation notes

To aid with interpretation of data presented in this report, the following notes are provided.

Characteristics of AEFI reports

Where age groups are presented, age refers to an individual's age in years at the date of their recorded vaccination. AEFI reports with missing age information were still eligible for inclusion in all analyses and were categorised as 'unknown' against the listed age group.

Limited information available in the AEFI reports received via the TGA may result in an inability to identify the individual for follow-up or may preclude determination of whether an event was likely to be causally related to vaccination.

Unless otherwise stated, where a year or year groups are presented, the year refers to the year of vaccination.

Causality

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.

Summary reporting interpretation

Descriptive statistics presented in this annual report are aggregated on either a (i) per AEFI report basis, (ii) per vaccine group basis, or (iii) per vaccine basis, dependent on the context. Analyses on the per AEFI report basis typically quantify details about the vaccinee or the reporter. Analyses on the per vaccination or per vaccine group basis reflect the fact that a person may have received more than one vaccine per vaccination event, e.g. young children who often receive multiple vaccines at the same time as part of the NIP schedule.[10] In these circumstances, it is usually not possible to attribute a subsequent AEFI to a single vaccine, so all the vaccines administered during the vaccination event are attributed as having suspected involvement in the AEFI.

One AEFI report can list up to 10 distinct reactions. Analyses describing reactions count each distinct reaction against the one or more vaccinations recorded in that vaccination encounter. For example, if a person received a COVID-19 vaccine and an influenza vaccine in the same vaccination encounter, all reported reactions would be recorded against both the COVID-19 vaccine and the influenza vaccine.

[10] "Western Australian Immunisation Schedule", WA Department of Health, https://www.health.wa.gov.au/~/media/Files/Corporate/general%20documents/Immunisation/PDF/WA-immunisation-schedule.pdf

3. Overview

3.1. Summary of AEFI reports

WAVSS received 850 distinct AEFI reports encompassing 1,267 vaccines administered in 2023. The overall AEFI reporting rate per 100,000 doses administered was relatively stable throughout 2023 (Figure 1). The highest rate over the 2019-2023 reporting period was observed in 2021 due to reported AEFI following COVID-19 vaccination (Figure 1). In 2022, 83.2% of AEFI reports were following COVID-19 vaccination, compared to 36.1% of AEFI reports in 2023.

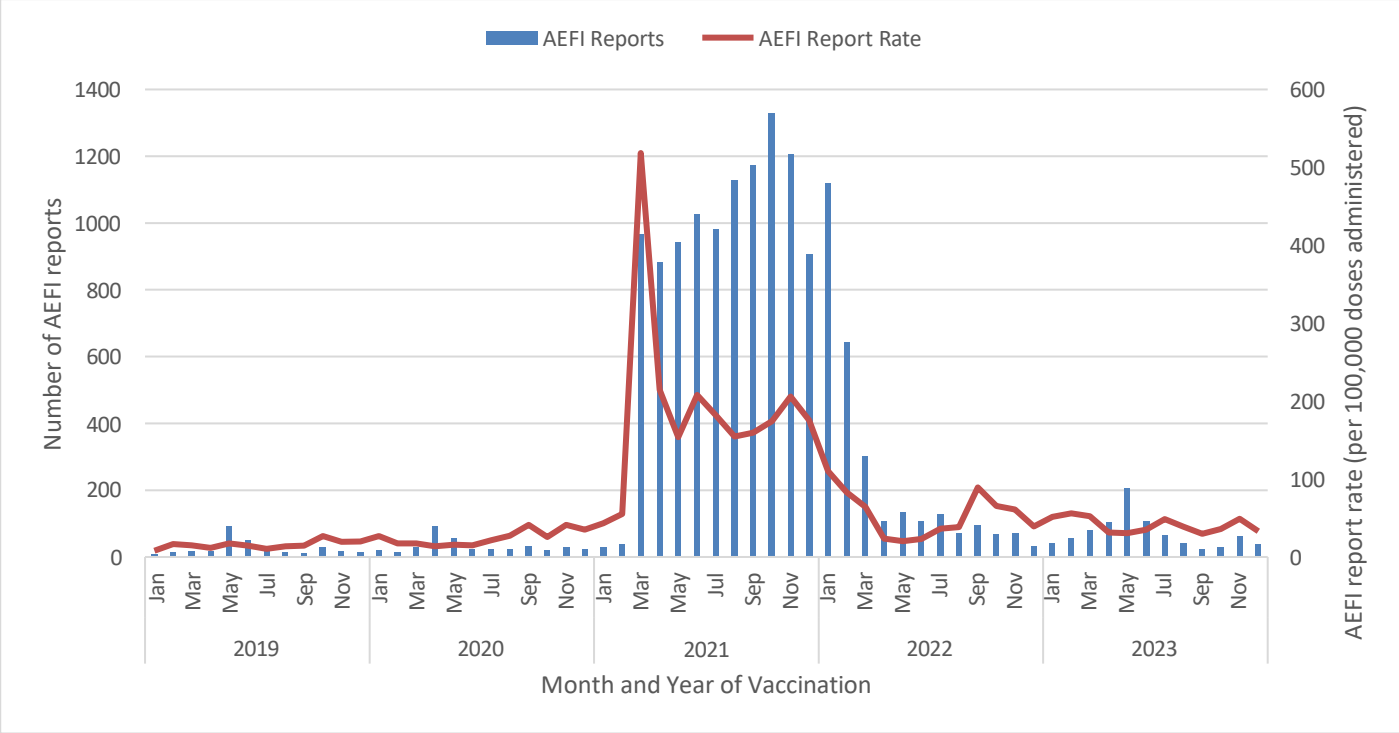

Figure 1: Number of AEFI reports by vaccination month and year with reporting rate per 100,000 doses administered by vaccination month and year (2019-2023).

3.2. Characteristics of AEFI reports

Table 1 describes the demographic details of the vaccine recipient, the AEFI reporter's details, the vaccine provider's details, the surveillance type used to receive the AEFI report and how the AEFI report was managed, for adverse events following vaccinations administered between 2019-2023.

Relative to previous years, the age profile of AEFI reports in 2023 was more similar to 2019-2020 (pre-COVID-19 vaccines) than to the previous two years, with children <5 years contributing the greatest proportion of AEFI reports (Table 1). AEFI reports for adults aged 65 years and older were a greater proportion of total reports than in the previous four years, which is due in large part to COVID-19 vaccines and Shingrix. The proportion of AEFI reports received via SmartVax active surveillance increased substantially in 2023. While the proportion of reports received via passive surveillance from healthcare professionals has decreased compared to pre-COVID-19, the number of AEFI reported by GPs and nurses in 2023 (approximately 200 per year) is similar to 2019-2020. The proportion of AEFI managed by GPs in 2023 was similar to 2019-2020, and the proportion of AEFI managed by nurses was lower than 2019-2020 but similar to 2021-2022.

Table 1: Characteristics of AEFI reports to WAVSS, 2019-2023

Characteristic	2019 N = 298	2020 N = 372	2021 N = 10,598	2022 N = 2,869	2023 N = 850
Gender					
Female	174 (58%)	217 (58%)	6,802 (64%)	1,649 (57%)	461 (54%)
Male	123 (41%)	155 (42%)	3,771 (36%)	1,208 (42%)	367 (43%)
Unknown*	1 (0.3%)	0 (0%)	25 (0.2%)	12 (0.4%)	22 (2.6%)
Aboriginal Status					
Aboriginal**	16 (5.4%)	29 (7.8%)	194 (1.8%)	75 (2.6%)	34 (4.0%)
Non-Aboriginal	220 (74%)	301 (81%)	9,493 (90%)	2,446 (85%)	726 (85%)
Unknown	62 (21%)	42 (11%)	911 (8.6%)	348 (12%)	90 (11%)
Age Group					
<5 years	123 (41%)	169 (45%)	153 (1.4%)	195 (6.8%)	268 (32%)
05-17 years	46 (15%)	68 (18%)	358 (3.4%)	409 (14%)	103 (12%)
18-64 years	77 (26%)	91 (24%)	8,450 (80%)	1,930 (67%)	257 (30%)
≥65 years	34 (11%)	33 (8.9%)	1,593 (15%)	326 (11%)	220 (26%)
Unknown	18 (6.0%)	11 (3.0%)	44 (0.4%)	9 (0.3%)	2 (0.2%)
Surveillance/Reporter Type					
Active					
Vaccine Linked Data Repository***	N/A	N/A	258 (2.4%)	372 (13%)	41 (4.8%)
SmartVax****	17 (5.7%)	88 (24%)	3,612 (34%)	522 (18%)	489 (58%)
Passive					
Administration/Other	17 (5.7%)	10 (2.7%)	144 (1.4%)	33 (1.2%)	10 (1.2%)
General Practitioner/Nurse	219 (73%)	211 (57%)	3,486 (33%)	914 (32%)	203 (24%)
Pharmacist	11 (3.7%)	27 (7.3%)	208 (2.0%)	99 (3.5%)	11 (1.3%)
Self/Parent/Guardian	34 (11%)	36 (9.7%)	2,890 (27%)	929 (32%)	96 (11%)
Immunisation Provider Type					
Community Clinic	46 (15%)	23 (6.2%)	2,667 (25%)	645 (22%)	204 (24%)
General Practitioner	146 (49%)	193 (52%)	1,803 (17%)	568 (20%)	239 (28%)
Hospital	30 (10%)	23 (6.2%)	1,393 (13%)	78 (2.7%)	42 (4.9%)
Other	16 (5.4%)	19 (5.1%)	128 (1.2%)	35 (1.2%)	14 (1.6%)
Pharmacy	13 (4.4%)	31 (8.3%)	467 (4.4%)	356 (12%)	138 (16%)
Unknown	47 (16%)	83 (22%)	4,140 (39%)	1,187 (41%)	213 (25%)
Any Medical Attendance					
Yes	215 (72%)	229 (62%)	7,982 (75%)	1,918 (67%)	598 (70%)
Management***** (% Yes)					
Admitted to Hospital	25 (8.4%)	19 (5.1%)	1,019 (9.6%)	320 (11%)	44 (5.2%)
Emergency Department	61 (20%)	67 (18%)	5,042 (48%)	1,063 (37%)	191 (22%)
General Practitioner	135 (45%)	151 (41%)	3,161 (30%)	906 (32%)	388 (46%)
Helpline	10 (3.4%)	16 (4.3%)	388 (3.7%)	109 (3.8%)	39 (4.6%)
Nurse	62 (21%)	45 (12%)	550 (5.2%)	131 (4.6%)	41 (4.8%)

N/A: not applicable

*Unknown includes AEFI reports where gender was not reported and those who reported 'neither'

** Within Western Australia, the term Aboriginal is used in preference to Aboriginal and Torres Strait Islander, in recognition that Aboriginal people are the original inhabitants of Western Australia. No disrespect is intended to our Torres Strait Islander colleagues and community

***Established in 2021

****Also includes self-report from other survey-based active surveillance sources

*****'Management' categories are not mutually exclusive, summing the rows will not equal 100%.

For all vaccine groups, the majority of AEFI reports were identified via active surveillance in 2023 (Figure 2).

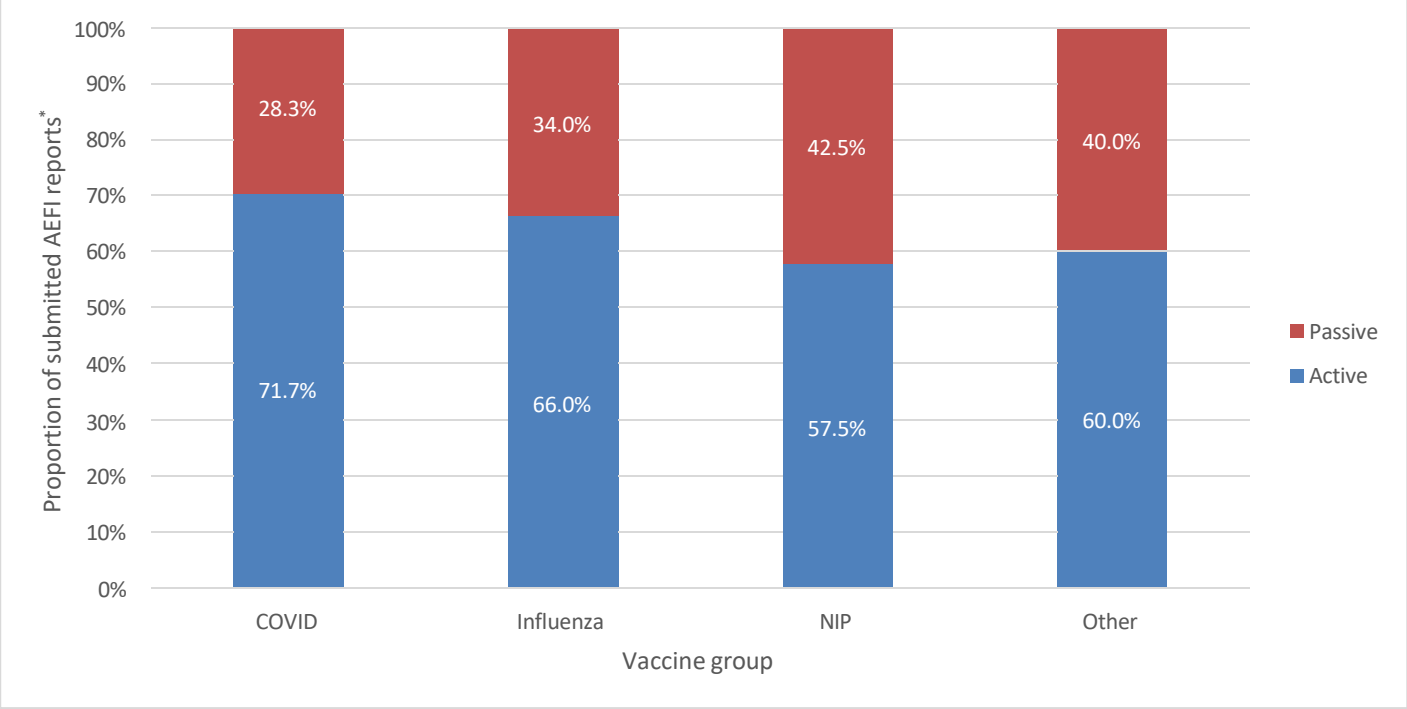

Figure 2: AEFI reports by surveillance type (passive or active) by vaccine group for vaccinations administered in 2023.
**Summary reporting of surveillance type by vaccine group counts co-administered vaccines once per distinct vaccine group.*

4. Adverse events following NIP vaccines

There were 358 distinct AEFI reports encompassing 650 NIP vaccines administered in 2023. An increase in the number of reports in 2023 was seen across all NIP vaccines.

Shingrix was added to the NIP in November 2023. In November and December, there were 21 AEFI reported following Shingrix with an AEFI rate of 70.7 per 100,000 Shingrix doses.

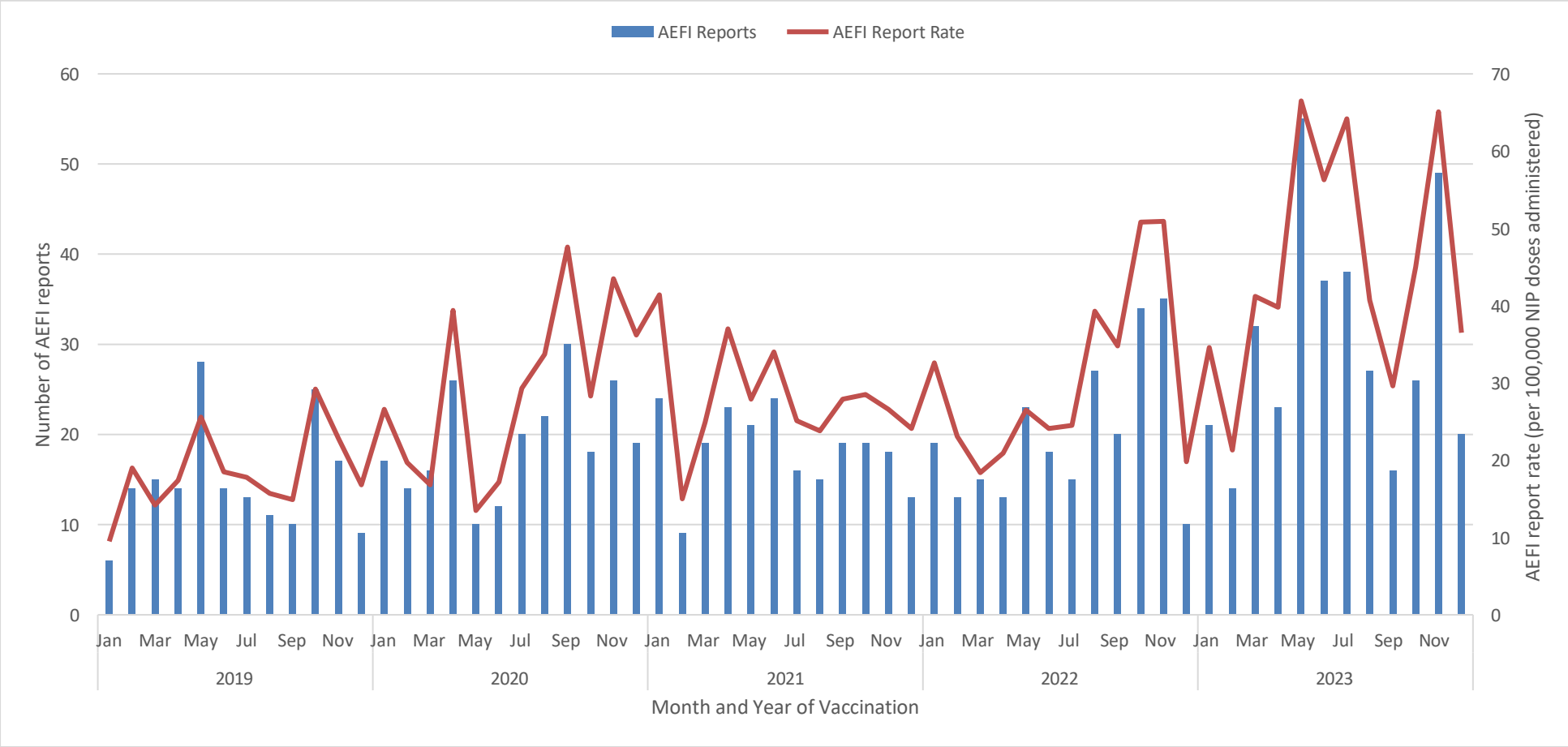

Figure 3: Number of AEFI reports following NIP vaccines by vaccination month and year and surveillance type overlayed with AEFI report rate per 100,000 NIP doses administered by vaccination month and year (2019-2023).

The most common reactions following NIP vaccines administered in 2023 were minor and expected reactions (Figure 4).

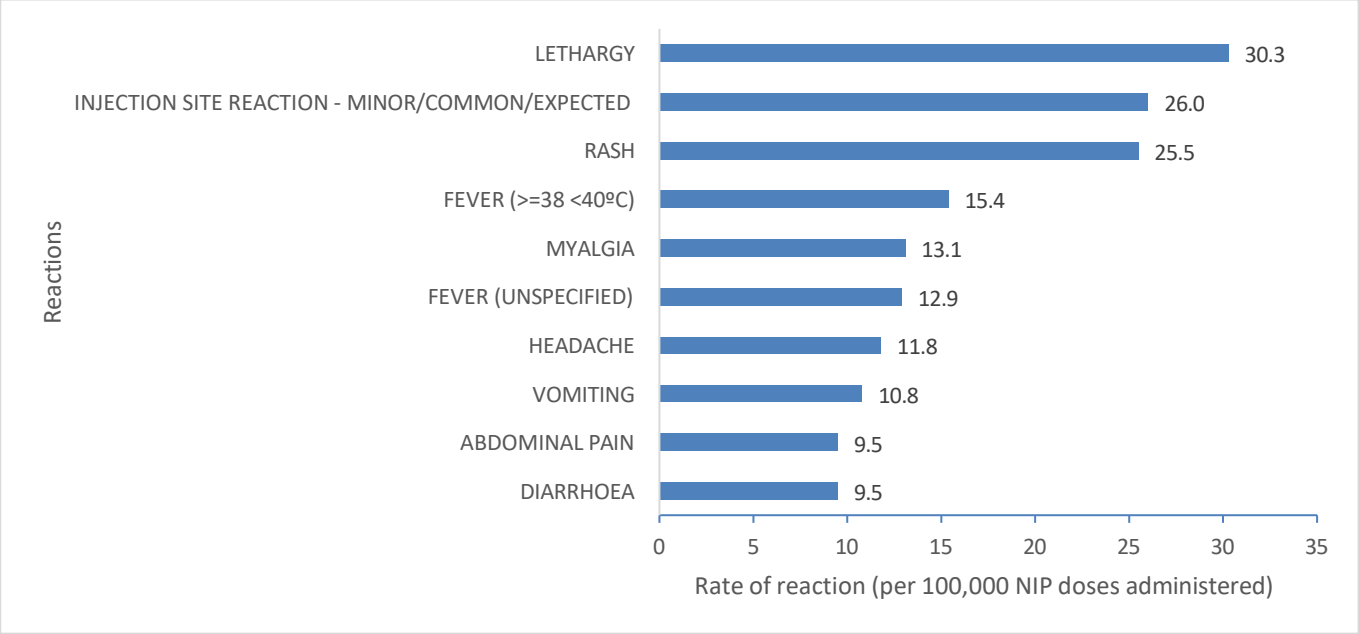

Figure 4: Ten most commonly reported reactions following NIP vaccines by rate (reactions per 100,000 NIP doses administered).

Table 2 presents the AEFI report rate for all vaccines available on the NIP to children aged less than 5 years. In 2023, the overall AEFI report rate for children under 5 years was 104.4 per 100,000 NIP doses administered.

The addition of Vaxelis to the NIP as an alternative for Infanrix hexa did not change expected AEFI reporting.

Table 2: Number of AEFI reported, doses administered and AEFI report rate per 100,000 doses administered for vaccines available on the NIP (excluding influenza vaccines) to children aged less than 5 years, 2019-2023, by antigen/s

Antigen/s	2019			2020			2021			2022			2023		
	AEFI	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**
DTPa	14	33,316	42	25	31,373	79.7	23	31,268	73.6	24	31,013	77.4	37	31,683	116.8
DTPa-hepB-IPV-Hib	20	95,560	20.9	46	92,013	50	45	95,623	47.1	64	91,279	70.1	69	83,549	82.6
DTPa-IPV	20	32,876	60.8	30	33,436	89.7	31	32,931	94.1	36	31,014	116.1	56	31,656	176.9
Hep A	-	5,349	-	2	3,619	55.3	1	2,424	41.3	3	2,824	106.2	4	4,084	97.9
Hep B	-	1,699	-	3	1,200	250	1	3,900	25.6	1	7,041	14.2	1	6,685	15.0
Hib	8	17,540	45.6	22	30,611	71.9	19	30,968	61.4	22	30,728	71.6	31	31,141	99.5
Men ACWY	14	54,342	25.8	32	40,433	79.1	34	37,032	91.8	29	38,472	75.4	46	38,170	120.5
Men B	10	15,105	66.2	14	16,664	84	12	21,857	54.9	15	20,685	72.5	24	23,113	103.8
MMR	16	34,381	46.5	33	32,117	102.7	28	31,139	89.9	30	32,864	91.3	41	31,721	129.3
MMRV	12	33,667	35.6	23	31,707	72.5	21	31,569	66.5	27	31,444	85.9	29	32,430	89.4
Pneumococcal	28	97,455	28.7	65	94,929	68.5	71	98,282	72.2	77	95,828	80.4	95	89,033	106.7
Rotavirus	17	60,302	28.2	30	57,974	51.7	33	60,641	54.4	37	56,793	65.1	41	50,769	80.8

Descriptive statistics presented in this table are aggregated on a per antigen/s basis where vaccines containing the same antigen/s are grouped together and AEFI reports are counted against all vaccines. For example, if an AEFI report was submitted following co-administration with a rotavirus and DTPa vaccine in the same vaccination encounter, a count of 1 AEFI report would be ascribed against both rotavirus and DTPa.

5. Adverse events following influenza vaccines

In 2023, there were 259 adverse event reports following influenza vaccines (Figure 5) which is greater than the average of the preceding four years (average 138.5 per year). In 2023, the overall AEFI report rate for influenza vaccines was 28.0 per 100,000 influenza doses administered compared to an average of 14.7 per 100,000 influenza doses administered between 2019-2022. A seasonal pattern of AEFI reporting was apparent in 2023, as in previous years, corresponding to the months when influenza vaccine is predominantly given – April, May and June.

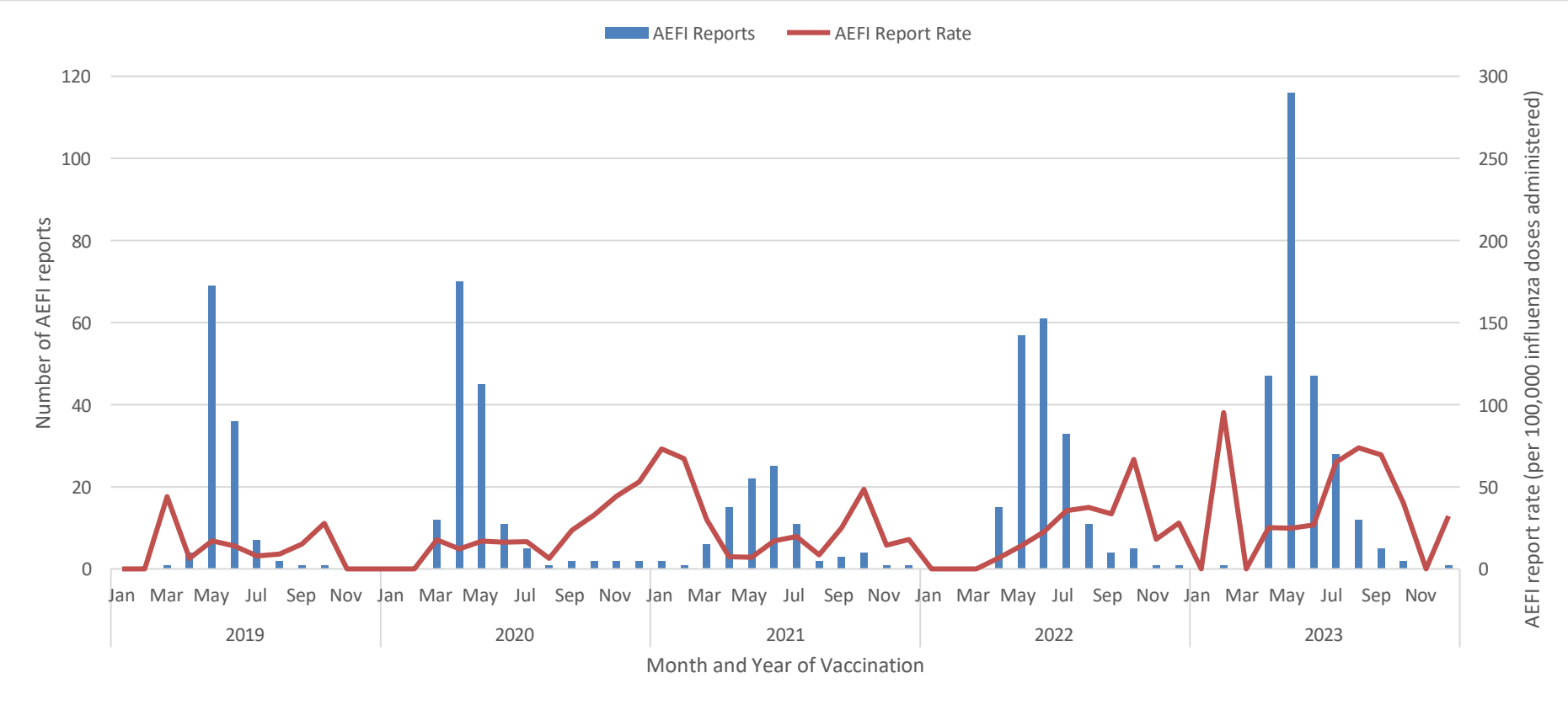

Figure 5: Number of AEFI reports following influenza vaccines by vaccination month and year overlayed with AEFI report rate per 100,000 influenza doses administered by vaccination month and year (2019-2023).

In 2023, the highest number of AEFI reports related to influenza vaccination occurred in those aged 18-64 years (96/259; 37.0%), who also proportionately received the highest number of influenza doses (467,803/925,550; 50.5%). Of 259 adverse event reports following influenza vaccination in 2023, 79 (30.5%) were reported in children aged under 5 years.

The most frequently reported reactions following influenza vaccines across all age groups were common, minor and expected (Figure 6).

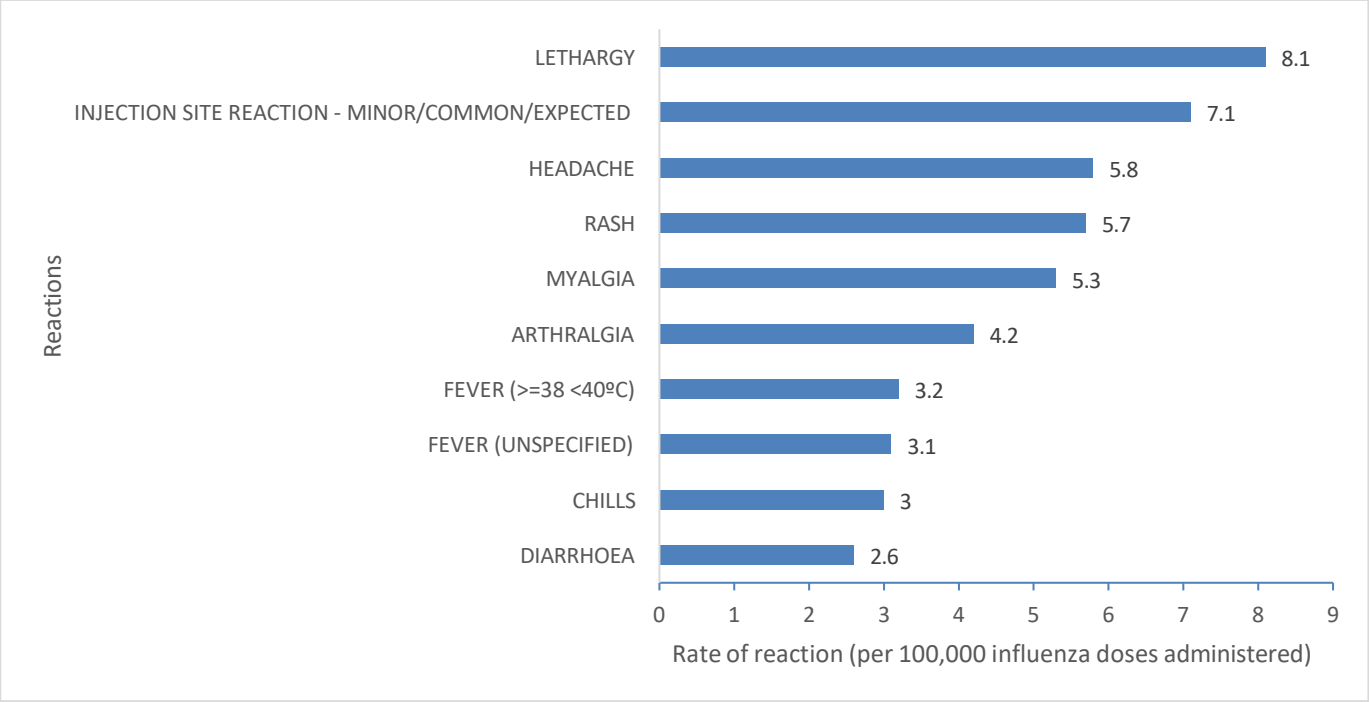

Figure 6: Ten most commonly reported reactions following influenza vaccines by rate (reactions per 100,000 influenza doses administered).

6. Adverse event following ‘Other’ vaccines

The ‘Other’ vaccine group is mainly comprised of travel vaccines, privately administered vaccines and vaccines recorded by antigen only (unspecified brand) in the AEFI report submitted to WAVSS. A total of 45 distinct AEFI reports were submitted to WAVSS following 51 ‘Other’ vaccines administered. The 10 most commonly reported reactions for this vaccine group were varied and influenced by co-administration and the low number of submitted AEFI reports, most were common and expected reactions (Figure 7).

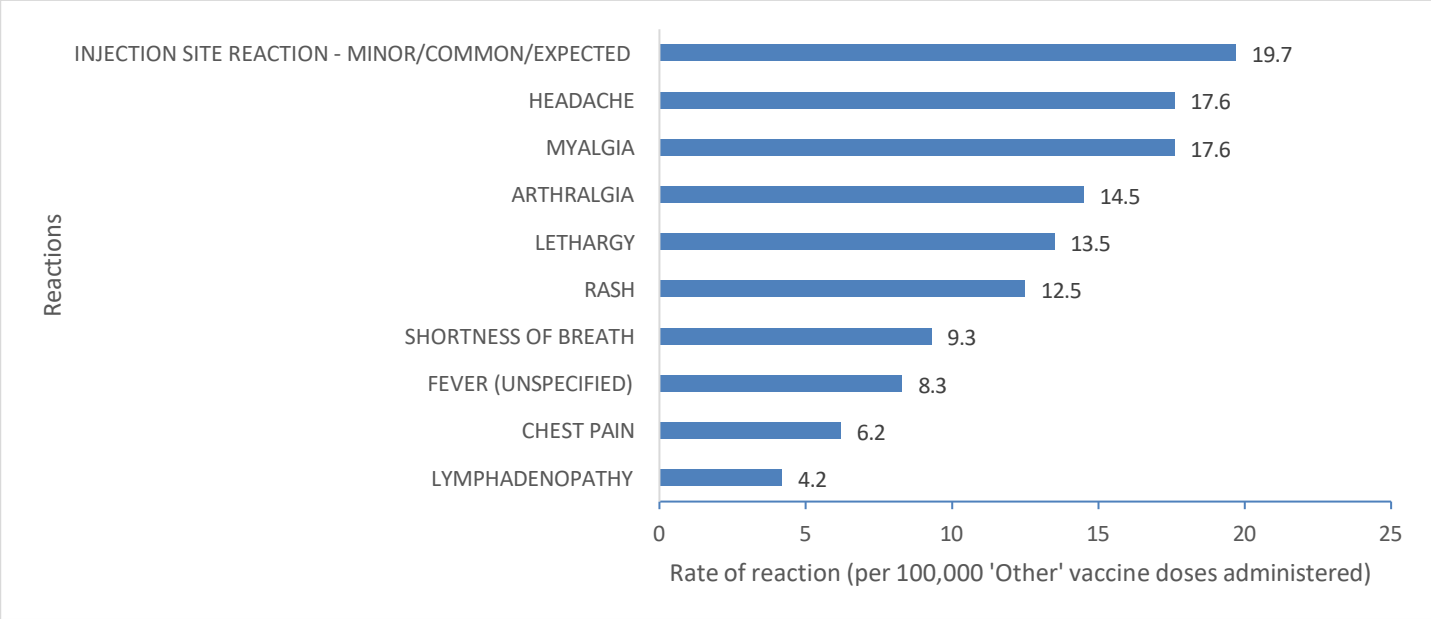

Figure 7: Ten most commonly reported reactions following ‘Other’ vaccines by rate (reactions per 100,000 ‘Other’ doses administered).

7. Adverse events following COVID-19 vaccines

There were 307 individual AEFI reports for persons vaccinated with a COVID-19 vaccine in 2023. Overall, the AEFI report rate following any COVID-19 vaccine was 63.4 per 100,000 doses administered in 2023, compared with 83.8 in 2022. Figure 8 shows the number of AEFI reports and AEFI report rate by month of vaccination, from February 2021 (the beginning of the WA COVID-19 Vaccination Program) to December 2023.

A complete breakdown of COVID-19-related AEFI reports and AEFI report rate is presented in Table 3, stratified by age group and vaccine brand.

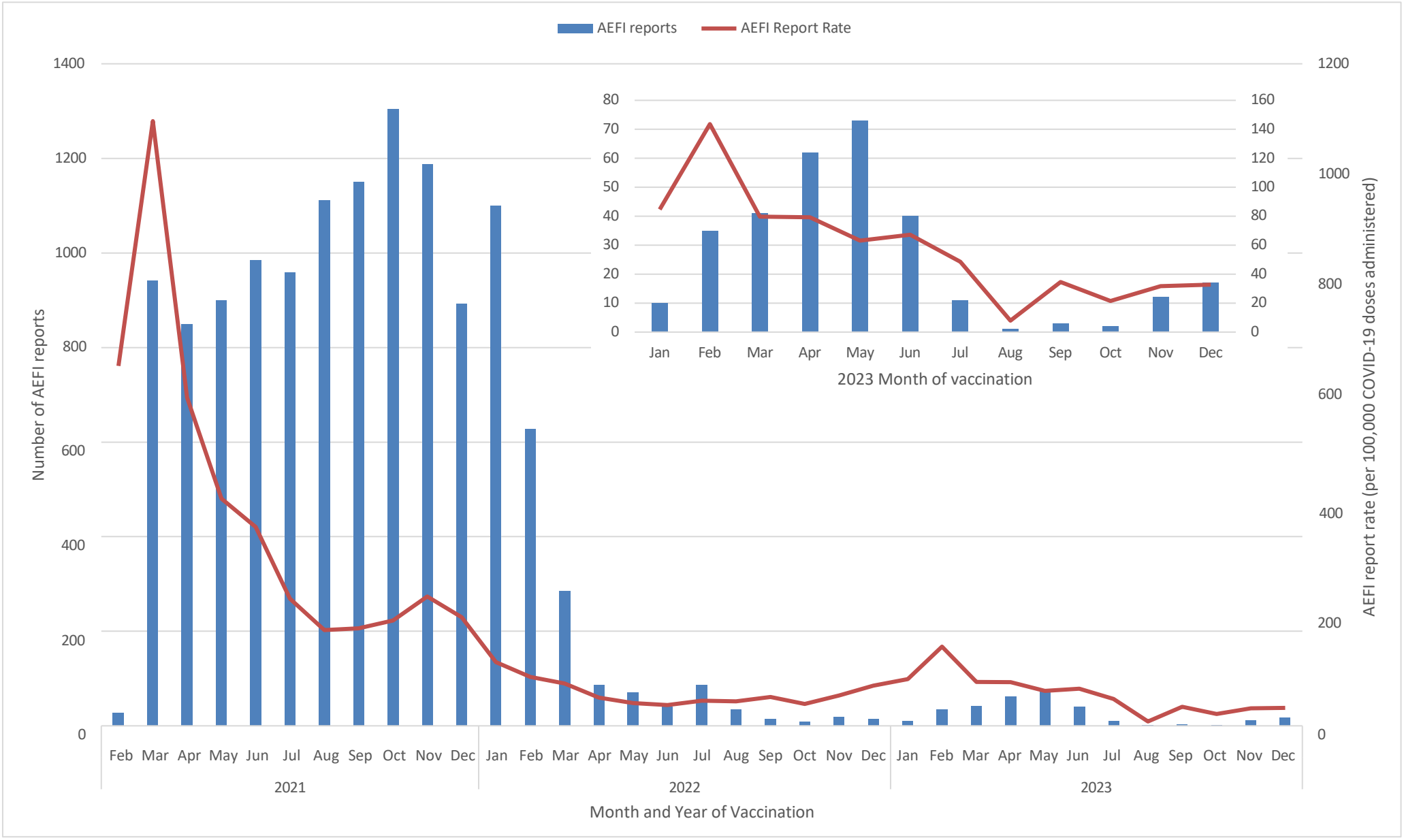

Figure 8: Number of AEFI reports following COVID-19 vaccination by month of vaccination, overlayed with AEFI reporting rate per 100,000 COVID-19 doses administered, 2021-2023. Inset shows 2023 data.

Table 3: AEFI reports following COVID-19 vaccination and AEFI report rate per 100,000 doses administered, by brand and age group, 2023

Age group (years)	Comirnaty*			Spikevax**			Nuvaxovid		
	AEFI	Doses	Rate	AEFI	Doses	Rate	AEFI	Doses	Rate
<5	0	37	0	1	36	[a]	0	0	0
05-17	2	4404	45.4	-	428	-	0	99	0
18-64	101	129159	78.2	40	61274	65.3	7	1709	409.6
≥65	102	204027	50.0	53	81768	64.8	1	986	101.4

AEFI: AEFI reports.
* Includes Pfizer, bivalent-Omicron BA-1, bivalent-Omicron BA-4 BA-5, monovalent-Omicron XBB-1.5.
** Includes Spikevax, bivalent-Omicron BA-1, bivalent-Omicron BA-4 BA-5, monovalent-Omicron XBB-1.5
[a] Rate not computable due to low numbers.

The 10 most commonly reported reactions following COVID-19 vaccination are shown in Figure 9, all are minor expected reactions.

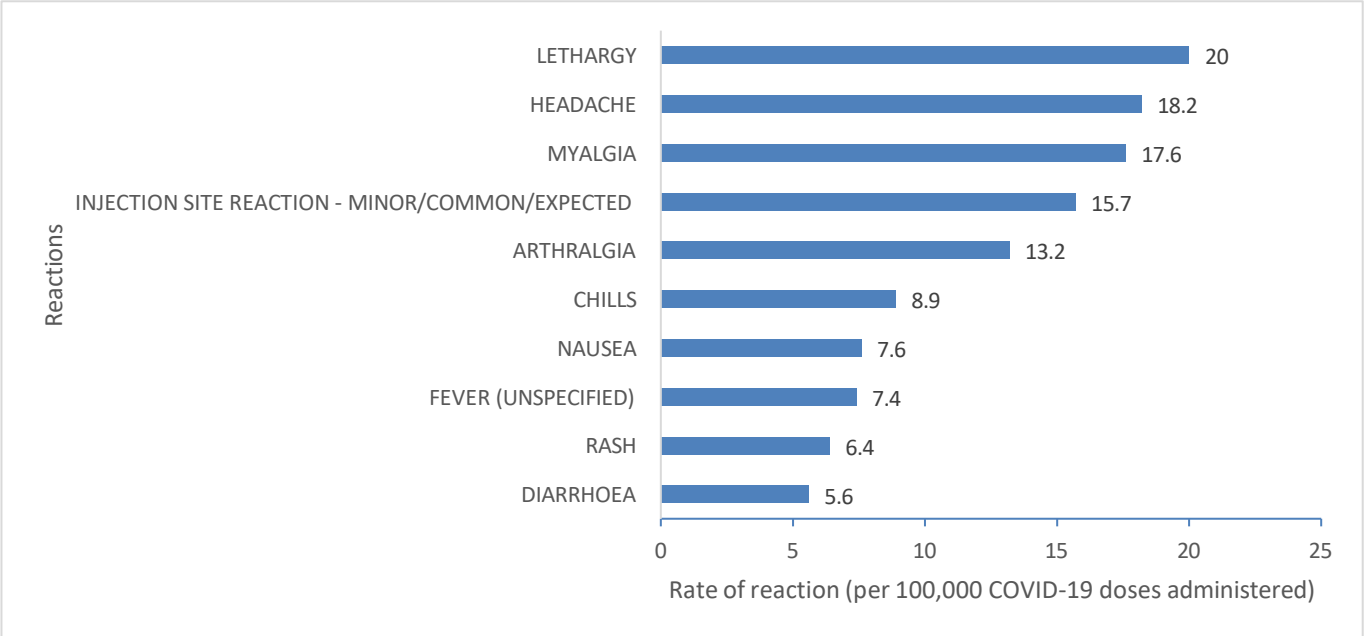

Figure 9: Ten most commonly reported reactions following COVID-19 vaccines by rate (reactions per 100,000 doses administered).

8. Adverse events of special interest reported to WAVSS

Specific AESI were monitored for three separate vaccine groups – COVID-19 vaccines, influenza vaccines, and the shingles vaccine, Shingrix. If an AESI resulted following co-administration across two of these groups, the count of that AESI was recorded against both vaccine groups. This process utilised routine passive surveillance, and active surveillance methods, specifically through the VLDR.

8.1. Adverse events of special interest– COVID-19 vaccines

Anaphylaxis

Anaphylaxis is a potentially life-threatening allergic reaction that occurs rarely after vaccination, with onset typically within minutes to hours.[11]

In 2023, one reaction was found to have sufficient evidence to provide a diagnosis of anaphylaxis resulting in a rate of 0.2 per 100,000 doses of COVID-19 vaccines administered.

Immune thrombocytopenic purpura

Immune thrombocytopenic purpura (ITP) is an autoimmune disease in which the immune system attacks platelets in the blood and megakaryocytes in the bone marrow resulting in low platelet counts, causing easy bruising and bleeding.[12] No ITP reactions were detected following COVID-19 vaccination in 2023.

Guillain-Barré syndrome

Guillain-Barré syndrome (GBS) is a rare but sometimes serious immune disorder where nerves are attacked by immune cells resulting in pain, numbness, muscles weakness and/or difficulty walking.

In 2023, one confirmed GBS was reported with a rate of 0.2 per 100,000 doses of COVID-19 vaccines administered.

Myocarditis, myopericarditis and pericarditis

Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the pericardium (the thin, sac-like tissue surrounding the heart muscle).[13] Myocarditis and pericarditis can occur together or separately. When they occur together it is called myopericarditis. Symptoms for myocarditis, pericarditis or myopericarditis can include chest pain or discomfort, shortness of breath, abnormal heart beats, fainting, or pain when breathing.[13] Diagnostic criteria for myocarditis, myopericarditis, and pericarditis have been established by both the United States Centres for Disease Control and Prevention (CDC) and the Brighton Collaboration.[14,15] Both these classification systems have been applied to cases of possible myocarditis, myopericarditis, and pericarditis that have been reported to WAVSS. For this report, myopericarditis has been grouped together with myocarditis due to its clinical severity and similar approach to management.

One myocarditis/myopericarditis reaction following COVID-19 vaccination in 2023 was confirmed by WAVSS, with an overall rate of 0.2 per 100,000 doses of COVID-19 vaccines administered.

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[11] McNeil MM, DeStefano F. "Vaccine-associated hypersensitivity", *J Allergy Clin Immunol* 141 (2018):463–72. doi: 10.1016/j.jaci.2017.12.971

[12] "What is ITP", ITP Australia, https://itpaustralia.org.au/about-itp/

[13] "COVID-19 vaccines and cardiac inflammation", Australian Government Department of Health and Aged Care, https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance/myocarditis-pericarditis

[14] "Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices – United States, June 2021", Centers for Disease Control and Prevention, https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

[15] "Myocarditis/pericarditis Case Definition", Brighton Collaboration, https://brightoncollaboration.org/myocarditis/

A total of 3 pericarditis reactions were confirmed in 2023, with a rate of 0.6 per 100,000 doses of COVID-19 vaccines administered.

Menstrual disturbance

WAVSS monitored reports of menstrual disturbance following cases emerging in national and international reports. There was one case reported in 2023, with a rate of 0.2 per 100,000 doses of COVID-19 vaccine administered.

Thrombosis with thrombocytopenia syndrome

Thrombosis with thrombocytopenia syndrome (TTS) is a rare but serious side-effect of Vaxzevria vaccine, first identified in 2021. No confirmed cases of TTS were reported in 2023, likely attributable to the reduction in Vaxzervria vaccines administered in WA comparative to 2021.

8.2. Adverse events of special interest– Influenza vaccines

Guillain-Barré syndrome

In 2023, WAVSS had one confirmed case of GBS with a rate of 0.1 per 100,000 doses of influenza vaccine administered.

Febrile convulsion

Febrile convulsions are seizures that occur mostly in children that result from a sudden rise in temperature, usually associated with an acute viral febrile illness. WAVSS monitored cases of febrile convulsion in children under the age of 5 years that were temporally associated with influenza vaccine administration. In 2023, 10 febrile convulsions were reported to WAVSS, with a rate of 18.8 per 100,000 doses of influenza vaccine administered to this age group.

8.3. Adverse events of special interest– Shingrix vaccine

Guillain-Barré syndrome

WAVSS monitored cases of GBS following Shingrix vaccine commencing in November 2023 when Shingrix was added to the NIP. No GBS were detected in November to December 2023 following Shingrix vaccine.

9. Possible serious adverse events following immunisation

AEFI reports to WAVSS undergo a staged clinical review process determined by the complexity and severity of the reported reaction(s).

The determination of ‘possible serious AEFI’ is based on the information provided in the initial AEFI report to WAVSS. Further assessment may upgrade or downgrade this determination. If upon further assessment a SAEFI is confirmed, or if there remains uncertainty, these cases are referred to ECRG and/or to a specialist immunisation clinic located at Sir Charles Gairdner Hospital (for adults) or Perth Children’s Hospital (for children and adolescents). Determination of a SAEFI does not automatically infer causality. Of the 850 possible serious AEFI reports reviewed in 2023, 777 were determined to not be serious and the remaining 73 were designated a WHO causality classification, as described in Table 4.

Table 4: WHO causality classification of SAEFI reports

WHO causality classification	Number of AEFI reports
A1 (consistent causal association: vaccine product-related reaction)	35
A3 (consistent causal association: immunisation error-related reaction)	1
A4 (consistent causal association: immunisation anxiety-related reaction)	1
B1 (indeterminate: consistent temporal relationship but insufficient evidence for causality)	21
B2 (indeterminate: conflicting trends of consistency and inconsistency with causality)	6
C (inconsistent causal association to immunisation [coincidental])	9
Total	73

All reports of death are included in safety surveillance results, even if a coroner or specialist review panel has concluded it is unrelated to vaccination. Of the 4 deaths that were reported to WAVSS in 2023, 2 were found to be not causally associated with vaccination, one had indeterminate causality, and one has classification pending.

10. Specialist clinic activity

10.1. Referrals following AEFI reports to WAVSS

As part of the case review of AEFI reports, an individual can be referred to a specialist immunisation clinic for further follow-up and management of future vaccination(s). The reported AEFI does not need to be classified as serious for individuals to be referred. A total of 133 AEFI reports resulted in a referral to a specialist clinic; 80 to the Perth Children's Hospital Specialist Immunisation Clinic (SIC) and 53 to the adult vaccine safety clinic at Sir Charles Gairdner Hospital (SCGH).

10.2. Adult clinic activity

In 2023, the adult vaccine safety clinic at Sir Charles Gairdner Hospital (SCGH) saw approximately 750 patients. The vast majority of appointments (>95%) related to possible AEFI following COVID-19 vaccines.

10.3. Child and adolescent clinic activity

In 2023, there were 531 appointments made at the Perth Children's Hospital Specialist Immunisation Clinic (SIC). As with the adult clinic, children may attend multiple appointments over the year and referrals can be received from sources outside the WAVSS referral service. In total, 440 individual children and adolescents attended the SIC. Of those who attended the SIC, 98 (18.5%) were due to possible AEFI, 184 (34.6%) for complex medically-at-risk immunisation requirements, 60 (11.3%) for vaccine hesitancy, and 189 (35.6%) for needle anxiety.

11. WA Vaccine Safety Advisory Committee (WAVSAC)

The Western Australia's Vaccine Safety Advisory Committee (WAVSAC) met 5 times in 2023.

WAVSAC's specialist sub-group, the Expert Clinical Review Group (ECRG), was established in 2021 and comprises clinicians with expertise in vaccine safety, public health and other specialities related to key AESI. This group individually review AEFI reports which require specialist assessment. The ECRG met 12 times in 2023 and reviewed 89 AEFI reports.

12. Summary and Discussion

A summary of the past 5 years of vaccine safety surveillance in WA is presented in Table 5.

Table 5: Doses administered, AEFI reported and AEFI report rate by vaccine group and year(s) of vaccination

Vaccine Group	AEFI Reports 2019-2022	Doses administered 2019-2022	AEFI Report Rate 2019-2022	AEFI Reports 2023	Doses administered 2023	AEFI Report Rate 2023
COVID-19*	12,795	6,927,653	184.7	307	484,000	63.4
Influenza	554	3,763,464	14.7	259	925,550	28.0
NIP**	1,530	3,323,231	46.0	650	777,888	83.6
Other**	175	286,610	61.1	51	96,344	52.9

*COVID-19 vaccines were only available in WA from 2021 onwards. AEFI report rates are presented per 100,000 doses administered.
**Where an AEFI report involved co-administration of vaccines within a group, all vaccines are counted.

The overall 2023 AEFI reporting rate was 37.2 per 100,000 doses administered a significant decrease from the 2022 AEFI report rate of 60.1 per 100,000 doses administered.

The overall AEFI report rate for COVID-19 vaccines continued to decline compared with the previous two years, with a further reduction of 24.6% compared to 2022. This decrease is likely due to the changes in COVID-19 vaccine recommendations, and the overall decrease in COVID-19 vaccine doses administered in 2023. The profile of most commonly reported reactions following COVID-19 vaccines also changed in 2023 to include only minor and expected reactions, which is also reflected in the decrease of all reported AESI for COVID-19 vaccines.

The AEFI report rates for NIP and influenza vaccines continued to increase in 2023. The increase can be attributed to an increase in the number of reports solicited via active surveillance, particularly SmartVax. Most adverse reactions identified via SmartVax for these vaccine groups were common, minor and expected reactions. New vaccines on the NIP in 2023 (Shingrix and Vaxelis) were monitored with no concerns.

In 2023, the use of the VLDR was expanded to the shingles vaccines (Shingrix) and influenza vaccines and has become the predominant surveillance method for adverse events of special interest.

The number of possible SAEFI and AESI decreased substantially; ECRG reviewed 89 AEFI reports in 2023 compared with over 350 in 2022.

13. Abbreviations

Term	Meaning
AEFI	Adverse event following immunisation
AESI	Adverse events of special interest
AIR	Australian Immunisation Register
ATAGI	Australian Technical Advisory Group on Immunisations
CAHS	Child and Adolescent Health Service
COVID-19	Coronavirus Disease 2019 (illness caused by SARS-CoV-2)
VLDR	Vaccination Linked Data Repository
ECRG	WAVSAC Expert Clinical Review Group
ED	Emergency Department
GBS	Guillain-Barré Syndrome
GP	General Practitioner
ITP	Immune thrombocytopenic purpura
NCIRS	National Centre for Immunisation Research and Surveillance
NIP	National Immunisation Program
PCH	Perth Children's Hospital
REDCap	Research Electronic Data Capture
SAEFI	Serious adverse event following immunisation
SAEFVIC	Surveillance of Adverse Events Following Vaccination in the Community
SASA	Structured Administration and Supply Arrangement
SCGH	Sir Charles Gairdner Hospital
SIC	Specialist Immunisation Clinic
TGA	Therapeutic Goods Administration
The department	WA Department of Health
TTS	Thrombosis with Thrombocytopenia Syndrome
WAVSAC	Western Australian Vaccine Safety Advisory Committee
WAVSS	Western Australian Vaccine Safety Surveillance
WHO	World Health Organization

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