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

Western Australian Vaccine Safety Surveillance – Annual Report 2024

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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 2024 and examines reporting trends over the 5-year period from 1 January 2020 to 31 December 2024.

In 2024, a total of 2,188,577 vaccinations were administered by Western Australian (WA) immunisation providers, as recorded in the Australian Immunisation Register (AIR).

WAVSS received 670 distinct AEFI reports encompassing 1,137 vaccine doses. Of the 1,137 vaccine doses included in the AEFI reports, 847 (74.5%) were vaccines on the National Immunisation Program (NIP) (excluding influenza vaccines), 165 (14.5%) were influenza vaccines, 69 (6.1%) were COVID-19 vaccines, and 56 (4.9%) were 'other' vaccines.

Compared to the average for 2020-2023, in 2024 there were more AEFI reports following NIP vaccines, less reports following influenza and COVID-19 vaccines, and a similar number of reports for 'other' vaccines. Compared to the average for 2020-2023, AEFI report rates in 2024 increased for NIP vaccines (from 33.8 to 47.5 per 100,000 vaccinations), was similar for influenza vaccines (from 18.0 to 20.5 per 100,000 vaccinations) and significantly decreased for COVID-19 vaccines (from 133.0 to 26.2 per 100,000 vaccinations) and 'other' vaccines (from 73.4 to 37.2 per 100,000 vaccinations).

The most common adverse reactions reported following NIP and influenza vaccines were common, minor, and expected reactions. This was also true for COVID-19 vaccines, with the exception of Bell's palsy and pericarditis, attributed to the WA Department of Health specifically monitoring these two adverse events of special interest (AESI) via active surveillance. The data linkage active surveillance system continued to be an important mechanism to monitor AESI, including for new immunisation products such as Beyfortus which protects newborns and infants from severe respiratory syncytial virus (RSV) illness, and Shingrix, which protects older adults from shingles.

The 2024 annual report provides an overview of the AESI specifically monitored by the WA Department of Health and reviewed by WAVSS, including: anaphylaxis, Bell's palsy, Guillain-Barré syndrome (GBS), myocarditis, myopericarditis, pericarditis, febrile convulsions, and afebrile convulsions. In 2024, the following AESI were monitored with no reports made to WAVSS: thrombosis with thrombocytopenia syndrome, immune thrombocytopenic purpura, menstrual disturbance, acute disseminated encephalomyelitis, or death.

In 2024, the four reports of GBS following Shingrix identified via data linkage contributed to the Therapeutic Goods Administration's investigation and safety update for Shingrix.

The Western Australian Vaccine Safety Advisory Committee Expert Clinical Review Group clinically reviewed 85 reports in 2024. Thirty-two AEFI (<5% of all reported in 2024) were classified as causally associated with immunisation.

This report shows the changes to AEFI reports and report rates across vaccine groups in 2024 compared to the previous 4 years. This report highlights current reporting in the context of changes to national COVID-19 immunisation recommendations, established mandatory vaccination reporting to the Australian Immunisation Register (AIR), increased public and provider awareness of AEFI and AEFI reporting, and utilisation of active surveillance systems in Western Australia.

1. Definitions

Immunisation

Immunisation is the process of becoming immune to a disease as result of a vaccine.[1] This can be active or passive. Active immunisation uses vaccines to induce an immune response in the person receiving the vaccine. Passive immunisation is the direct transfer of antibodies to a non-immune person to provide temporary protection, such as vaccinating a pregnant woman and the antibodies made are transferred to the foetus which protect the newborn in their first months of life.[2]

Adverse event following immunisation

An adverse event following immunisation (AEFI) is defined as any unwanted or unexpected event following the administration of a vaccine or vaccines, including those not inherently related to the vaccine itself.[3] AEFI 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.

Serious adverse events following immunisation

An AEFI is determined as serious (SAEFI) if the report indicates a reaction that is considered life-threatening[4]. This report uses reports of hospitalisation as a proxy indicator for serious AEFI.

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. This includes anaphylaxis, febrile seizures, and neurological events such as Guillain-Barré syndrome.

Passive surveillance

Passive surveillance refers to a system which receives reports of AEFI submitted voluntarily by the recipient, a person on the recipient's behalf (i.e. their parent, guardian, carer, or relative), or the recipient's healthcare provider.

Active surveillance

Active surveillance refers to searching for and eliciting reports of AEFI.

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[1] "Fundamentals of immunisation", Australian Immunisation Handbook, https://immunisationhandbook.health.gov.au/contents/fundamentals-of-immunisation

[2] Immunisation products (i.e. monoclonal antibodies) are included when referring to vaccines and vaccinations in this report.

[3] "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

[4] "Reporting and managing adverse vaccination events", Australian Government Department of Health and Aged Care https://www.health.gov.au/topics/immunisation/immunisation-information-for-health-professionals/reporting-and-managing-adverse-vaccination-events#:~:text=A%20serious%20AEFI%20is%20one,or%20one%20of%20its%20ingredients

2. Background

2.1. AEFI reporting in Western Australia

In WA, there is a statutory requirement for medical and nurse practitioners to report AEFI to the department, per the requirements of the *Public Health Act 2016*[5] and the *Public Health Regulations 2017*[6]. Pharmacists, Aboriginal Health Practitioners, 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).[7]

2.2. Western Australian Vaccine Safety Surveillance system

The Western Australia Vaccine Safety Surveillance (WAVSS) system is a public health partnership between the WA Department of Health (the department) and Child and Adolescent Health Services (CAHS) to monitor safety of vaccines. WAVSS reviews AEFI reports and provides clinical support and education to vaccinees and immunisation providers. The WAVSS database is a repository for AEFI reported through passive and active surveillance methods and is essential for detecting rare, late onset or unexpected events that may not have been identified in clinical trials undertaken for licensure of vaccines. AEFI can be reported to WAVSS by phone, e-mail, or online using the online reporting portal 'SAFEVAC' (www.safevac.org.au) created by Victoria's SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community). All AEFI reports in the WAVSS database 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 SAEFI report.

2.3. Active surveillance

WAVSS has two active surveillance systems: SmartVax and the WA Health Vaccination Linked Data Repository (VLDR).

2.3.1. SmartVax

SmartVax 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 108 sites (General Practitioners (GP), community health clinics, and one 'site' for all metropolitan school-based immunisation programs) across WA. Surveys following vaccination at GP clinics are reported directly to the GP, who can review

[5] "Public Health Act 2016", Government of Western Australia, https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13791_homepage.html
[6] "Public Health Regulations 2017: Government of Western Australia, https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_s49088.html
[7] Structured Administration and Supply Arrangements: Government of Western Australia, https://www.health.wa.gov.au/Articles/S_T/structured-administration-and-supply-arrangements

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 being anaphylaxis-like symptoms.

For non-COVID-19 vaccines, surveys are sent 3 days post-vaccination. For COVID-19 vaccines, between March 2021 to July 2023 surveys were sent on days 3, 8 and 42 post-vaccination and from July 2023 onwards, sent on day 3 only.

De-identified, aggregated, national active surveillance data from SmartVax is shared with AusVaxSafety, 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.

2.3.2. Vaccination Linked Data Repository

The department conducts data linkage case finding to identify potential AEFI signals and mitigates the scenario where a healthcare provider or vaccine recipient does not report a potential SAEFI or AESI which resulted in ED presentation or hospital admission. The search criteria for specific medical conditions were modified throughout 2024 based on findings from local, national, and international vaccine safety surveillance reports. Potential AEFI identified through data linkage were reviewed by clinicians and entered into WAVSS when appropriate.

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 and hospital admission. Within the context of the 2024 annual report, routine scheduled data linkage was conducted to identify potential AESI associated with COVID-19 vaccines, influenza vaccines, mpox vaccines, the shingles vaccine Shingrix, and the RSV immunisation Beyfortus. The data linkage process searches for specific conditions of interest within a pre-defined time window following vaccination.

2.4. Expert Clinical Review Group

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. Where possible, assessment of causality for AESI was also undertaken by the ECRG using World Health Organization (WHO) criteria.

2.5. The Australian Immunisation Register

In 2021, a legislative change to the AIR Act 2015 made it mandatory for all vaccination providers to report influenza vaccinations on or after 1 March 2021 and National Immunisation Program (NIP) vaccinations administered on or after 1 July 2021 to the AIR.[8]

2.6. Changes to vaccine recommendations in 2024

Reports summarising WA AEFI surveillance data have been published regularly since 2011.[9] Changes to the State and National Immunisation Programs can influence trends in reported

[8] https://www.health.gov.au/news/mandatory-reporting-of-national-immunisation-program-vaccines-to-the-australianimmunisation-register-began-on-1-july-2021
[9] "Adverse event following immunisation: Reports & Publications", https://www.health.wa.gov.au/Articles/A_E/Adverse-event-following-immunisation-AEFI

AEFI over time. Recent changes to the immunisation schedule that impact AEFI data presented in this report include:

- *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.
- *February 2024:* COVID-19 vaccine booster dose recommended for specific groups[10] if their last vaccine dose or confirmed infection was ≥6 months ago.
- *March 2024:* Flucelvax Quad vaccine available for pregnant people and people aged 5 to 64 who identify as Aboriginal or Torres Strait Islander or with specific medical conditions.
- *April 2024:* WA RSV infant immunisation program provides free Beyfortus for all newborn infants, infants entering their first RSV season and children at-risk of severe RSV infection entering their second RSV season from 2nd April to 30th September 2024. Beyfortus was offered year-round from 2nd April to eligible infants in the Kimberley and Pilbara regions because of the increased risk of RSV transmission occurring outside the winter months.
- *May-June 2024:* WA Government provided state-funded influenza vaccination program for all residents from 1 May to 30 June 2024.
- *July 2024:* MenQuadfi becomes the MenACWY vaccine funded under NIP for adolescents and catch-up schedule for up to 19 years. Children aged 12 months and people with specific medical conditions continue to be funded to receive Nimenrix.
- *July 2024:* In response to an increase in mpox cases, mpox vaccination recommended to at-risk groups who are partially vaccinated or unvaccinated complete the 2-dose schedule as soon as possible.[11]

[10] "Significant events in COVID-19 vaccination practice in Australia", https://ncirs.org.au/sites/default/files/2024-05/COVID-19_May%202024.pdf

[11] "Significant events in mpox vaccination practice in Australia", https://ncirs.org.au/sites/default/files/2024-11/Mpox_November%202024.pdf

3. Methodology

3.1. Inclusion and exclusion criteria

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

- the vaccination occurred between 1 January 2020 and 31 December 2024,
- the address of the vaccination provider or the AEFI reporter was recorded as Western Australia,
- the suspected reaction was captured in the state reporting system (WAVSS), and
- the vaccination was initially assessed as ‘possibly’ or ‘definitely’ being the cause of, or contributing to, the reported adverse event. This includes AEFI reports where a determination is still pending.

AEFI reports were excluded from this report 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 of 31 March 2025. 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 2020 to 2024 in this report may differ slightly from previous annual reports due to delayed reporting.

3.2. 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) and/or month 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 of 11 April 2025.

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

- NIP vaccines; comprising all vaccines available on the 2024 WA Immunisation Schedule, excluding influenza vaccines
- Influenza vaccines
- COVID-19 vaccines
- Other vaccines; comprising all vaccines not included in the above groups.

3.3. Interpretation notes

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

3.3.1. 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.

3.3.2. 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.

3.3.3. Summary reporting interpretation

Descriptive statistics presented in this annual report are aggregated on either a

(i) per AEFI report basis,
(ii) (ii) per vaccine group basis, or
(iii) (iii) per vaccine basis, dependent on the context.

Analyses on the per AEFI report basis typically quantify details about the vaccinee. 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.[12] 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.

[12] "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

4. Overview of AEFI reported to WAVSS

WAVSS received 670 distinct AEFI reports encompassing 1,137 vaccines administered in 2024, resulting in an overall reporting rate of 30.6 per 100,000 vaccinations. The month with the highest number of AEFI reported was May, as also seen in 2023 (Figure 1). Monthly AEFI reports and reporting rate was relatively stable throughout 2024 (Figure 1) and similar to 2023.

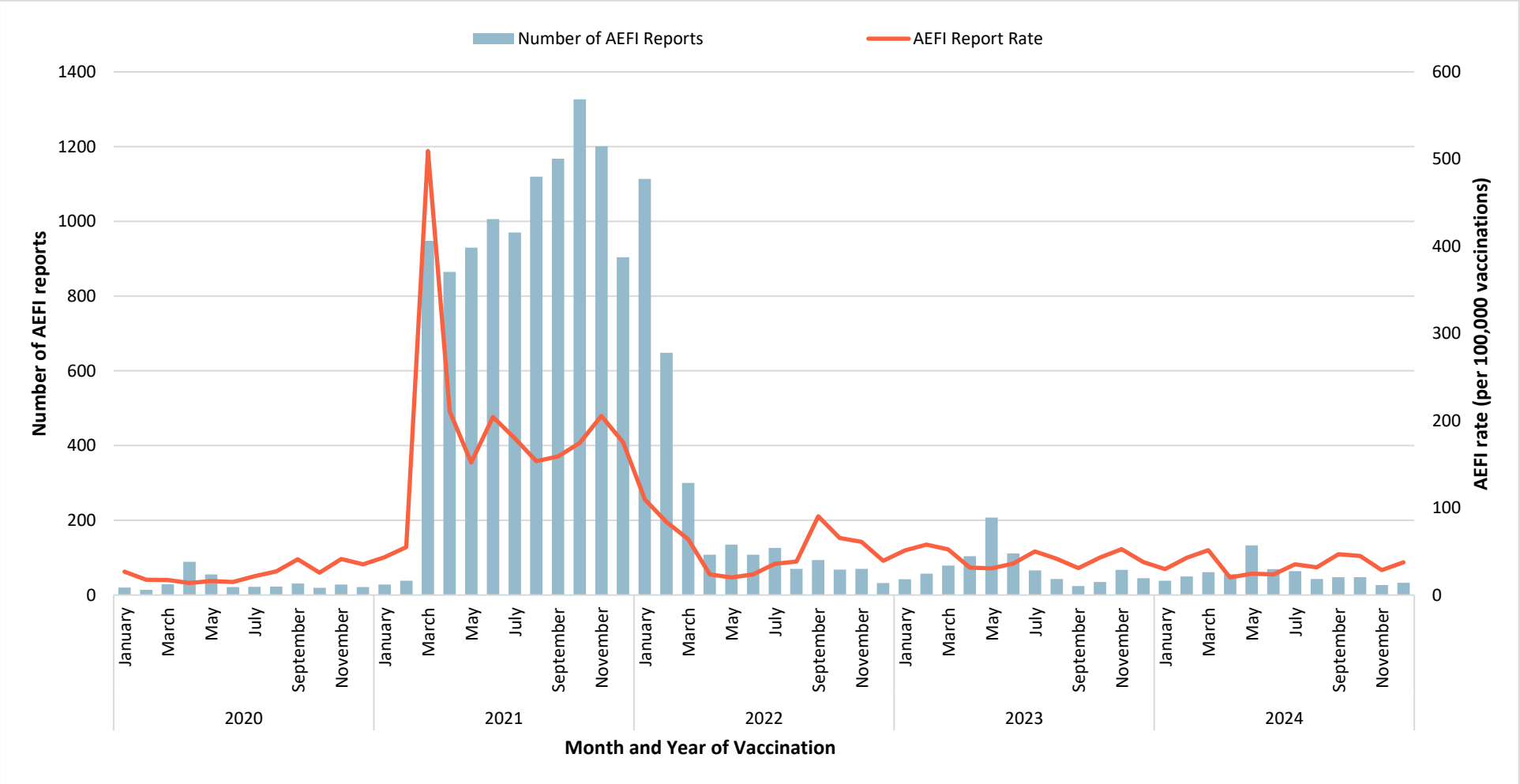

Figure 1. Number of AEFI reports and reporting rate per 100,000 vaccinations by vaccination month and year (2020-2024).

Over the 5-year reporting period, 2021 had the highest number of reports and reporting rate (Figure 1). This was due to reported AEFI following COVID-19 vaccination, which made up 97% of 2021 reports compared to 9% in 2024 (Figure 2).

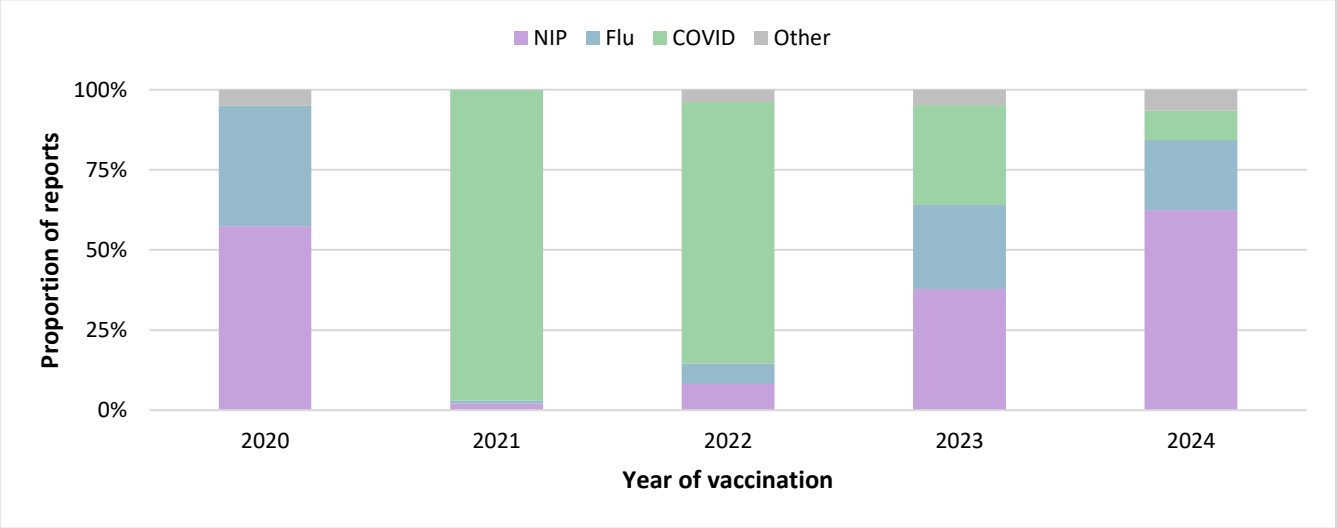

Figure 2. Proportion of AEFI reports by vaccine group and vaccination year (2020-2024).

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 2020-2024. Reports for 2024 had similar proportions for gender and Aboriginal status compared to the last 4 years (2020-2023).

AEFI reported for children aged under 5 comprised 41% of all reports, similar to 2020 and higher than the previous 3 years (Table 1 and Figure 3). This was due to decreased reports for adults aged 18 to 64 years compared to 2021 to 2023, with 2024 having the smallest proportion of reports for this age group (15%) in the reporting period. Proportion of reports for adults aged 65 and above in 2024 (26%) was the same as 2023 and higher than 2020-2022, largely due to Shingrix and COVID-19 vaccinations. Lastly, the proportion of reports for children and adolescents aged 5 to 17 (18%) in 2024 was the same as 2020 and similar to 2022-2023.

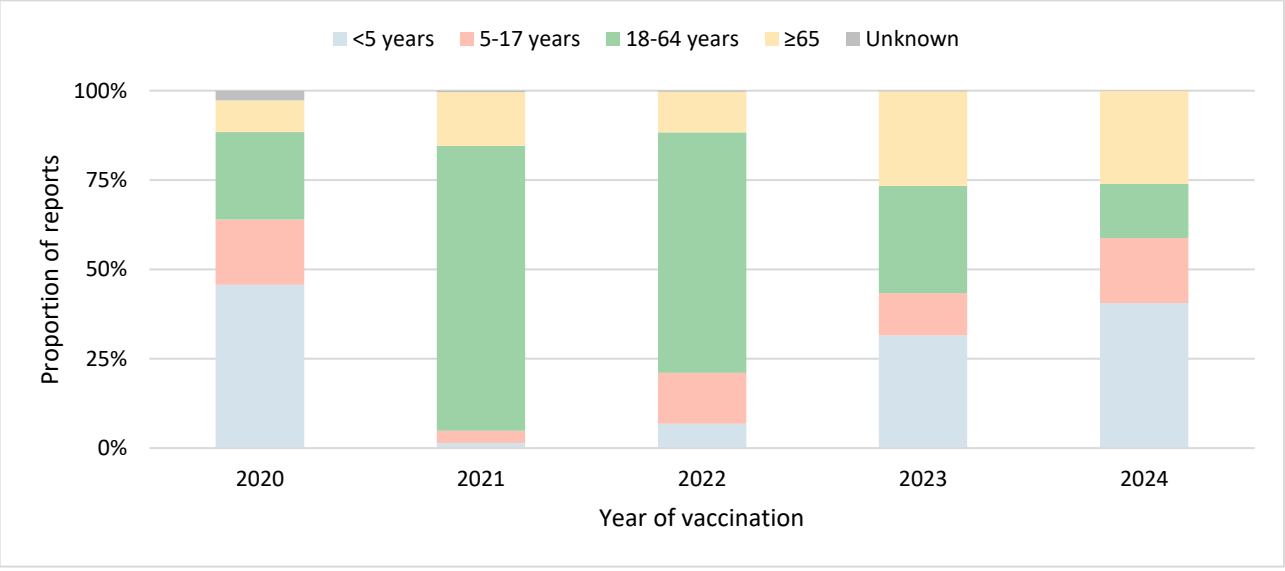

Figure 3. Proportion of AEFI reported by age group and year of vaccination, 2020-2024.

Table 1. Characteristics of AEFI reports to WAVSS, 2020-2024

Characteristic	2020 N = 372	2021 N = 10,505	2022 N = 2,873	2023 N = 880	2024 N = 670
Gender					
Female	217 (58%)	6,719 (64%)	1,650 (57%)	478 (54%)	383 (57%)
Male	155 (42%)	3,716 (36%)	1,211 (42%)	380 (43%)	285 (43%)
Unknown*	0 (0%)	25 (0.2%)	12 (0.4%)	22 (2.5%)	2 (0.3%)
Aboriginal Status					
Aboriginal**	29 (7.8%)	193 (1.8%)	75 (2.6%)	35 (4.0%)	34 (5.1%)
Non-Aboriginal	301 (81%)	9,409 (90%)	2,447 (85%)	755 (86%)	570 (85%)
Unknown	42 (11%)	903 (8.6%)	351 (12%)	90 (10%)	66 (9.9%)
Age Group					
<5 years	170 (46%)	152 (1.4%)	195 (6.8%)	278 (32%)	272 (41%)
5-17 years	68 (18%)	358 (3.4%)	410 (14%)	104 (12%)	122 (18%)
18-64 years	91 (24%)	8,373 (80%)	1,932 (67%)	264 (30%)	101 (15%)
≥65 years	33 (8.9%)	1,578 (15%)	327 (11%)	232 (26%)	174 (26%)
Unknown	10 (2.7%)	44 (0.4%)	9 (0.3%)	2 (0.2%)	1 (0.1%)
Surveillance/Reporter Type					
Active					
Vaccine Linked Data Repository***	N/A	256 (2.4%)	372 (13%)	44 (5.0%)	70 (10%)
SmartVax****	88 (24%)	3,589 (34%)	522 (18%)	489 (56%)	289 (43%)
Passive					
Administration/Other	10 (2.7%)	145 (1.4%)	34 (1.2%)	14 (1.6%)	6 (0.9%)
General Practitioner/Nurse	211 (57%)	3,451 (33%)	917 (32%)	221 (25%)	236 (35%)
Pharmacist	27 (7.3%)	209 (2%)	100 (3.5%)	11 (1.3%)	18 (2.7%)
Self/Parent/Guardian	36 (9.7%)	2,855 (27%)	928 (32%)	101 (11%)	51 (7.6%)
Immunisation Provider Type					
General Practitioner	222 (60%)	3,212 (31%)	930 (32%)	351 (40%)	291 (43%)
Community Clinic	52 (14%)	3,558 (34%)	744 (26%)	229 (26%)	198 (30%)
Pharmacy	31 (8.3%)	712 (6.8%)	720 (25%)	168 (19%)	65 (9.7%)
Hospital	27 (7.3%)	2,100 (20%)	203 (7.1%)	59 (6.7%)	48 (7.2%)
Other	21 (5.6%)	159 (1.5%)	45 (1.6%)	18 (2%)	14 (2.1%)
Unknown	19 (5.1%)	764 (7.3%)	231 (8%)	55 (6.3%)	54 (8.1%)
Any medical attendance					
Yes	228 (61%)	7,914 (75%)	1,925 (67%)	618 (70%)	450 (67%)
Management*** (% Yes)**					
Admitted to Hospital	19 (5.1%)	1,009 (9.6%)	320 (11%)	49 (5.6%)	60 (9%)
Emergency Department	66 (18%)	4,997 (48%)	1,064 (37%)	199 (23%)	153 (23%)
General Practitioner	150 (40%)	3,122 (30%)	909 (32%)	399 (45%)	258 (39%)
Helpline	15 (4%)	382 (3.6%)	108 (3.8%)	39 (4.4%)	39 (5.8%)
Nurse	45 (12%)	543 (5.2%)	131 (4.6%)	44 (5%)	43 (6.4%)

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%.

Over half of reports received by WAVSS for 2024 were reported via active surveillance (Table 1 and Figure 4). In 2024 there were fewer AEFI reported via self/parent/guardian or SmartVax than in 2023 and thus a lower proportion of overall reports. AEFI reported via data linkage increased in 2024, resulting in representing a higher proportion of all reports (10%).

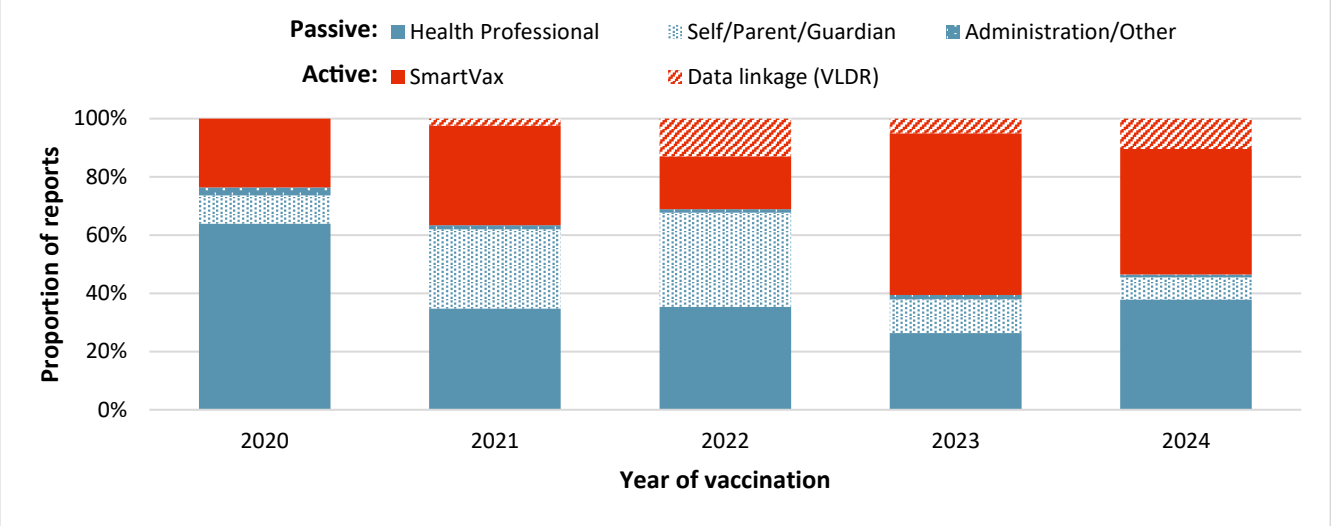

Figure 4. Proportion of AEFI reported by surveillance type and year of vaccination, 2020-2024.

The majority of AEFI reported for 2024 were following vaccination provided by a general practitioner (43%) or community clinic (30%), reflecting these as prominent service providers (Table 1). Proportion of reports with vaccination provided by pharmacist decreased from 19% in 2023 to 9.7% in 2024. Other provider types of AEFI reported for 2024 were similar to 2023.

Reported medical attendance in 2024 was similar to 2020-2023, with the proportion of AEFI managed by general practitioners slightly less than 2023, and reports of hospital admission slightly increased. Increased reports of hospital admission in 2024 are in part due to data linkage, which identified possible AEFI by hospital admission or attendance to an emergency department.

5. Adverse events following NIP vaccines

In 2024, there were 470 distinct AEFI reports encompassing 847 NIP vaccines administered in 2024, greater than the average of the preceding four years (268 reports per year). In 2024, the overall AEFI report rate for NIP vaccines was 47.5 per 100,000 NIP vaccinations, greater than the average of 33.8 per 100,000 NIP vaccinations between 2020-2023 (Figure 5). This was due to increased AEFI reporting rates for DTPa-HepB-IPV-Hib, pneumococcal, rotavirus, meningococcal vaccines in young children, and dTPa, meningococcal and HPV vaccines in adolescents (Table 2). There was no seasonality to AEFI reported following NIP vaccinations between 2020 and 2024.

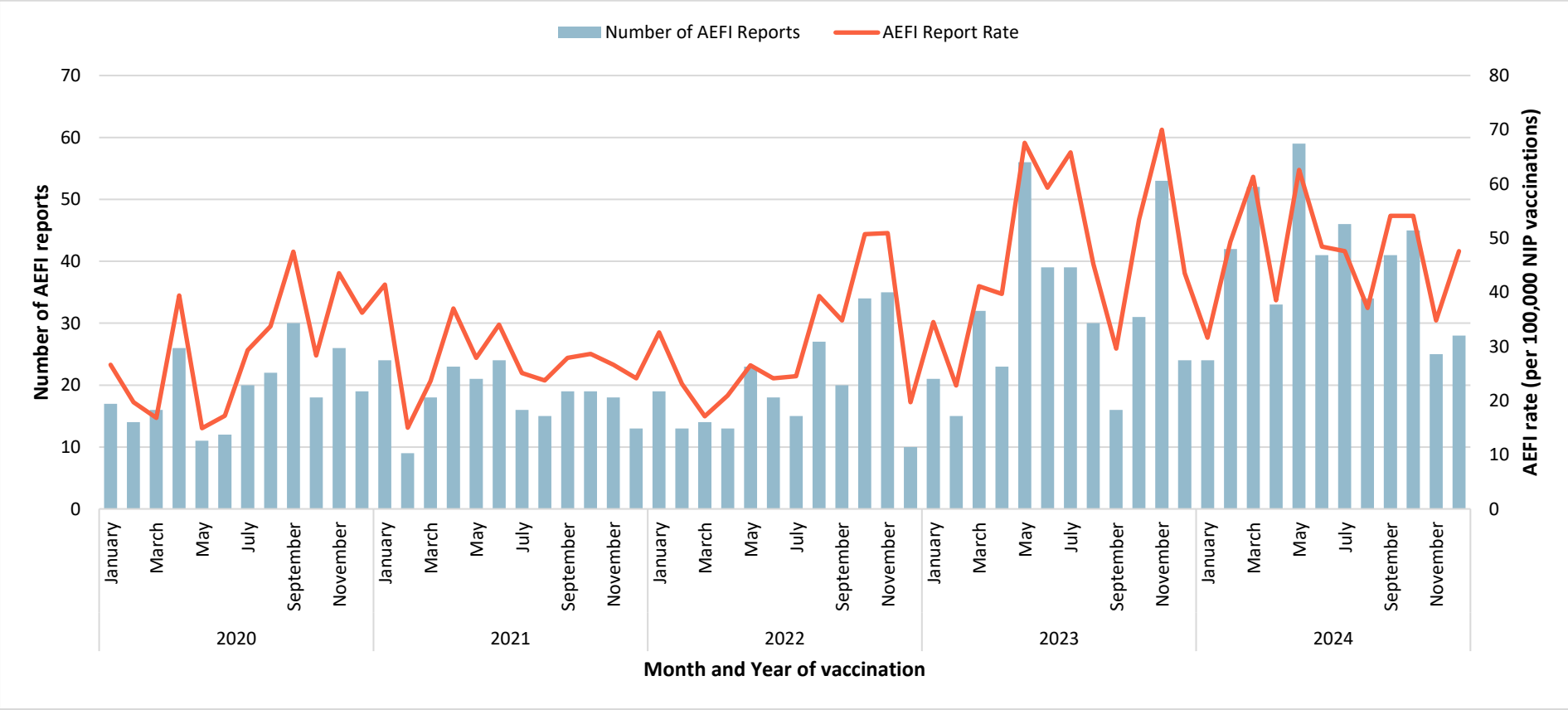

Figure 5: Number of AEFI reports following NIP vaccines and AEFI report rate per 100,000 NIP vaccinations by vaccination month and year (2020-2024).

Half (53%) of AEFI reports following NIP vaccinations were for children aged under 5, almost a quarter (24%) were for older adults over 65, 18% were for children and adolescents aged 5 to 17, and the remaining 5% were for adults 18 to 64 years of age.

In 2024, the AEFI reporting rate for children under 5 was 53.0 per 100,000 NIP vaccinations, 128.0 per 100,000 NIP vaccinations for persons aged 5-17 years, 17.9 per 100,000 NIP vaccinations for 18-64 years and 42.5 per 100,000 NIP vaccinations for adults 65 years and above. Table 2 presents the AEFI report rate for vaccines available on the NIP by antigen and age group.

For children aged under 5 years, the most AEFI were reported following pneumococcal and DTPa-HepB-IPV-Hib[13] vaccines. MenACWY, MMR and pneumococcal antigens had increased AEFI reports and reporting rates in 2024, similar to what was observed in 2023 (Table 2). These antigens are offered at the same time to 12-month-old infants on the WA Immunisation Schedule. Reporting for these antigens increased via SmartVax in community health clinic sites and to a lesser extent data linkage which monitored medical attendance following influenza or nirsevimab which were co-administered with these vaccines.

AEFI reporting rates of HPV, meningococcal and dTpa in people aged 5 to 17 increased in 2024, similar to in 2023 (Table 2). This is in part due to increased reporting of AEFI via SmartVax, and for HPV partly due to reduced number of doses administered as the schedule of Gardasil-9 became a single dose in 2023.

The majority (92%) of reports following NIP vaccines for older adults (≥65) were following Shingrix, which was added to the NIP in November 2023 for adults aged 65 years and over, people with certain medical conditions, and Aboriginal people aged 50 years and over. In 2024, the 108 AEFI reported following Shingrix in older adults resulted in an AEFI rate of 43.2 per 100,000 Shingrix doses.

The most common reactions following NIP vaccines administered in 2024 to all age groups were minor and expected reactions (Figure 6).

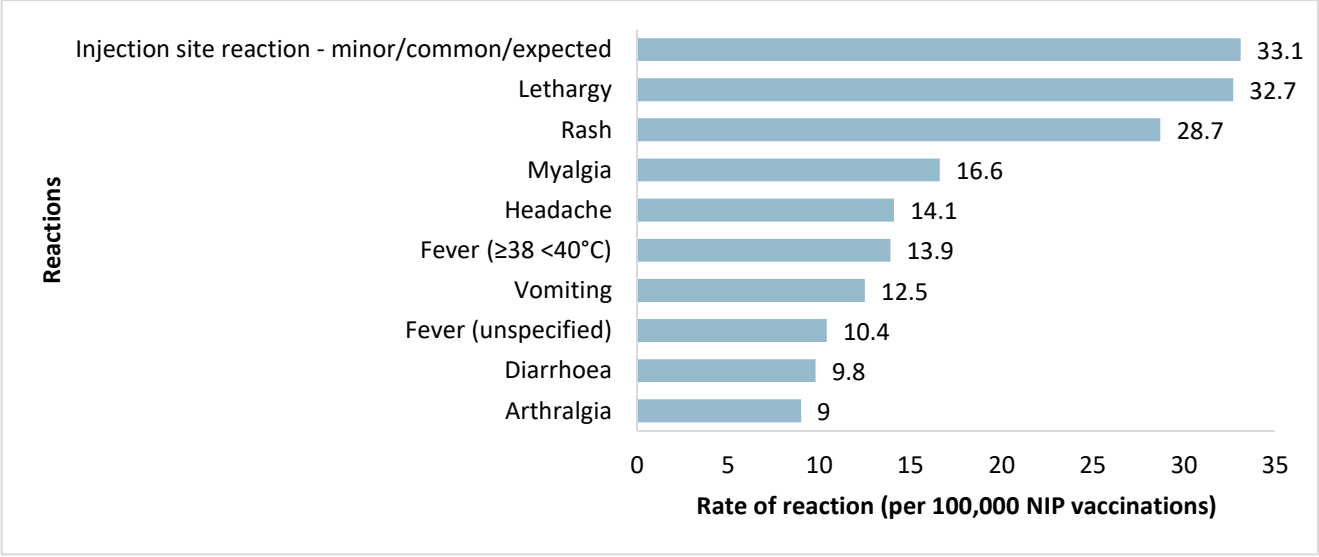

Figure 6: Ten most commonly reported reactions following NIP vaccines by rate (reactions per 100,000 NIP vaccinations).

[13] Diphtheria-tetanus-pertussis-hepatitis B–polio-Hib

Table 2. Number of AEFI reported and AEFI report rate per 100,000 NIP vaccinations (excluding influenza) by age group and antigen/s, 2020-2024.

		2020		2021		2022		2023		2024	
Age group (years)	**Antigen**	**AEFI**	**Rate**	**AEFI**	**Rate**	**AEFI**	**Rate**	**AEFI**	**Rate**	**AEFI**	**Rate**
<5	DTPa	25	79.7	23	73.6	24	77.4	37	116.7	26	87.8
	DTPa-HepB-IPV-Hib	49	53.3	44	46.0	64	70.1	75	89.4	104	122.9
	DTPa-IPV	30	89.7	31	94.1	36	116.0	56	176.8	42	135.7
	Hep A	2	55.3	1	41.3	3	106.0	4	97.9	4	82.5
	Hep B	3	250.0*	1	25.7	1	14.2	1	15.0	1	9.2
	Hib	22	71.9	19	61.4	22	71.6	31	99.5	26	89.9
	Men ACWY	33	81.6	34	91.8	29	75.3	46	120.3	58	157.8
	Men B	14	84.0	12	54.9	15	72.5	26	112.2	27	120.2
	MMR	34	105.9	28	89.9	30	91.3	42	132.3	40	134.3
	MMRV	23	72.5	21	66.5	26	82.7	29	89.4	27	88.6
	Pneumococcal	69	72.7	70	71.2	76	79.3	98	109.6	128	145.1
	Rotavirus	31	53.5	32	52.8	37	65.1	43	84.2	66	127.2
5-17	dTpa	8	23.3	11	34.5	8	25.6	35	113.5	44	139.9
	HPV	27	43.9	27	51.1	21	34.4	32	108.2	46	160.2
	Men ACWY	7	24.4	9	33.3	8	29.5	31	108.9	36	121.7
18-64	MMR	1	9.9	1	13.9	1	13.6	3	33.2	-	-
65+	Pneumococcal	18	30.7	14	31.4	7	17.1	6	19.5	10	28.7
	Zoster	1	6.7	5	29.5	6	23.5	37	73.1	108	45.1

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 pneumococcal vaccine in the same vaccination encounter, a count of 1 AEFI report would be ascribed against both rotavirus and DTP.
Excludes reports with unknown age (n=2).
* Less than 1250 doses on AIR.

6. Adverse events following influenza vaccines

In 2024, there were 165 adverse event reports following influenza vaccines, slightly less than the average of the preceding four years (174 reports per year). In 2024, the overall AEFI report rate for influenza vaccines was 20.5 per 100,000 influenza vaccinations, similar to the average of 18.0 per 100,000 influenza vaccinations between 2020-2023.

A seasonal pattern of AEFI reporting was apparent in 2024 (Figure 7), as in previous years, corresponding to the months when influenza vaccine is predominantly given – April, May and June. AEFI rate peaks are seen each year between November and March, corresponding to lower number of influenza vaccinations in that time period.

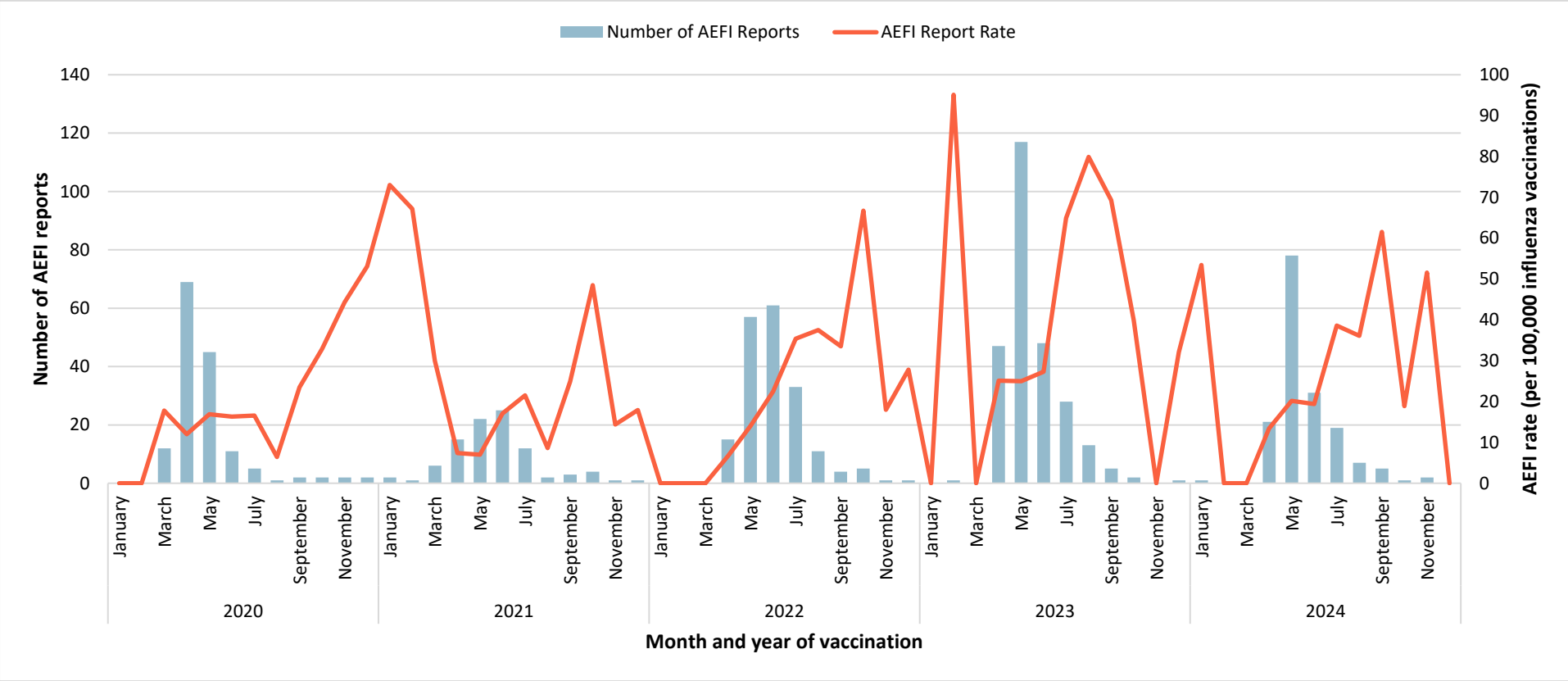

Figure 7: Number of AEFI reports following influenza vaccines by vaccination month and year overlayed with AEFI report rate per 100,000 influenza vaccinations by vaccination month and year (2020-2024).

In 2024, the highest number of AEFI reports following influenza vaccination occurred in children aged under 5 years (32.7%), then adults aged 18 to 64 years (29.1%), persons aged 5 to 17 years (19.4%) and finally adults over 65 years (18.2%). Fewer AEFI following influenza vaccination were reported in 2024 compared to 2023 for children under 5, adults 18 to 64 years and older adults aged ≥65 years, all with reduced reporting rates (Table 3).

Table 3. Number of AEFI reported and AEFI report rate per 100,000 influenza vaccinations by age group, 2020-2024.

	2020		2021		2022		2023		2024	
Age group (years)	AEFI	Rate	AEFI	Rate	AEFI	Rate	AEFI	Rate	AEFI	Rate
<5	25	25.3	21	46.5	33	57.2	80	150.2	54	126.9
5-17	30	19.3	11	16.3	31	32.8	30	34.9	32	50.7
18-64	71	14.2	46	11.7	84	14.7	97	20.7	48	12.2
65+	19	6.5	16	5.4	38	11.2	53	16.6	30	9.9

Excludes reports with unknown age (n=11).

The most frequently reported reactions following influenza vaccines across all age groups were common, minor and expected (Figure 8).

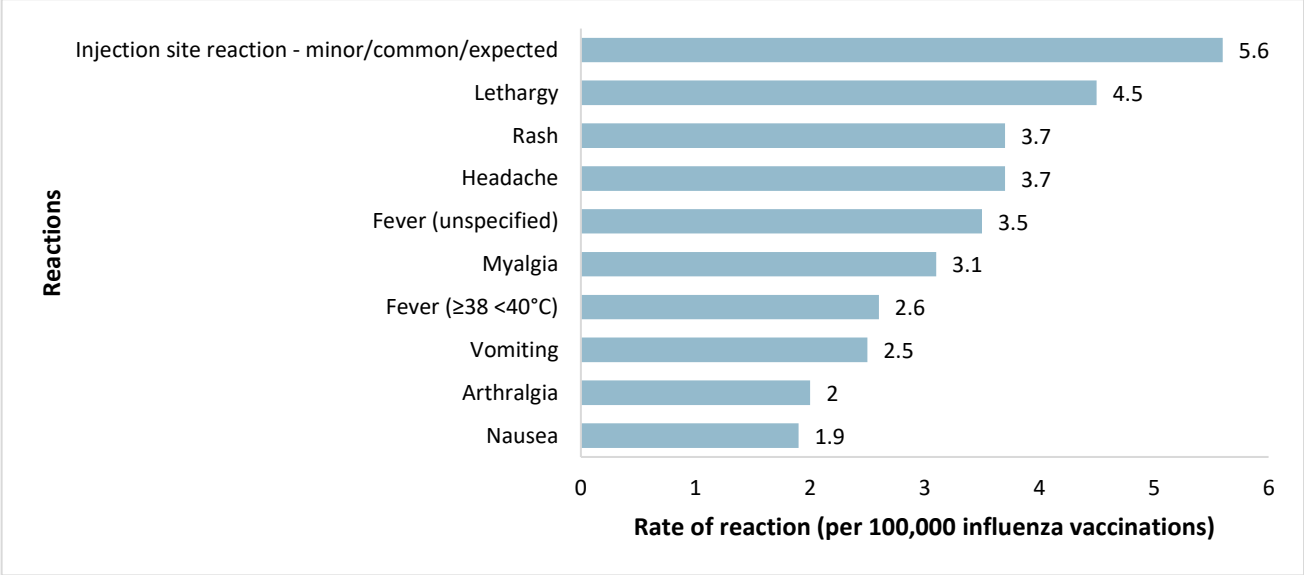

Figure 8: Ten most commonly reported reactions following influenza vaccine by rate (reactions per 100,000 influenza vaccinations).

7. Adverse events following COVID-19 vaccines

In 2024, there were 69 individual AEFI reports for persons vaccinated with a COVID-19 vaccine, resulting in a reporting rate of 26.2 per 100,000 COVID-19 vaccinations. This is significantly lower than the average for 2021-2023 (4,307 AEFI reports and rate of 133.0 per 100,000 COVID-19 vaccinations), and lower than 2023 (312 AEFI reports and rate of 64.4 per 100,000 COVID-19 vaccinations). Figure 9 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 2024. In 2024, more AEFI were reported in January, May and June, and the reporting rate remained relatively stable (Figure 9 inset).

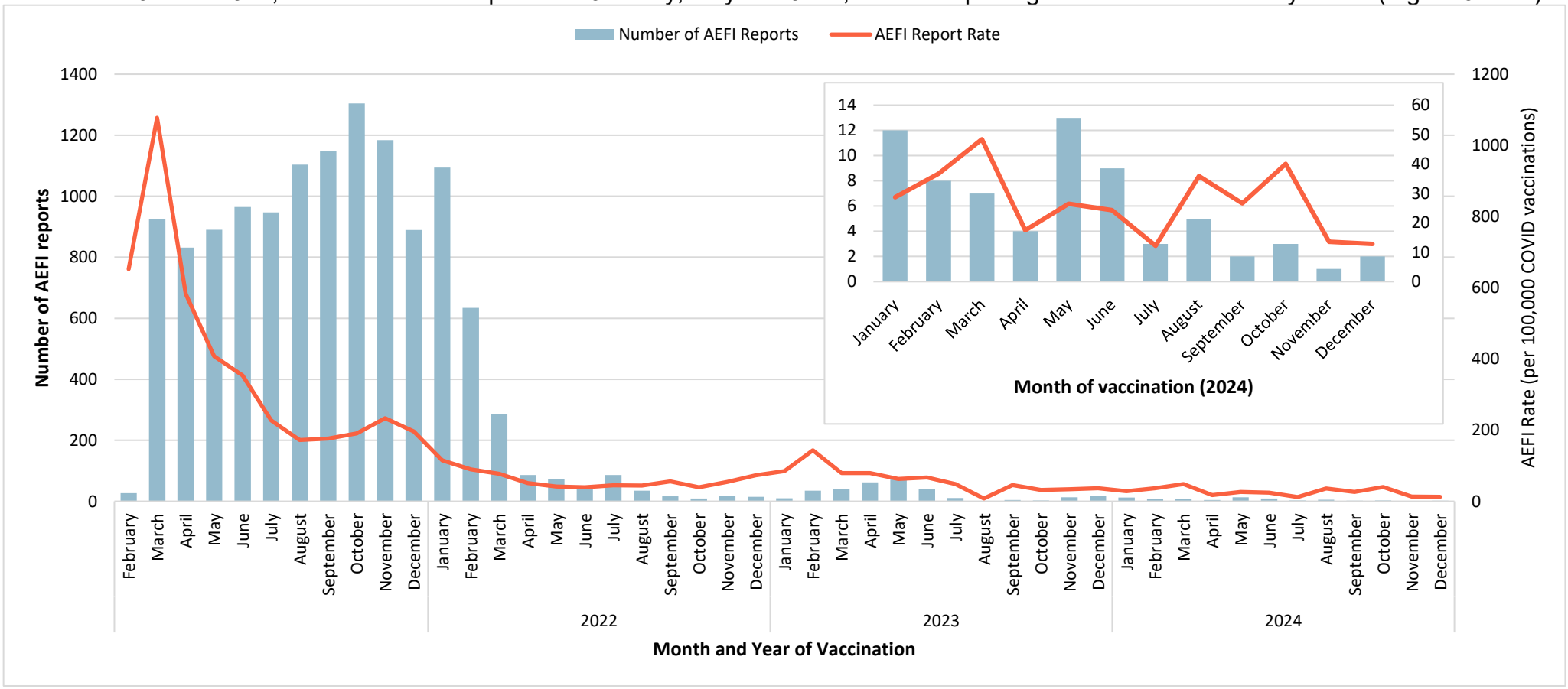

Figure 9: Number of AEFI reports following COVID-19 vaccines by month of vaccination, overlayed with AEFI reporting rate per 100,000 COVID-19 vaccinations, 2021-2023. Inset shows 2023 data.

In 2024, the highest number of AEFI reports following COVID-19 vaccination occurred in adults aged 65 and above (55%), then adults aged 18 to 64 years (41%), and persons aged 5 to 17 years (4%). There were no AEFI reported following COVID-19 vaccination for children aged under 5 years. Fewer AEFI following COVID-19 vaccination were reported in 2024 compared to previous years for children under 5, adults 18 to 64 years and older adults aged ≥65 years, and similar number of reports for persons aged 5 to 17 (Table 4). The reporting rate for persons aged 5 to 17 years for 2024 is affected by the low number of COVID-19 vaccinations (<1,200) recorded on AIR.

Table 4. Number of AEFI reported and AEFI report rate per 100,000 COVID-19 vaccinations by age group, 2020-2024.

	2021		2022		2023		2024	
Age group (years)	**AEFI**	**Rate**	**AEFI**	**Rate**	**AEFI**	**Rate**	**AEFI**	**Rate**
<5	0	-	1	#	1	#	0	-
5-17	305	115.3	351	85.5	2	40.5	3	263.6^
18-64	8,400	283.2	1,744	98.2	149	77.5	28	32.6
65+	1,559	184.6	292	43.9	160	55.8	38	21.5

Rate not computable due to low numbers.
^ Less than 1,200 doses recorded on AIR.
Excludes reports with unknown age (n=50).

Eight of the 10 most commonly reported reactions following COVID-19 vaccination are minor expected reactions (Figure 10). There were two adverse events of special interest (AESI) in the top 10 reactions; six reports of pericarditis and six reports of Bell's palsy, all were identified via data linkage.

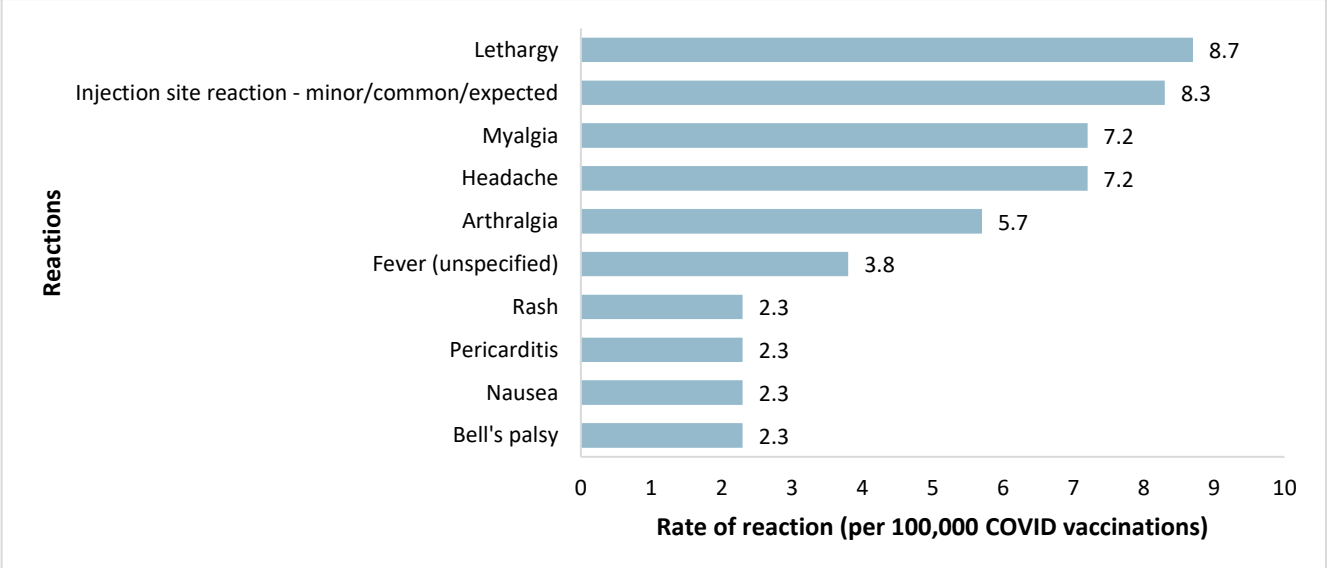

Figure 10: Ten most commonly reported reactions following COVID-19 vaccines by rate (reactions per 100,000 COVID-19 vaccinations). Fever (unspecified) means no determined temperature was reported.

8. Adverse events following other vaccines

The ‘Other’ vaccine group is comprised of AEFI reported following travel vaccines, privately administered vaccines, state-funded immunisation programs (excluding influenza), or vaccines recorded by antigen only (unspecified brand).

During the reporting period, an unusually high number of AEFI were reported in 2022 (n=119; Figure 11). This was because of specialised active monitoring of reactions following newly introduced mpox vaccinations (n=100).[14]

In 2024, there were 49 distinct AEFI reports encompassing 56 vaccines, similar to the average number of reports for 2020-2023 (48 reports per year; Figure 11). Of the 49 reports, 25 were following Beyfortus, accounting for the relative peak in April and May (Figure 11). Beyfortus, a monoclonal antibody, protects infants from severe Respiratory Syncytial Virus (RSV) illness and was offered to all infants in WA entering their first RSV season and infants at risk of severe RSV illness entering their second season. No serious reactions were assessed as being due to Beyfortus.

In 2024, the ‘other’ vaccine group had a reporting rate of 37.2 per 100,000 ‘other’ vaccinations, lower than the average rate for 2020-2023 (73.4 per 100,000 vaccinations) which was impacted by the atypical peak in reports in 2022.

[14] Mpox immunisation vaccine history: https://ncirs.org.au/health-professionals/history-immunisation-australia

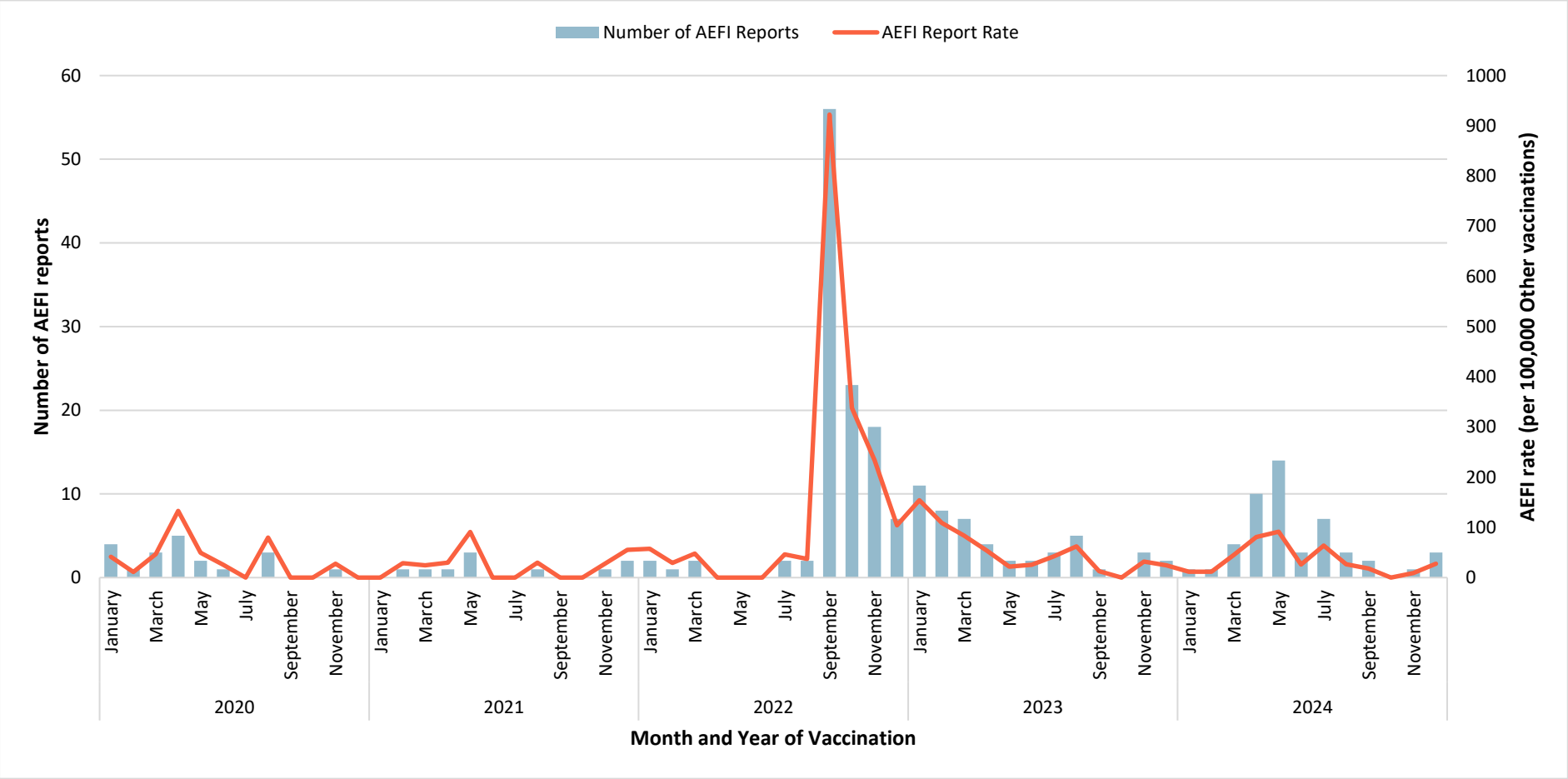

Figure 11. Number of AEFI reports following 'other' vaccines by vaccination month and year overlayed with AEFI report rate per 100,000 'other' vaccinations by vaccination month and year (2020-2024).

For 2024, the 10 most commonly reported reactions for ‘other’ vaccines were common and expected reactions (Figure 12).

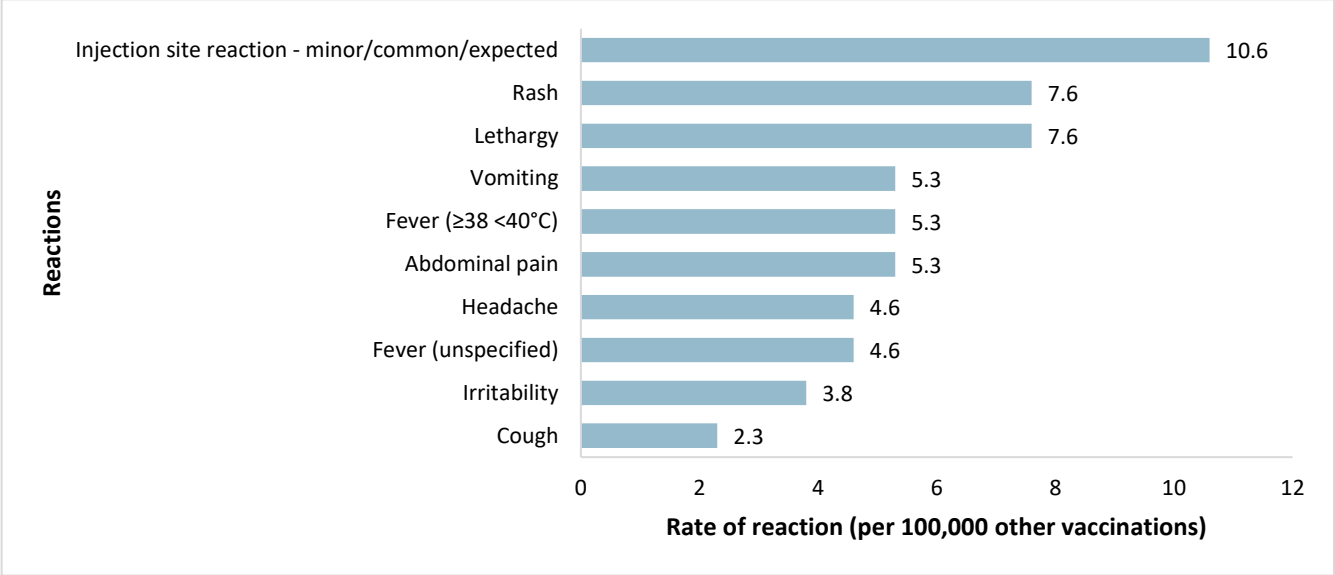

Figure 12. Ten most commonly reported reactions following ‘other’ vaccines by rate (reactions per 100,000 vaccinations).

9. Adverse events of special interest

As defined in Table 5, specific adverse events of special interest (AESI) were monitored across all vaccine groups, utilising routine passive surveillance and active surveillance methods, specifically through the data linkage case finding.

Table 5. Defined adverse events of special interest, 2024.

AESI	Definition	
Anaphylaxis	A potentially life-threatening allergic reaction occurring rarely after vaccination, with onset typically within minutes to hours.	
Acute disseminated encephalomyelitis (ADEM)	A brief but intense attack of inflammation (swelling) in the brain and spinal cord.	
Bell's palsy	Paralysis of the facial nerve causing muscular weakness in one side of the face.	
Febrile convulsions	Seizures that occur mostly in children that result from a sudden rise in body temperature.	
Afebrile convulsions	Seizures that occur in the absence of fever.	
Guillain-Barré syndrome (GBS)	An immune disorder where nerves are attacked by immune cells resulting in pain, numbness, muscles weakness and/or difficulty walking.	
Immune thrombocytopenic purpura (ITP)	An autoimmune disease where the immune system attacks platelets in the blood and megakaryocytes in the bone marrow, resulting in low platelet counts, causing easy bruising and bleeding.	
Thrombosis with thrombocytopenia syndrome (TTS)	A very rare syndrome with blood clots (thrombosis) and low platelet count (thrombocytopenia).	
Menstrual disturbance	A deviation from normal or expected menstrual cycle, can include irregular periods, heavy or prolonged bleeding, or painful cramps.	
Myocarditis	Inflammation of the heart muscle.	Can manifest as chest pain, shortness of breath, abnormal heart beats, or pain with breathing.
Pericarditis	Inflammation of the tissue surrounding the heart muscle.	
Myopericarditis	Both myocarditis and pericarditis.	
Death	End of life.	

Table 6 summarises AESI reports and reporting rates by vaccine group for 2024. If an AESI resulted following co-administration of vaccines across these groups, that AESI is recorded against both vaccine groups.

In 2024, WAVSS received:

- 6 reports of anaphylaxis
- 7 reports of Bell's palsy (2 following co-administered vaccines)
- 15 reports of febrile convulsion
- 5 reports of afebrile convulsion (1 following co-administered vaccines; 4 had a confirmed medical condition associated with seizures)
- 6 reports of GBS
- 2 reports of ITP
- 2 reports of myocarditis (1 following co-administered vaccines)
- 6 reports of pericarditis (2 following co-administered vaccines), and
- no reports of ADEM, TTS, menstrual disturbance, or death.

Of the 6 reports of GBS, 4 were following Shingrix vaccine, and one was classified with consistent causal association for a vaccine product-related reaction, under the World Health Organization classification criteria. On 29 October 2024, the TGA published a safety update that the product information and consumer medicine information documents for Shingrix were updated to recognise that GBS is a very rare adverse event.[15]

Table 6. Number of adverse events of special interest (AESI) reported and AESI report rate per 100,000 vaccinations by vaccine group, 2024.

	Vaccine Group							
	NIP		Influenza		COVID-19		Other	
AESI	Event	Rate	Event	Rate	Event	Rate	Event	Rate
Anaphylaxis	3	0.3	3	0.4	-		-	
Bell's Palsy	2	0.2	2	0.3	6	2.3	-	
Convulsion - febrile	9	2.0*	5	10.3*	-		1^	4.3*
Convulsion - afebrile	4	0.9*	2	4.1*	-		1^^	4.3*
GBS	4	1.4**	2	0.7**	-		-	
ITP	1	0.1	1	0.1	-		-	
Myocarditis	-		1	0.1	2	0.8	-	
Pericarditis	-		2	0.3	5	1.9	1^^^	0.8

Event = Number of AEFI reported. Rate = AEFI reported per 100,000 vaccine group doses in 2024.
*AEFI per 100,000 vaccine group doses in children aged up to and including 5 years.
**AEFI per 100,000 vaccine group doses in adults aged 65 years and above.
^Following DTPa-IPV (brand unspecified) vaccine.
^^following Beyfortus co-administered with NIP vaccine.
^^^following mpox vaccine.

[15] Shingrix vaccine and very rare risk of Guillain-Barre Syndrome. https://www.tga.gov.au/news/safety-updates/shingrix-vaccine-and-very-rare-risk-guillain-barre-syndrome

10. Causality assessment of serious AEFI

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 serious AEFI (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 670 AEFI reports reviewed in 2024, 585 were determined to not be serious. The remaining 85 reports were designated a WHO causality classification, as described in Table 7. Of the 32 reports with A1 classifications there were 5 AESI: 3 reports of anaphylaxis and 2 reports of febrile convulsion.

Table 7. WHO causality classification of serious AEFI reports

WHO causality classification	**Number of AEFI reports**
A1 (consistent causal association: vaccine product-related reaction)	32
A3 (consistent causal association; immunisation error-related reaction)	2
A4 (consistent causal association: immunisation anxiety-related reaction)	3
B1 (indeterminate: consistent temporal relationship but insufficient evidence for causality)	15
B2 (indeterminate: conflicting trends of consistency and inconsistency with causality)	13
C (inconsistent causal association to immunisation [coincidental])	16
D (ineligible)	4
Total	85

11. Specialist clinic activity

11.1. 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 165 AEFI reports resulted in a referral to a specialist clinic; 100 to the Perth Children's Hospital Specialist Immunisation Clinic (SIC) and 65 to the adult vaccine safety clinic at Sir Charles Gairdner Hospital (SCGH).

11.2. Child and adolescent clinic activity

In 2024, there were 756 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. Of the 550 attended appointments, 106 (19.3%) were due to possible AEFI with 75 of those via WAVSS referrals, 170 (31.0%) for complex medically-at-risk immunisation requirements, 59 (10.7%) for vaccine hesitancy, and 215 (39.1%) for needle anxiety.

12. WA Vaccine Safety Advisory Committee and Expert Clinical Review Group

The Western Australia's Vaccine Safety Advisory Committee (WAVSAC) met 4 times in 2024.

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 10 times in 2024 and reviewed 85 AEFI reports (Table 7).

13. Summary and Discussion

A summary of the past 5 years of vaccine safety surveillance in WA is presented in Table 8.

Table 8: AEFI reported, vaccinations, and AEFI report rate (per 100,000 vaccinations) by vaccine group and year(s) of vaccination

Vaccine Group	AEFI Reports 2020-2023	Vaccinations 2020-2023	Report Rate 2020-2023	AEFI Reports 2024	Vaccinations 2024	Report Rate 2024
NIP**	1,955	3,171,548	61.6	847	988,677	85.7
Influenza	695	3,837,552	18.1	165	804,526	20.5
COVID-19*	13,014	7,411,700	175.6	69	263,622	26.2
Other**	209	258,320	80.9	56	131,752	42.5

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

Relative to 2020-2023, the 2024 AEFI report rate increased for NIP vaccines, due to an increase in the number of reports via active surveillance. In 2024, the highest AEFI reporting rate for children under 5 was following MenACWY and pneumococcal vaccines. The 2024 AEFI report rate for influenza vaccines remained similar to the rate for 2020-2023. The AEFI report rate for COVID-19 vaccines significantly decreased in 2024 compared to 2020-2023 (from 175.6 to 26.2 per 100,000 vaccinations). This reflects the national recommendations of COVID-19 booster vaccinations only for adults aged 65 and above.[16] The lower AEFI rate for 'other' vaccines in 2024 compared to 2020-2023 is affected by 2022 having an atypical high number of reports from actively monitoring AEFI following mpox vaccination.

The most common reactions across vaccine groups were common and minor, with the exception of the AESI pericarditis and Bell's palsy being in the top 10 reactions following COVID-19 vaccinations, both solely identified via data linkage.

Data linkage is the predominant surveillance method for SAEFI and AESI in WA, and in 2024 was used to monitor AESI for Shingrix, Beyfortus, and mpox, COVID-19 and influenza vaccines. Key findings from data linkage included reports of GBS following Shingrix which contributed to the TGA's safety update for Shingrix, reduced reports of myocarditis and pericarditis following COVID-19 vaccines, and a favourable safety profile of Beyfortus, a novel immunisation product to protect newborns and infants from RSV. Of the 670 possible serious AEFI reports received by WAVSS in 2024, less than 5% (n=32) were classified as having consistent causal association for a vaccine product-related reaction.

WAVSS continues to be well-supported by WAVSAC and ECRG, providing specialists with expertise in vaccine safety, and clinicians with expertise in assessing and managing SAEFI and AESI. WA's comprehensive immunisation safety surveillance system enhances monitoring of possible safety concerns and ensures public confidence in the state immunisation program.

[16] COVID-19 vaccine advice and recommendations. https://www.health.gov.au/our-work/covid-19-vaccines/getting-your-vaccination

Abbreviations

Term	Meaning
AEFI	Adverse event following immunisation
AESI	Adverse events of special interest
AIR	Australian Immunisation Register
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
NIP	National Immunisation Program
PCH	Perth Children's Hospital
SAEFI	Serious adverse event following immunisation
SAEFVIC	Surveillance of Adverse Events Following Vaccination in the Community
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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