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

Western Australian Vaccine Safety Surveillance – Annual Report 2022

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 2022.

This year's report includes both passive and active surveillance mechanisms for AEFI detection allowing for a more robust view of the vaccine safety landscape, in line with continuous efforts to improve vaccine safety surveillance in the Western Australian (WA) population.

In 2022, a total of 4,737,775 vaccinations were administered by WA immunisation providers, as recorded in the Australian Immunisation Register (AIR). Of this total, 2,835,773 (59.9%) were doses of a COVID-19 vaccine. WAVSS received 2,853 distinct AEFI reports describing 3,108 vaccines administered in 2022. Of the 3,108 vaccines described in the AEFI reports, 2,385 (76.7%) were COVID-19 vaccines, 188 (6.1%) were influenza vaccines, 411 (13.2%) were vaccines on the National Immunisation Program (NIP) (excluding influenza vaccines), 103 (3.3%) were Mpox vaccines, and 21 (0.7%) were 'Other' vaccines not belonging to those vaccine groupings.

In 2022, slight increases were observed in the AEFI reporting rate for NIP, influenza and 'Other' vaccine groups relative to the previous four-year (2018-2021) period. This increase likely reflects the expanding role of active surveillance methods for detecting AEFI, and greater public awareness of the passive surveillance program following the 2021 COVID-19 vaccine roll-out. The high rate of AEFI reports observed in the Mpox vaccine group illustrates how effective active safety surveillance can be in a closely monitored targeted vaccination program. It is expected that the combination of both passive and active surveillance will lead to a sustained higher background AEFI report rate for all vaccines, when compared to historical reporting data in WA prior to 2021.

Relative to 2021, the number of AEFI reports related to COVID-19 vaccination decreased by over 75% in 2022. The AEFI report rate per 100,000 primary course COVID-19 doses administered decreased by 38.8%. Similarly, the AEFI report rate for booster course COVID-19 doses decreased by 45.1%. This sharp decline in the AEFI report rate likely reflects the WA population's improved understanding of the common, minor reactions associated with COVID-19 vaccines.

This annual report will provide 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, and thrombosis with thrombocytopenia syndrome.

1. Background

1.1. Western Australian Vaccine Safety Surveillance (WAVSS) system

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

Western Australia Vaccine Safety Surveillance (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) to monitor vaccine safety. WAVSS has an important role in post-licensure surveillance of AEFI, which is essential to detect uncommon events that may not have been identified in clinical trials undertaken for licensure of vaccines. WAVSS receives AEFI reports through various reporting channels. 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 SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community). The system accepts: (i) passive surveillance reports of suspected AEFI from health care providers; (ii) passive surveillance AEFI reports directly from the public; (iii) passive surveillance AEFI reports received directly to the Therapeutic Goods Administration (TGA); (iv) active surveillance AEFI reports through the active surveillance system 'SmartVax'; and (v) active surveillance AEFI reports via cases identified by the department through a data linkage process.

1.2. Adverse events following immunisation (AEFI)

An adverse event following immunisation (AEFI) is defined as any unwanted or unexpected event following the administration of a vaccine, which could be mild, such as a sore arm, or serious, such as anaphylaxis.[2] AEFI also include conditions which may 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 a vaccine. Factors such as medical history, diagnostic testing, and other medication given near the time of vaccination must be examined to help determine the likely cause of an adverse event. For serious AEFI (termed SAEFI), an assessment of causality based on World Health Organization (WHO) criteria[3] is undertaken by specialist clinicians and immunisation experts.

1.3. Serious adverse events following immunisation (SAEFI)

A serious adverse event following immunisation (SAEFI) is defined[4] as an event that:

- results in death, or
- is life threatening, or
- requires in-patient hospitalisation or prolongation of existing hospitalisation, or
- results in persistent or significant disability/incapacity, or
- results in a congenital anomaly/birth defect, or
- is deemed medically serious by WAVSS clinicians.

[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

[4] CIOMS/WHO Working Group on Vaccine Pharmacovigilance, *Definition and application of terms for vaccine pharmacovigilance* (Geneva: Council for International Organizations of Medical Sciences, 2012), https://cdn.who.int/media/docs/default-source/pvg/global-vaccine-safety/cioms_report_wg_vaccine.pdf

1.4. Adverse events of special interest (AESI)

Adverse events of special interest (AESI) are medically significant events that have the potential to be causally associated with a vaccine product and need to be carefully monitored. In 2020, a list of potential AESI for COVID-19 vaccines was determined by the Safety Platform for Emergency Vaccines and the Brighton Collaboration[5] (a global vaccine safety research network). This list was used in addition to AEFI and AESI routinely monitored by WAVSS and the department and was modified throughout the course of the COVID-19 vaccination program based on findings in national and international literature. Established AESI for influenza, NIP and other non-COVID-19 vaccines continued to be monitored throughout 2022. Where possible, assessment of causality for AESI is also undertaken by clinicians using the WHO criteria.[3]

1.5. Passive surveillance

Passive surveillance refers to the spontaneous reporting of AEFI and relies on people to report reactions 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 practitioners to report AEFI to the department, per the requirements of the *Public Health Act 2016*[6] and the *Public Health Regulations 2017*.[7] Pharmacists, nurses and midwives administering vaccines are required under their respective Structured Administration and Supply Arrangements (SASAs) to report AEFI to the WAVSS system and the patient's nominated healthcare provider. All AEFI reports received by the department are forwarded to the TGA within 48 hours. In addition, the TGA may receive AEFI reports directly from clinicians, the public, and pharmaceutical companies that manufacture vaccines. The TGA provides the department with weekly 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 entered into the WAVSS system where missing. The TGA also notifies the department within 24 hours of a SAEFI report. Spontaneous AEFI reporting enables the early detection of safety signals which can then be investigated more rigorously.

1.6. Active surveillance

Active surveillance refers to active monitoring of post-vaccination clinical manifestations for all individuals in a defined population. The two ongoing active surveillance systems contributing to WAVSS are SmartVax and a data linkage process.

1.6.1. SmartVax

SmartVax[8] is an application installed in sentinel immunisation providers' patient management software which sends a post-vaccination survey directly to the person who received the vaccine at defined intervals following vaccination. Survey responses are reported back to either the vaccine provider or the department, depending on the location where a person received their vaccination. SmartVax is installed in 137 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

[5] Safety Platform for Emergency Vaccines, *Priority List of COVID-19 Adverse events of special interest: Quarterly update December 2020* (2020), https://brightoncollaboration.us/wp-content/uploads/2021/01/SO2_D2.1.2_V1.2_COVID-19_AESI-update-23Dec2020-review_final.pdf
[6] "Public Health Act 2016", Government of Western Australia, https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13791_homepage.html
[7] "Public Health Regulations 2017:, Government of Western Australia, https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_s49088.html
[8] "SmartVax", https://www.smartvax.com.au/

directly to the department. Surveys following vaccination at GP clinics are reported directly to the GP, which can then be forwarded-on to WAVSS following review by the GP.

In 2022, surveys were sent on day 3 for non-COVID-19 vaccinations and day 3, 8 and 42 following vaccination with a COVID-19 vaccine. For COVID-19 vaccinations administered by immunisation providers other than GPs, SmartVax responses were entered into WAVSS if the vaccinee attended an Emergency Department (ED) or was admitted to hospital, or the vaccinee reported any medical attendance and (i) was under 18, (ii) received a booster dose, or (iii) was vaccinated with a newly-released vaccine e.g., Nuvaxovid (Novavax). All SmartVax AEFI reports for influenza vaccines administered at State-run clinics and pharmacies were entered into WAVSS.

De-identified, aggregated, national active surveillance data from SmartVax is monitored by AusVaxSafety[9], which is 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.

1.6.2. COVID-19 Vaccination Linked Data Repository (CVLDR)

The department also conducts data linkage to identify potential AEFI. The COVID-19 Vaccination Linked Data Repository (CVLDR) was established in April 2021; the CVLDR links an individual's vaccination information captured in the AIR to ED presentation, hospital admission and death records. Within the context of the 2022 annual report, routine scheduled data linkage was conducted to identify potential SAEFI or AESI associated with COVID-19 vaccines. The data linkage process searches for specific medical conditions following vaccination, and also identifies any presentation within a pre-defined window following vaccination. Utilising data linkage mitigates the risk that a healthcare provider or vaccine recipient does not report an AEFI 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 2022 based on findings from local, national and international vaccine safety surveillance reports, and from the literature. Cases identified through data linkage were reviewed by clinicians, and if identified as a possible SAEFI, entered into the WAVSS database.

1.6.3. Mpox active surveillance

In May 2022, there was a global increase of Mpox cases outside of endemic areas, and Mpox was declared as a 'Communicable Disease of National Significance' by the Australian Government's Chief Medical Officer. To help manage the potential outbreak in WA, the JYNNEOS vaccine was procured from the Department of Health and Aged Care. Subsequently, the department established an enhanced active surveillance system to monitor vaccine safety using Research Electronic Data Capture (REDCap) linked to a SMS system (Twilio), that was implemented at vaccinating clinics in the Perth metropolitan area. Vaccine recipients were sent a survey at day 7, 14 and 42 after each vaccine dose. Reminder text messages were also sent to participants to increase response rates. For WA Health-managed clinics in metropolitan and regional areas, a self-registration surveillance system using VaxTracker[10] was also established. VaxTracker is managed by NCIRS and is an online active vaccine safety surveillance tool that people register with after receiving a vaccination. For both surveillance systems, any medically attended event or AEFI report containing key words related to 'seizures', 'rash' or 'chest pain' symptoms were entered into WAVSS for clinical follow-up. De-identified active surveillance data were transferred to NCIRS for national monitoring and reporting.

[9] "AusVaxSafety", http://ausvaxsafety.org.au/
[10] "VaxTracker", https://www.vaxtracker.net/

2. Methodology

2.1. Inclusion/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 2022 and 31 December 2022; and
- the suspected reaction was captured in the state reporting system (WAVSS).

AEFI reports were excluded if:

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

This annual report includes AEFI reports of vaccinations administered between 1 January and 31 December 2022 and may not necessarily reflect the year in which an AEFI report was submitted to WAVSS. For example, a vaccination occurring on 31 December 2022, which led to an AEFI report received by WAVSS on 7 January 2023, is eligible for inclusion in this annual report.

Data included in this annual report were captured in the WAVSS system as at 31 August 2023. 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-term period.

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 15 September 2023 with immunisation data current to 14 September 2023 (accounting for a one-day lag in receiving AIR data).

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

- National Immunisation Program (NIP) vaccines; comprising all vaccines available on the 2022 WA Immunisation Schedule, excluding influenza vaccines
- Influenza vaccines
- Mpox 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 analyses, 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.

SmartVax responses are classified as 'self-reported'.

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

Reported reactions

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 (i) a 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.[11] 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 counts 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.

[11] "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

The number of AEFI reports was substantially lower in 2022 than in 2021 (Figure 1), declining from a total of 10,576 in 2021 to 2,853 in 2022. Additionally, the overall AEFI report rate declined in 2022 relative to 2021 as indicated by the downward trending 'AEFI Report Rate' line (Figure 1). However, reporting remains higher than the average annual number prior to the introduction of COVID-19 vaccines (2,853 compared with an average of 323 per year for the 2018-2020 period). In 2022, January to March saw the highest number of AEFI reports corresponding with the sustained high number of COVID-19 vaccinations administered at that time. The high uptake in COVID-19 vaccinations was likely in anticipation of the WA hard-border re-opening and the potential threat of COVID-19 infection being re-introduced to the WA community.

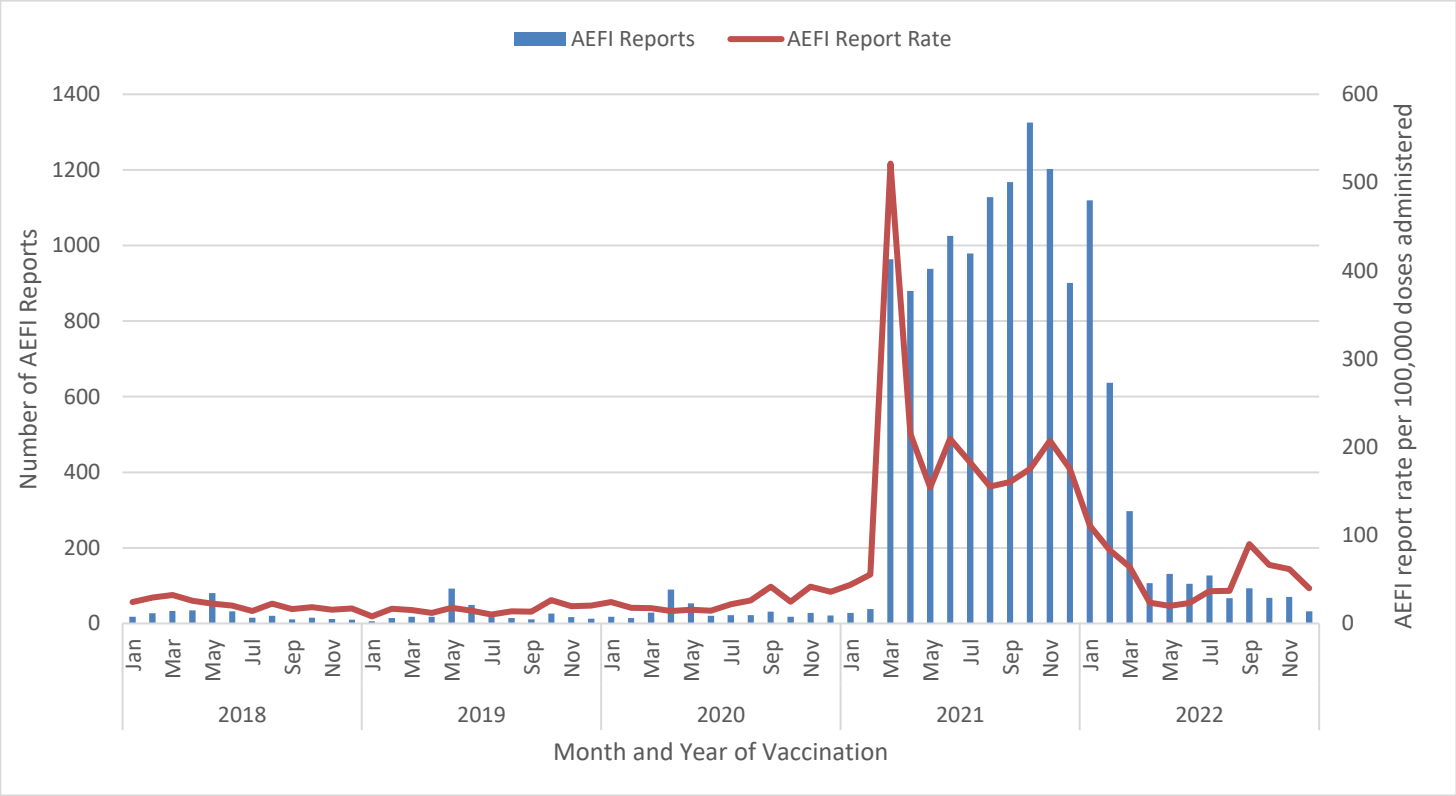

Figure 1: Number of AEFI reports by vaccination month and year overlayed with reporting rate per 100,000 doses administered by vaccination month and year (2018-2022).

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 2018-2022.

Consistent with previous years, a greater proportion of AEFI reports were submitted by, or on behalf of, females (57%) as compared to males (42%). The greatest proportion of AEFI reports (35%) were for 30–49-year-olds, as was the case for the 2021 vaccination period, reflecting a high number of vaccines administered in this group. Prior to the availability of COVID-19 vaccines (first administered

in WA in February 2021), the majority of AEFI reports (and the majority of vaccines administered) were in the less than 5 years old age group. The proportion of self-reported AEFI reports (including those submitted by a parent or guardian) decreased from 60% in 2021 to 50% in 2022. GPs and nurses, who historically have reported the majority of AEFI reports, contributed 45% of AEFI reports in 2022.

Table 1 shows the growing contribution of active surveillance across vaccination years. The proportion of active surveillance AEFI reports increased from 1.3% in 2018 to a high of 37% in 2021. The proportion of AEFI reports received via active surveillance slightly reduced in 2022 relative to the previous year, declining from 37% to 31%. The proportion of AEFI reports with ED attendance decreased in 2022 to 37% from 48% in 2021. A similar proportion of AEFI reports were managed by a GP in 2022 as compared to 2021 with 32% and 30% respectively.

Table 1: Characteristics of AEFI reports to WAVSS, 2018-2022

Characteristic	**2018**, N = 308	**2019**, N = 295	**2020**, N = 366	**2021**, N = 10,576	**2022**, N = 2,853
Gender					
Female	181 (59%)	172 (58%)	216 (59%)	6,791 (64%)	1,636 (57%)
Male	124 (40%)	122 (41%)	150 (41%)	3,760 (36%)	1,205 (42%)
Unknown*	3 (1.0%)	1 (0.3%)	0 (0%)	25 (0.2%)	12 (0.4%)
Aboriginal Status					
Aboriginal**	12 (3.9%)	16 (5.4%)	29 (7.9%)	193 (1.8%)	73 (2.6%)
Non-Aboriginal	206 (67%)	217 (74%)	295 (81%)	9,473 (90%)	2,433 (85%)
Unknown	90 (29%)	62 (21%)	42 (11%)	910 (8.6%)	347 (12%)
Age Group					
<5 years	125 (41%)	122 (41%)	164 (45%)	148 (1.4%)	186 (6.5%)
05-11 years	18 (5.8%)	18 (6.1%)	24 (6.6%)	14 (0.1%)	260 (9.1%)
12-15 years	20 (6.5%)	22 (7.5%)	40 (11%)	220 (2.1%)	86 (3.0%)
16-17 years	3 (1.0%)	4 (1.4%)	3 (0.8%)	123 (1.2%)	63 (2.2%)
18-29 years	22 (7.1%)	24 (8.1%)	16 (4.4%)	1,560 (15%)	411 (14%)
30-49 years	37 (12%)	38 (13%)	44 (12%)	4,231 (40%)	999 (35%)
50-64 years	26 (8.4%)	15 (5.1%)	31 (8.5%)	2,647 (25%)	513 (18%)
≥65 years	43 (14%)	34 (12%)	33 (9.0%)	1,589 (15%)	326 (11%)
Unknown	14 (4.5%)	18 (6.1%)	11 (3.0%)	44 (0.4%)	9 (0.3%)
Surveillance Type					
Active	4 (1.3%)	16 (5.4%)	88 (24%)	3,869 (37%)	898 (31%)
Passive	304 (99%)	279 (95%)	278 (76%)	6,707 (63%)	1,955 (69%)
Reporter Type					
Administration/Other	20 (6.5%)	17 (5.8%)	14 (3.8%)	147 (1.4%)	32 (1.1%)
GP/Nurse	242 (79%)	221 (75%)	267 (73%)	3,828 (36%)	1,298 (45%)
Pharmacist	17 (5.5%)	11 (3.7%)	27 (7.4%)	208 (2.0%)	98 (3.4%)
Self/Parent/Guardian	29 (9.4%)	46 (16%)	58 (16%)	6,393 (60%)	1,425 (50%)
Immunisation Provider Type					
Aboriginal Health Service	1 (0.3%)	0 (0%)	2 (0.5%)	3 (<0.1%)	2 (<0.1%)
Community Clinic	45 (15%)	46 (16%)	23 (6.3%)	2,665 (25%)	645 (23%)
GP	171 (56%)	146 (49%)	193 (53%)	1,802 (17%)	567 (20%)
Hospital	39 (13%)	30 (10%)	23 (6.3%)	1,393 (13%)	77 (2.7%)
Other	14 (4.5%)	10 (3.4%)	11 (3.0%)	71 (0.7%)	20 (0.7%)
Pharmacy	8 (2.6%)	13 (4.4%)	31 (8.5%)	466 (4.4%)	352 (12%)
Unknown	30 (9.7%)	44 (15%)	77 (21%)	4,123 (39%)	1,177 (41%)
Workplace	0 (0%)	6 (2.0%)	6 (1.6%)	53 (0.5%)	13 (0.5%)
Managed by*** (% Yes)					
Admitted to Hospital	18 (5.8%)	24 (8.1%)	19 (5.2%)	1,015 (9.6%)	319 (11%)
ED	68 (22%)	61 (21%)	66 (18%)	5,036 (48%)	1,056 (37%)
GP	146 (47%)	134 (45%)	151 (41%)	3,155 (30%)	900 (32%)
Helpline	8 (2.6%)	10 (3.4%)	16 (4.4%)	387 (3.7%)	109 (3.8%)
Nurse	69 (22%)	62 (21%)	45 (12%)	549 (5.2%)	130 (4.6%)

*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; ***'Managed by' categories are not mutually exclusive.

Thirty-one percent of total AEFI reports were reported via active surveillance. The breakdown of reporting modality (active or passive surveillance) by vaccine group is presented in Figure 2. The proportion of COVID-19-related AEFI reports received via active surveillance was lower than that for influenza and NIP vaccines. Mpox AEFI reports were almost entirely received via active surveillance, reflecting the close monitoring of this vaccination program by the department.

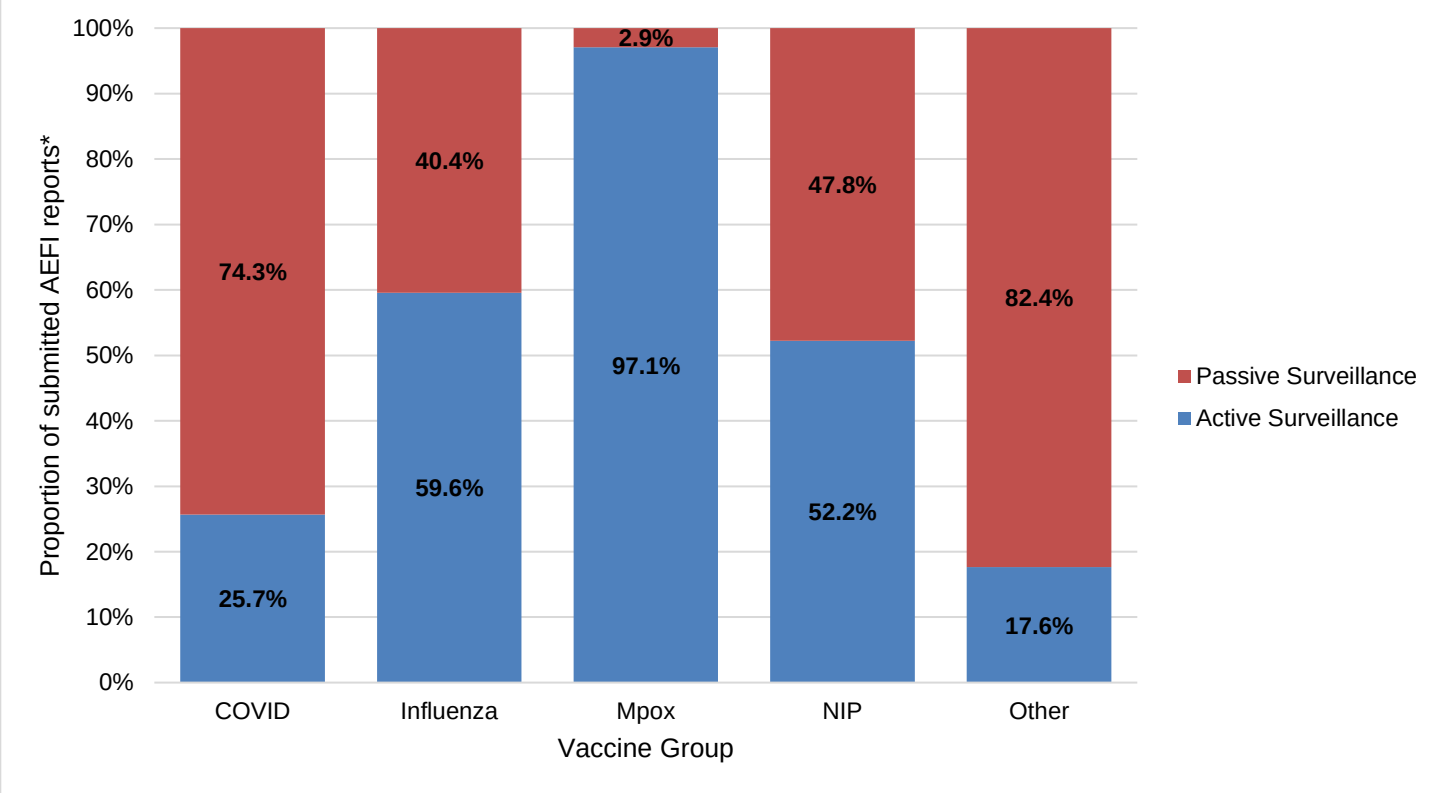

Figure 2: AEFI reports by surveillance type (passive or active) by vaccine group for vaccinations administered in 2022.
**Summary reporting of surveillance type by vaccine group counts co-administered vaccines once per distinct vaccine group.*

4. Adverse events following NIP vaccines

There were 224 distinct AEFI reports relating to a total of 411 administered NIP vaccines (Figure 3). In 2022, the AEFI report rate for this group of vaccines was 53.0 per 100,000 NIP vaccine doses administered compared to an average of 39.9 per 100,000 NIP doses administered between 2018-2021. Analyses of AEFI reports related to the NIP group of vaccines exclude influenza vaccines. Analyses of AEFI reports related to influenza vaccines are reserved for discrete analyses of the influenza vaccine group.

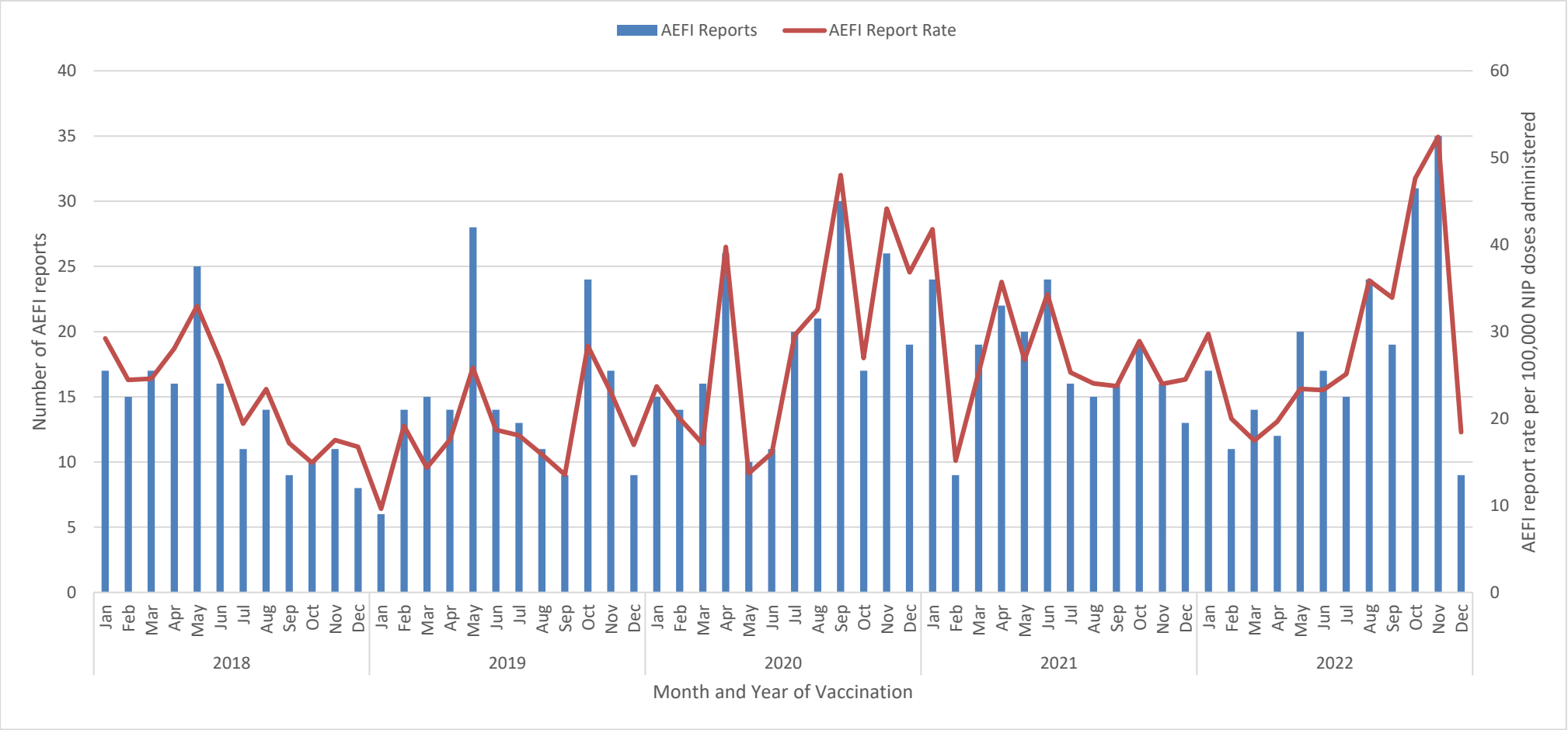

Figure 3: Number of AEFI reports following NIP vaccines by vaccination month and year overlayed with AEFI report rate per 100,000 NIP doses administered by vaccination month and year (2018-2022).

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

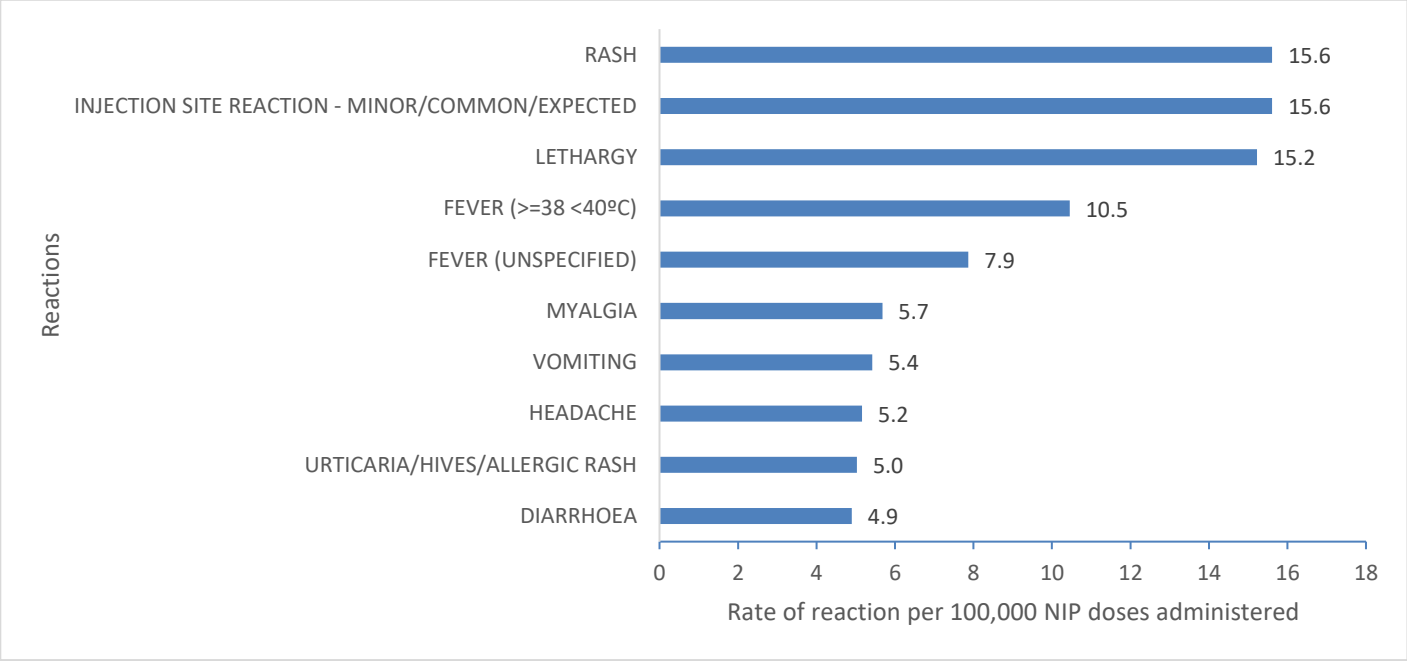

Figure 4: Ten most commonly reported reactions following NIP vaccines by rate (reactions per 100,000 NIP doses administered).

Table 2 presents the AEFI report rate for all vaccines available on the NIP to children aged less than 5 years. In 2022, the overall AEFI report rate for children under 5 for this group of vaccines was 73.8 per 100,000 NIP doses administered.

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, 2018-2022

Vaccine	2018			2019			2020			2021			2022		
	AEFI	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**	**AEFI**	**Doses**	**Rate**
DTPa – Infanrix	17	27,054	62.8	7	23,835	29.4	15	21,880	68.6	18	24,462	73.6	18	22,016	81.8
DTPa – Tripacel	0	5,552	0	7	9,087	77.0	8	9,085	88.1	4	6,464	61.9	6	8,709	68.9
DTPa-hepB-IPV-Hib – Infanrix hexa	22	93,924	23.4	20	94,254	21.2	46	91,148	50.5	42	94,728	44.3	59	89,716	65.8
DTPa-IPV – Infanrix-IPV	6	14,921	40.2	7	17,054	41.1	17	19,359	87.8	15	15,958	94.0	18	16,544	108.8
DTPa-IPV – Quadracel	14	16,147	86.7	13	15,551	83.6	13	13,741	94.6	16	16,684	95.9	18	14,026	128.3
Hep A – VAQTA Paediatric/Adolescent	1	4,800	20.8	0	5,279	0	2	3,553	56.3	1	2,398	41.7	3	2,795	107.3
Hep B – Engerix-B Paediatric	0	312	0	0	637	0	3	862	348.0	0	1,577	0	1	1,766	56.6
Hep B – H-B-Vax II Paediatric	0	1,614	0	0	1,046	0	0	329	0	1	2,277	43.9	0	5,181	0
Hib – ActHib	0	62	0	8	17,281	46.3	20	30,206	66.2	19	30,631	62.0	22	30,423	72.3
Men ACWY – Nimenrix	21	56,912	36.9	13	53,719	24.2	32	39,934	80.1	33	36,703	89.9	26	37,982	68.5
Men B – Bexsero	7	19,203	36.5	10	14,876	67.2	14	16,463	85.0	11	21,574	51.0	15	20,333	73.8
MMR – M-M-R II	10	22,310	44.8	5	17,836	28.0	13	16,301	79.8	7	13,589	51.5	12	14,722	81.5
MMR – Priorix	13	10,658	122.0	10	16,089	62.2	18	15,368	117.1	21	17,282	121.5	16	17,734	90.2
MMRV – Priorix-Tetra	6	16,146	37.2	2	7,951	25.2	5	7,516	66.5	4	8,636	46.3	14	13,867	101.0
MMRV – ProQuad	5	16,917	29.6	10	25,314	39.5	16	23,774	67.3	16	22,584	70.9	13	17,279	75.2
Pneumococcal – Pneumovax 23	1	189	529.1	1	221	452.5	3	871	344.4	4	1,698	235.6	4	1,633	245.0
Pneumococcal – Prevenar 13	22	88,886	24.8	26	95,898	27.1	61	93,035	65.6	64	95,663	66.9	64	92,681	69.1
Rotavirus – Rotarix	10	59,042	16.9	17	59,483	28.6	30	57,442	52.2	31	60,048	51.6	33	55,778	59.2

Descriptive statistics presented in this table are aggregated on a per vaccine basis. For example, if an AEFI report was submitted following co-administration with Rotarix and Infanrix hexa in the same vaccination encounter, a count of 1 AEFI report would be ascribed against both Rotarix and Infanrix hexa.

5. Adverse events following Influenza vaccines

In 2022, there were 188 AEFI reports following influenza vaccines that were assessed as events possibly or certainly related to vaccination (Figure 5) which is higher than the average of the preceding four years (116 per year). In 2022, the overall AEFI report rate for influenza vaccines was 17.8 per 100,000 influenza doses administered compared to an average of 14.8 per 100,000 influenza doses administered between 2018-2021.

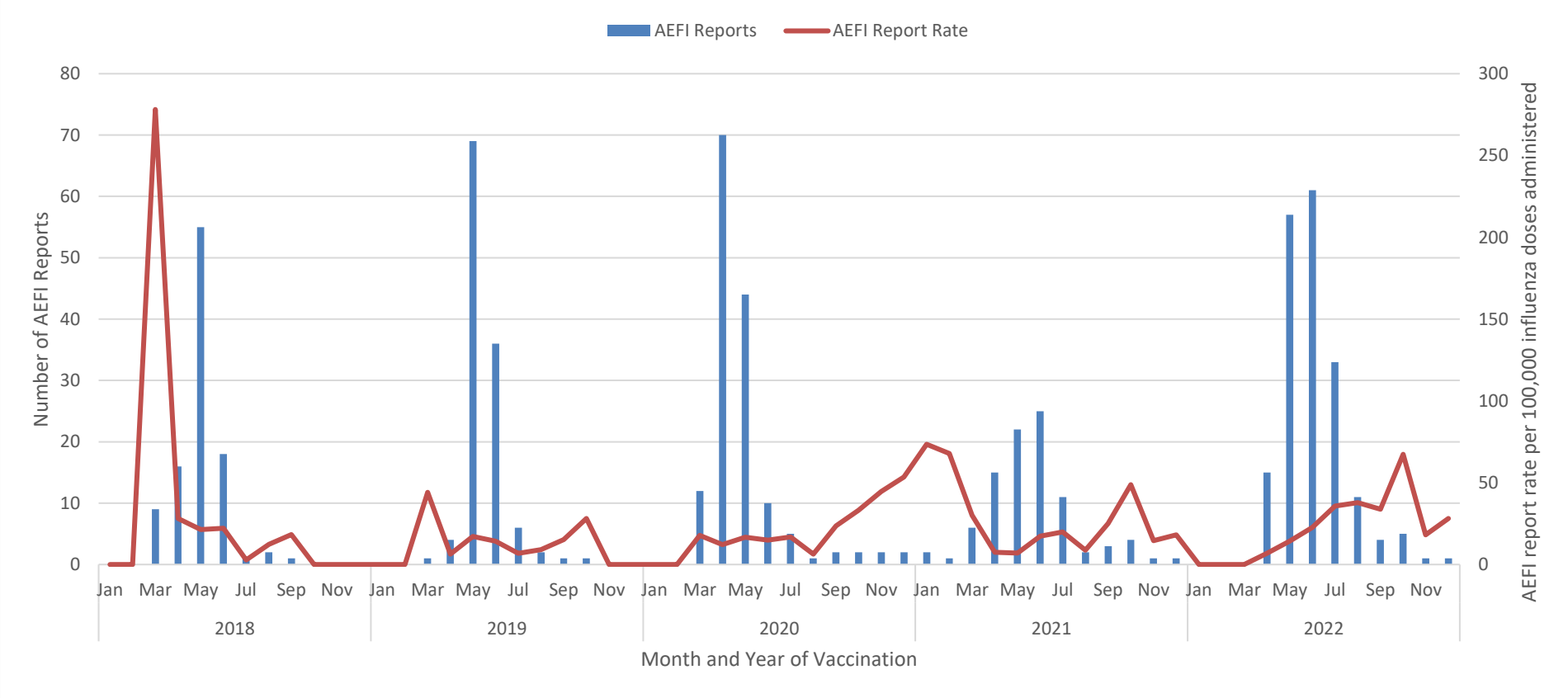

Figure 5: Number of AEFI reports following influenza vaccines by vaccination month and year overlayed with AEFI report rate per 100,000 influenza doses administered by vaccination month and year (2018-2022).

In 2022, the highest number of AEFI reports related to influenza vaccination occurred in those aged 18-64 years (84/188; 44.7%), who also proportionately receive the highest number of influenza doses (567,885/1,057,551; 53.7%). Only 33 (17.6%) AEFI reports following influenza vaccination 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).

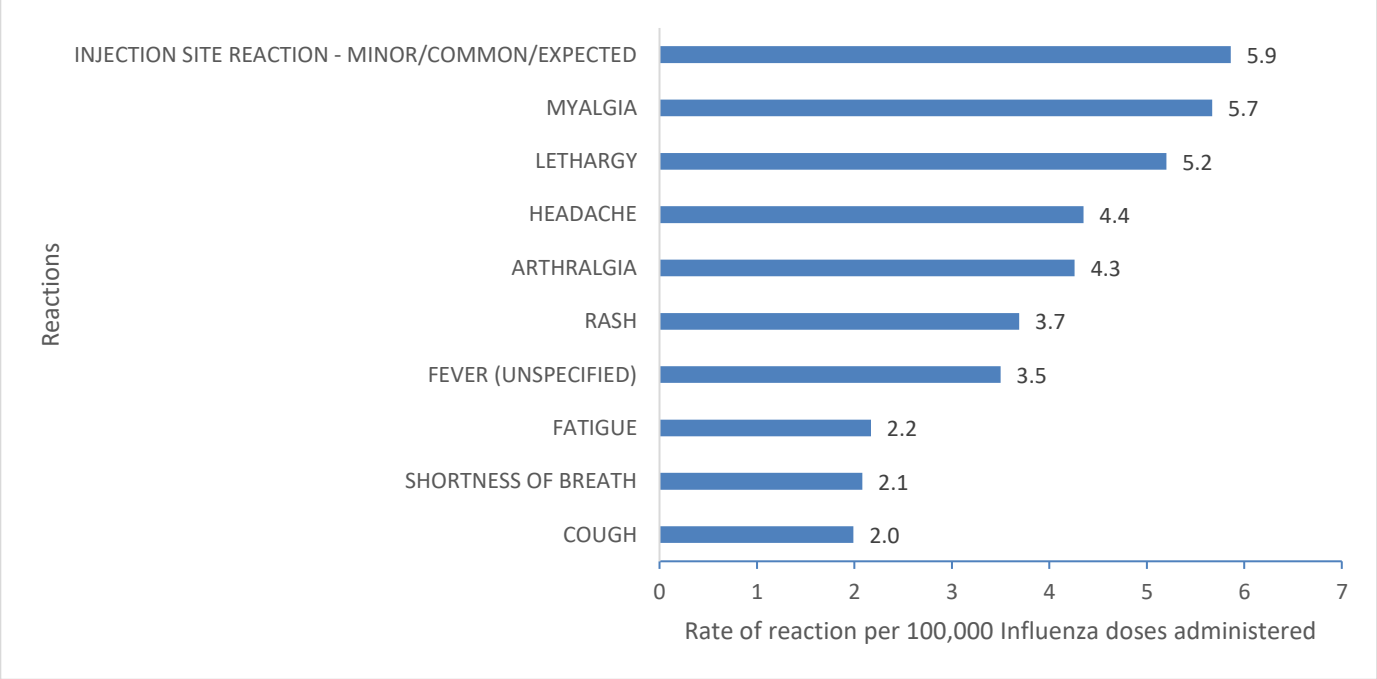

Figure 6: Ten most commonly reported reactions following influenza vaccines by rate (reactions per 100,000 influenza doses administered).

6. Adverse events following Mpox vaccines

There were 103 AEFI reports following administration of Mpox vaccines in 2022 that were assessed as events possibly or certainly related to vaccination. The total AEFI report rate was 3,163.4 per 100,000 Mpox doses administered. The high AEFI report rate in this group of vaccines is due to the close monitoring of this vaccination program via active surveillance mechanisms. The ten most commonly reported reactions by rate per 100,000 Mpox doses administered are presented in Figure 7.

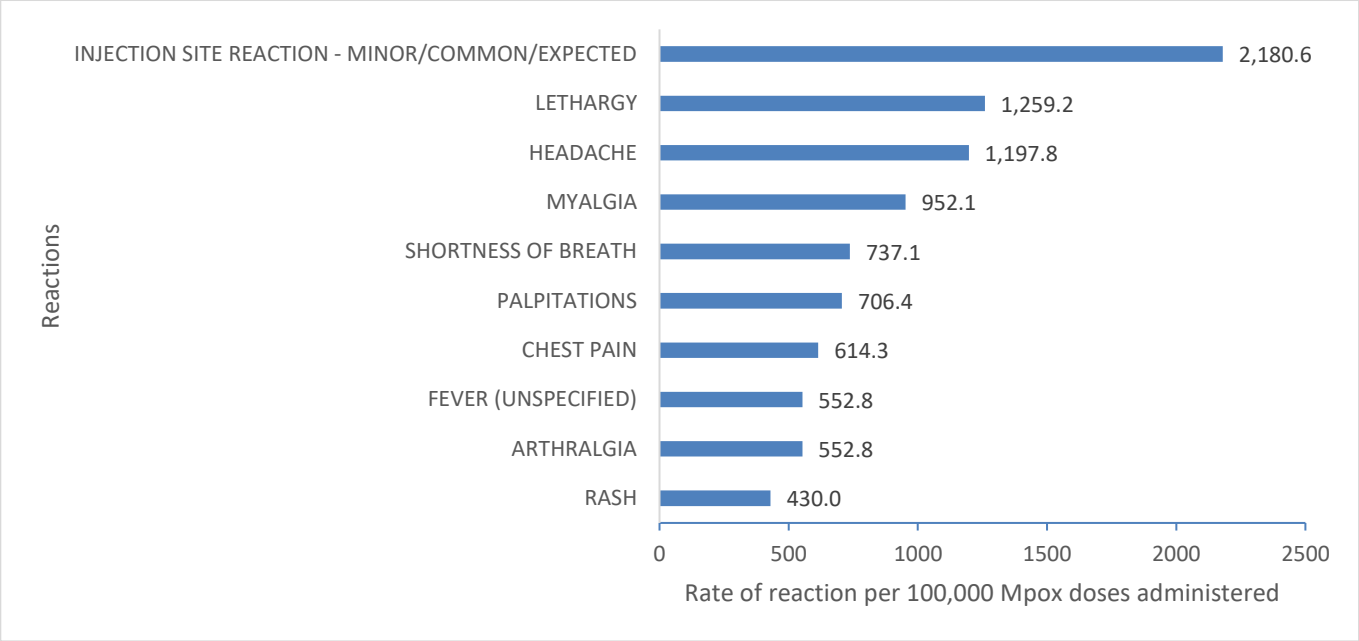

Figure 7: Ten most commonly reported reactions following Mpox vaccines by rate (reactions per 100,000 Mpox doses administered).

Due to the introduction of the new Mpox vaccines and their increased active surveillance, the WAVSS team attempted to contact all patients who reported cardiac symptoms following Mpox vaccination to recommend clinician review or to obtain medical records if they had already been reviewed. No Mpox vaccinations resulted in a confirmed AESI and most patients experienced short-lived symptoms that resolved without intervention or with simple analgesia. Data linkage methods were also implemented to investigate co-administration of JYNNEOS and COVID-19 vaccines, which were jointly offered at targeted vaccination clinics. No vaccine safety signals were reported.

7. Adverse event following 'Other' vaccines

The 'Other' vaccine group is mainly comprised of travel vaccines, privately administered vaccines and vaccines where the brand was not specified in the AEFI report submitted to WAVSS. A total of 17 distinct AEFI reports were submitted to WAVSS following 21 'Other' vaccines administered. The ten most commonly reported reactions for this vaccine group were varied and influenced by co- administration and low numbers of submitted AEFI reports (Figure 8). Visual disturbance, tinnitus and rash were reported as the top three reactions; however, these relate to one AEFI report following co-administration of four separate travel vaccines in the same vaccination encounter.

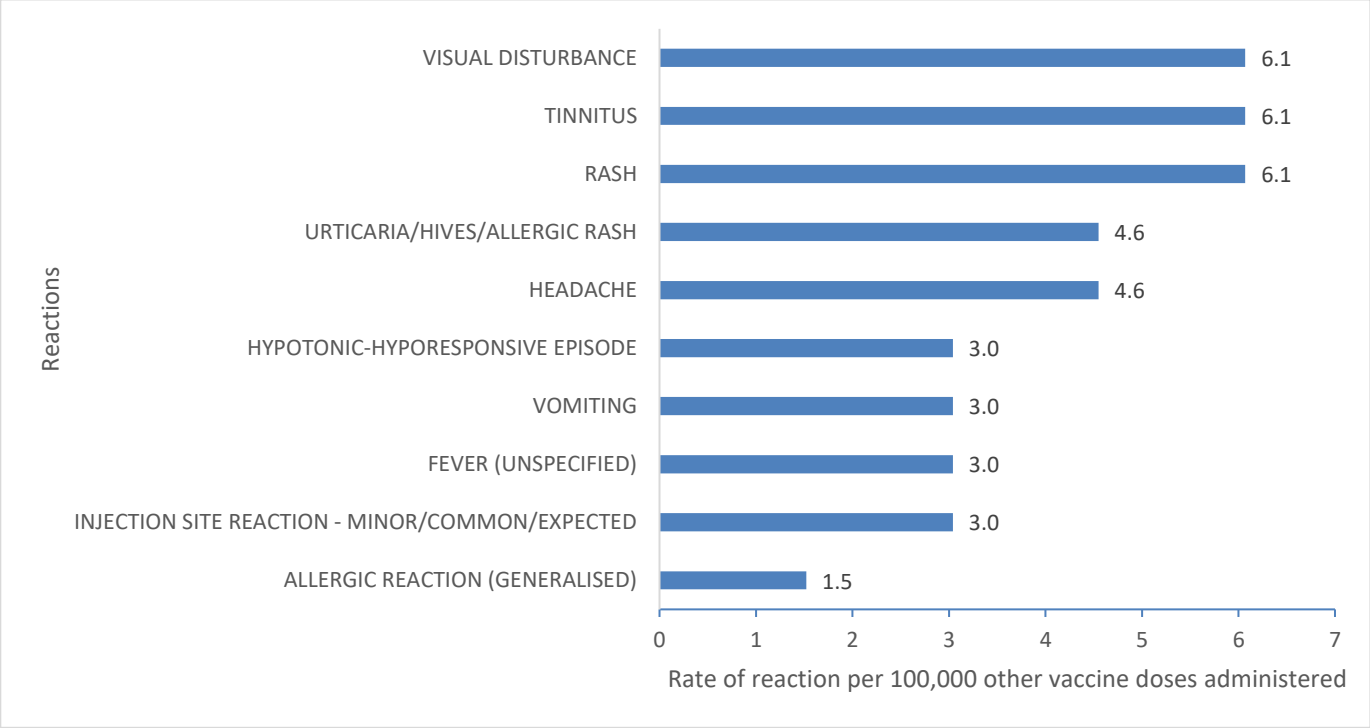

Figure 8: Ten most commonly reported reactions following 'Other' vaccines by rate (reactions per 100,000 'Other' doses administered).

8. Adverse events following COVID-19 vaccines

There were 2,385 individual AEFI reports received for persons vaccinated with a COVID-19 vaccine in 2022 that were assessed as events possibly or certainly related to vaccination. Overall, the AEFI report rate of any COVID-19 vaccine was 84.1 per 100,000 doses administered in 2022. This figure is lower than the current reported national rate of COVID-19 vaccine AEFI, 200 per 100,000, which includes all COVID-19 vaccines administered since the beginning of the COVID-19 vaccine roll-out.[12] This figure is likely a reflection of the increased proportion of booster doses administered in 2022, which is consistent with international data demonstrating lower AEFI rates following booster doses as compared to primary course doses. Additionally, this figure also reflects a reduction in reporting of common, minor AEFI, likely due to increased public awareness of these AEFI. Figure 9 shows the number of AEFI reports and AEFI report rate by month of vaccination in 2022. The highest number of AEFI reports were following vaccinations received between January and March 2022, coinciding with the largest period of uptake of COVID-19 vaccinations in anticipation of the reopening of the WA hard-border. Between January and March 2022, 84.2% of the yearly total of COVID-19-related AEFI reports were submitted. From April onwards, a 4th dose (Winter booster) of COVID-19 vaccine was made available to older and medically vulnerable populations. The uptake of the 4th dose was proportionately lower than the uptake of the 3rd dose. With a decline in COVID-19 vaccination uptake, the number of submitted COVID-19-related AEFI reports declined (Figure 9). The AEFI report rate remained largely consistent between April and November. The sharp decline in both COVID-19 vaccination and AEFI reporting after March contributed to the observed decline in AEFI report rate. The increase in AEFI report rate in December is likely due to the small numbers of immunisations provided, which can lead to a greater influence on the rate.

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

[12] "COVID-19 vaccine safety report - 07-09-2023", Australian Government Department of Health and Aged Care, https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-07-09-2023

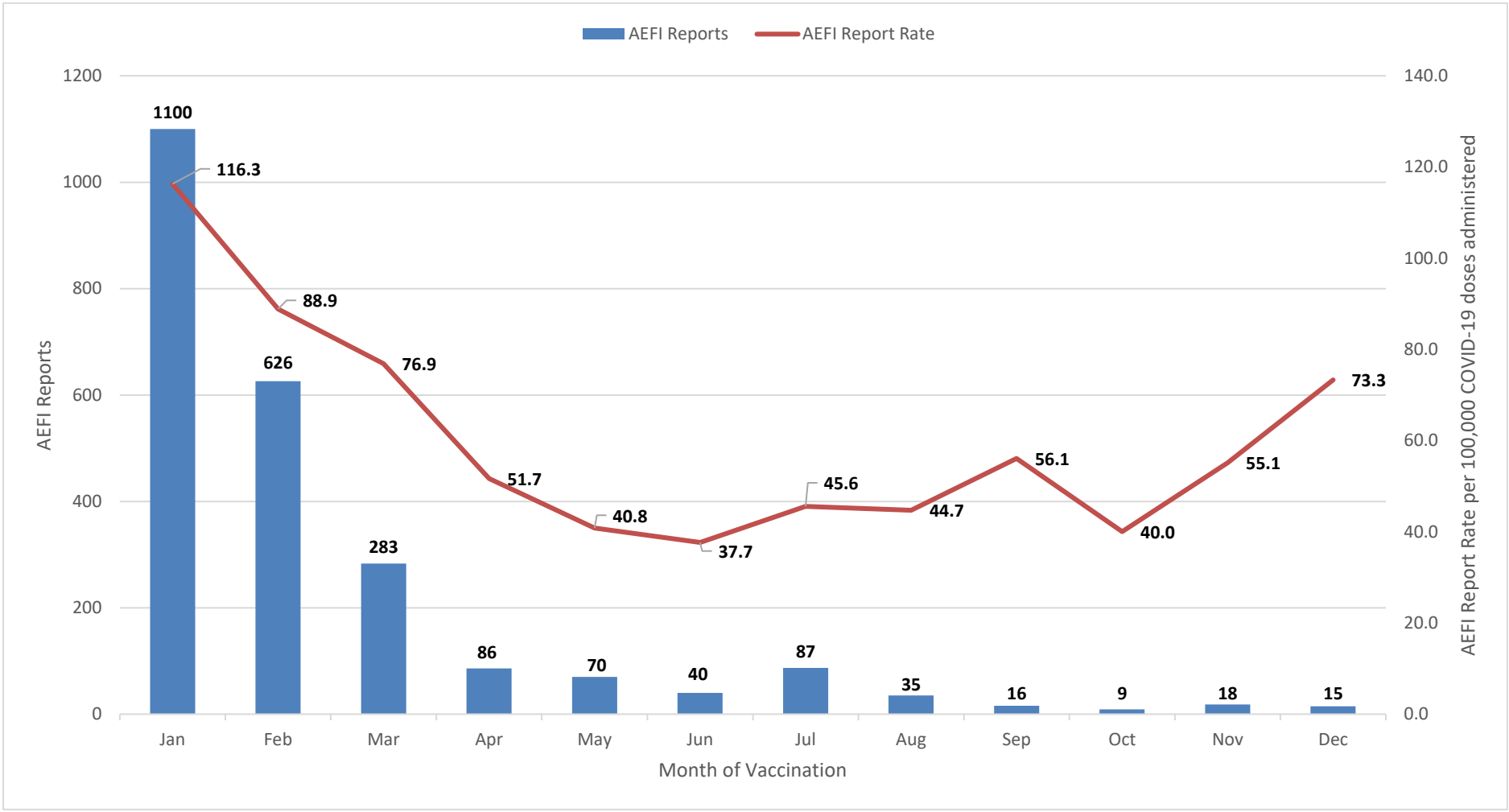

Figure 9: Number of AEFI reports following COVID-19 vaccination by month of vaccination, overlayed with AEFI reporting rate per 100,000 COVID-19 doses administered, 2022.

Table 3: AEFI reports following COVID-19 vaccination and AEFI report rate per 100,000 doses administered, by brand, age group and course, 2022

Age group (years)	Course	Comirnaty (Pfizer)			Comirnaty (bivalent-Omicron BA-1)			Spikevax (Moderna)			Spikevax (bivalent-Omicron BA-1)			Vaxzevria (AstraZeneca)			Nuvaxovid (Novavax)		
		AEFI	Doses	Rate	AEFI	Doses	Rate	AEFI	Doses	Rate	AEFI	Doses	Rate	AEFI	Doses	Rate	AEFI	Doses	Rate
<5	Primary	0	25	0	0	0	0	1	97	1030.9*	0	0	0	0	0	0	0	0	0
05-11	Primary	232	262,841	88.3	0	0	0	1	1,036	96.5	0	0	0.0	0	0	0.0	0	3	0.0
05-11	Booster	3	212	1415.1**	0	0	0	0	7	0.0	0	0	0	0	0	0	0	0	0
12-15	Primary	45	68,489	65.7	0	0	0	4	7,402	54.0	0	2	0	0	7	0	0	57	0
12-15	Booster	6	1,911	314.0	0	0	0	1	331	302.1	0	2	0	0	0	0	0	7	0
16-17	Primary	22	22,810	96.5	0	0	0	3	3,561	84.3	0	2	0	0	31	0	0	35	0
16-17	Booster	28	34,735	80.6	0	0	0	6	2,416	248.3	0	15	0	0	1	0	0	37	0
18-29	Primary	134	108,767	123.2	0	47	0	49	19,534	250.8	0	229	0	3	1,997	150.2	22	5,548	396.5
18-29	Booster	126	199,265	63.2	0	138	0	37	56,409	65.6	1	888	112.6	0	296	0.0	3	1,811	165.7
30-49	Primary	304	130,165	233.6	0	98	0	103	26,885	383.1	0	604	0.0	23	4,378	525.4	84	12,712	660.8
30-49	Booster	278	454,997	61.1	0	1,083	0	80	129,193	61.9	4	9,923	40.3	5	1,056	473.5	16	5,664	282.5
50-64	Primary	96	49,482	194.0	0	70	0	45	13,224	340.3	1	509	196.5	12	3,671	326.9	35	6,417	545.4
50-64	Booster	188	373,033	50.4	0	969	0	65	124,614	52.2	7	13,912	50.3	3	2,346	127.9	12	4,961	241.9
≥65	Primary	46	39,099	117.7	0	42	0	16	8,937	179.0	0	335	0	1	3,705	27.0	14	4,520	309.7
≥65	Booster	166	475,808	34.9	1	461	216.9	39	116,907	33.4	0	7,403	0	1	2,991	33.4	7	4,589	152.5
U	Primary	3	0	0	0	0	0	0	0	0.0	0	0	0	1	0	0	0	0	0
U	Booster	1	0	0	0	0	0	0	0	0.0	0	0	0	1	0	0	0	0	0

AEFI: AEFI reports. U: Unknown – date of birth not recorded in the submitted AEFI report. Course: Primary course represents a first or second dose. Booster course represents a third dose and above. The AIR has no mechanism to distinguish between a scheduled 3rd dose as part of a primary course for immunocompromised or medically vulnerable individuals vs. a third dose as part of a booster course for otherwise healthy individuals. This may have led to the misattribution of some Booster-related AEFI reports and Booster doses particularly in the case of individuals 15 years and under. Calculated rate estimates in the context of low counts should be interpreted with caution. * 95% Confidence Interval for AEFI report rate (-989.7, 3051.5).** 95% Confidence Interval for AEFI report rate (-186.2, 3016.4).

The age groups presented in this table are consistent with the evolving ATAGI recommendations for COVID-19 vaccine eligibility observed in 2022.

The ten most commonly reported reactions following COVID-19 vaccination are shown in Figure 10.

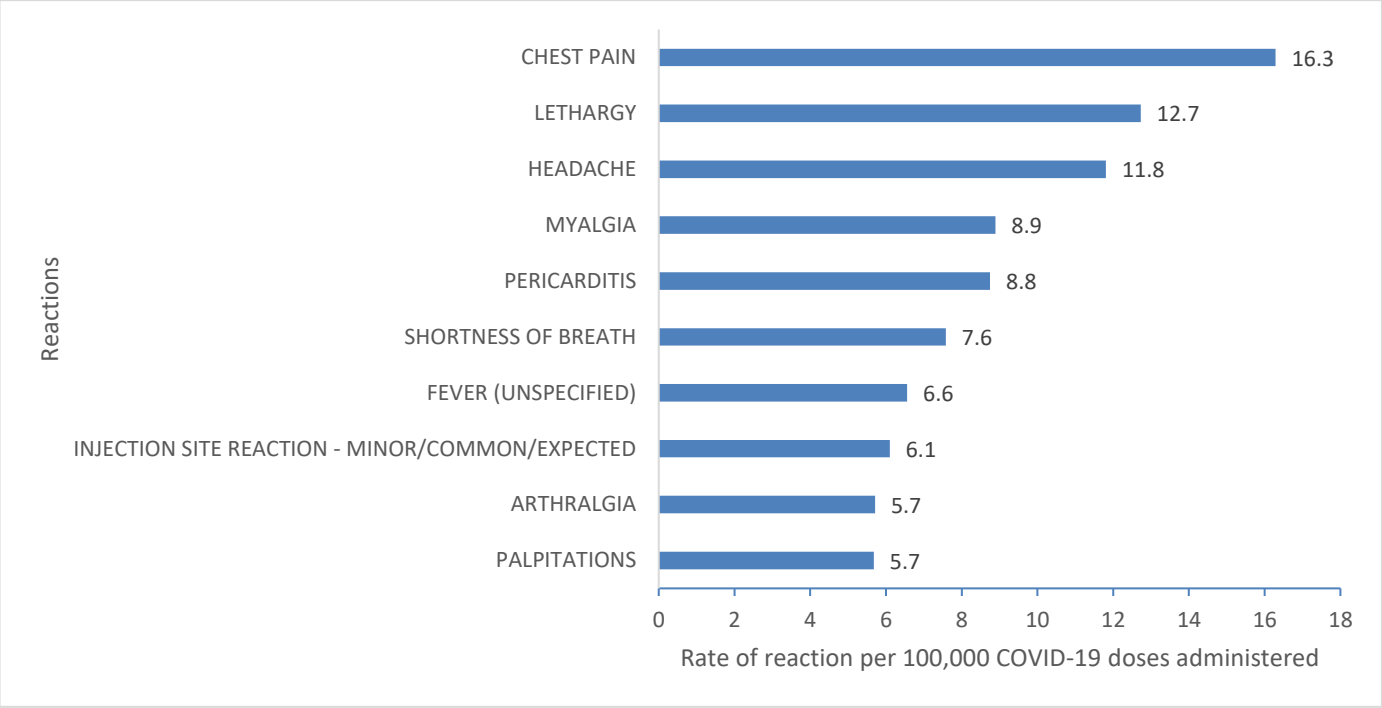

Figure 10: Ten most commonly reported reactions following COVID-19 vaccines by rate (reactions per 100,000 doses administered).

The data outlined in Figure 10 is mostly consistent with national data reported by the TGA, which identifies headache, swollen lymph nodes, chest pain, muscle pain and fever as the most common side effects associated with COVID-19 vaccination.[13] Reported rates of chest pain and pericarditis are comparatively over-represented, which is partially attributable to the data linkage active surveillance processes undertaken by WAVSS, which specifically sought hospital presentation codes and keywords relating to these symptoms and diagnoses – a process not universally undertaken by other state jurisdictions (see 8.1 and Table 4 below).

8.1. COVID-19 active surveillance - data linkage

In 2022, 376 AEFI reports following COVID-19 vaccination were identified using the data linkage active surveillance system. These AEFI reports had not already been captured in the WAVSS system via other surveillance mechanisms. The events described in these AEFI reports have been aggregated into their respective event group and presented in Table 4.

[13] "COVID-19 vaccine safety report - 07-09-2023", Australian Government Department of Health and Aged Care, https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-07-09-2023

Table 4: Events identified through data linkage active surveillance following COVID-19 vaccination.

Event group	Number and percent of total data linkage events identified
Cardiac	241 (50.0%)
Common minor	74 (15.4%)
Neurological	54 (11.2%)
Other*	34 (7.1%)
Respiratory	30 (6.2%)
Haematological	14 (2.9%)
Allergic	11 (2.3%)
Immunological	9 (1.9%)
Infectious Disease	6 (1.2%)
Unspecified	5 (1.0%)
Accident & Injury	4 (0.8%)
Total number of events	**482**

*Other is a collective grouping of events not attributable to the defined categories.

While the data linkage active surveillance system is calibrated to detect and report on SAEFI and AESI, other reported events, including common, minor reactions or unrelated events captured in patient case notes during that episode of care can be entered into the AEFI report. Cardiac events were the most identified event through the data linkage process, comprising 50% of the total events detected via this method, followed by common, minor reactions. All events detected via data linkage underwent clinical review at WAVSS, and if the event was determined to be a SAEFI or AESI, it received additional specialist review (see sections 9 and 10).

8.2. COVID-19 active surveillance - data linkage, deaths

Data linkage active surveillance processes specifically searched death records for temporal association with vaccination and identified 130 deaths that occurred within 21-days of a COVID-19 vaccination. These events are often coincidental, rather than being caused by the vaccine.[14] Of these deaths, the median age at vaccination was 63.5 years, with a range of 19 to 96 years. All cases received specialist review, and where information was sufficient to determine classification (n = 86), none were found to be causally associated with vaccination. Of the outstanding cases that have yet to be formally classified (n = 44, 33.8% of deaths identified through data linkage), specialist review has occurred but confirmation of the final cause of death from a death certificate or coroner report is pending. There is no indication that these deaths are likely to be attributed to vaccination based on initial investigation. See section 10 for further information on the case review process.

9. Adverse events of special interest (AESI) reported to WAVSS

Table 5 describes the count of each AESI against the vaccine(s) administered. If an AESI resulted following the co-administration of an influenza vaccine and COVID-19 vaccine, the count of that AESI was recorded against both vaccines. While AESI detection through active surveillance via data linkage processes was primarily established for the purpose of monitoring the safety of COVID-19 vaccines, the fact that AESI are recorded against non-COVID-19 vaccines in Table 5

[14] "COVID-19 vaccine safety report – 02-12-2021", Australian Government Department of Health and Aged Care, https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-02-12-2021#reports-of-death-in-people-who-have-been-vaccinated

reflects (i) co-administration of other vaccines alongside COVID-19 vaccines, (ii) reporting of established AESI for non-COVID-19 vaccines, and (iii) the other pathways through which an AESI can be reported to WAVSS.

Table 5: Number and rate per 100,000 doses administered of confirmed cases of adverse events of special interest by vaccine (and course where applicable)

Vaccine	Course	Doses administered	Anaphylaxis		ITP		GBS		Myocarditis/ myopericarditis		Pericarditis		Menstrual disorder	
			Cases	Rate	Cases	Rate	Cases	Rate	Cases	Rate	Cases	Rate	Cases	Rate
Comirnaty (Pfizer)	Primary	681,678	19	2.8	1	0.2	0	0	20	2.9	83	12.2	12	1.8
Comirnaty (Pfizer)	Booster	1,539,961	9	0.6	1	0.1	7	0.5	26	1.7	71	4.6	10	0.7
Nuvaxovid (Novavax)	Primary	29,292	3	10.2	1	3.4	0	0	1	3.4	8	27.3	2	6.8
Nuvaxovid (Novavax)	Booster	17,069	4	23.4	0	0	0	0	1	5.9	4	23.4	0	0
Spikevax (Moderna)	Primary	80,676	3	3.7	0	0	1	1.2	7	8.7	26	32.2	7	8.7
Spikevax (Moderna)	Booster	429,877	5	1.2	1	0.2	1	0.2	10	2.3	20	4.7	3	0.7
Spikevax (bivalent-Omicron BA-1)	Primary	1,681	0	0	0	0	0	0	0	0	0	0	1	59.5
Vaxzevria (AstraZeneca)	Primary	13,789	1	7.3	0	0	0	0	0	0	2	14.5	3	21.8
Vaxzevria (AstraZeneca)	Booster	6,690	0	0	0	0	0	0	0	0	0	0	1	15
Afluria Quad		219,162	1	0.5	0	0	0	0	0	0	0	0	0	0
FluQuadri		192,113	2	1.0	1	0.5	0	0	0	0	1	0.5	0	0
Fluad Quad		327,436	0	0	0	0	1[+]	0.3	0	0	0	0	0	0
Vaxigrip Tetra		168,837	1[+]	0.6	0	0	0	0	0	0	0	0	0	0
Nimenrix		66,164	1[#]	1.5	0	0	0	0	0	0	0	0	0	0
Prevenar 13		135,027	1[#]	0.7	0	0	0	0	0	0	0	0	0	0
Priorix		24,665	1[#]	4.1	0	0	0	0	0	0	0	0	0	0

ITP: immune thrombocytopenic purpura. GBS: Guillain-Barré syndrome

[+]Vaccine co-administered with a COVID-19 vaccine

[#]Vaccines co-administered in the same vaccination encounter

AEFI case rate per 100,000 doses administered of the respective vaccine (and course where applicable). Calculated rate estimates in the context of low counts should be interpreted with caution.

Data linkage actively searched for the presented AESI against all COVID-19 vaccines. AESI and their associated rates are only presented with respect to the vaccine(s) (and course) against which the AESI was recorded.

Anaphylaxis

Anaphylaxis is a potentially life-threatening allergic reaction that occurs rarely after vaccination, with onset typically within minutes to hours.[15]

In 2022, a total of 44 cases were found to have sufficient evidence to provide a diagnosis of anaphylaxis following COVID-19 vaccination. One of these followed co-administration with an influenza vaccine. The rate of confirmed anaphylaxis cases was 1.6 per 100,000 doses of COVID-19 vaccinations. Excluding the co-administered report, six additional cases of anaphylaxis were reported following non-COVID-19 vaccines.

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.[16] In 2022, four cases of confirmed ITP were reported to WAVSS following COVID-19 vaccination; one of these followed co-administration with an influenza vaccine. The rate of confirmed ITP cases was 0.1 cases per 100,000 doses of COVID-19 vaccinations.

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 2022, WAVSS had nine confirmed cases of GBS following COVID-19 vaccinations. One of these followed co-administration with an influenza vaccine. The rate of confirmed GBS cases was 0.3 cases per 100,000 doses of COVID-19 vaccinations.

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).[17] 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.[17] 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.[18,19] Both these classification systems have been applied to cases of possible myocarditis, myopericarditis, and pericarditis that have been reported to WAVSS. Cases confirmed using these diagnostic criteria are included in Table 5 above and Figure 11 and Figure 12 below. For this report, myopericarditis has been grouped together with myocarditis due to its clinical severity and similar management approach post-vaccination.

Sixty-five cases of myocarditis/myopericarditis following COVID-19 vaccination in 2022 were confirmed by WAVSS, with an overall rate of 2.3 cases per 100,000 doses of COVID-19 vaccines administered. By course, this rate was 3.5 cases per 100,000 primary course doses administered

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

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

[17] "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

[18] "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

[19] "Myocarditis/pericarditis Case Definition", Brighton Collaboration, https://brightoncollaboration.us/myocarditis-case-definition-update/

and 1.8 cases per 100,000 booster course doses administered. The highest rate of myocarditis following a primary course vaccination was following Spikevax (Moderna) in the 18–29-year age group (Figure 11), with a rate of 25.6 cases per 100,000 primary course Moderna doses administered.

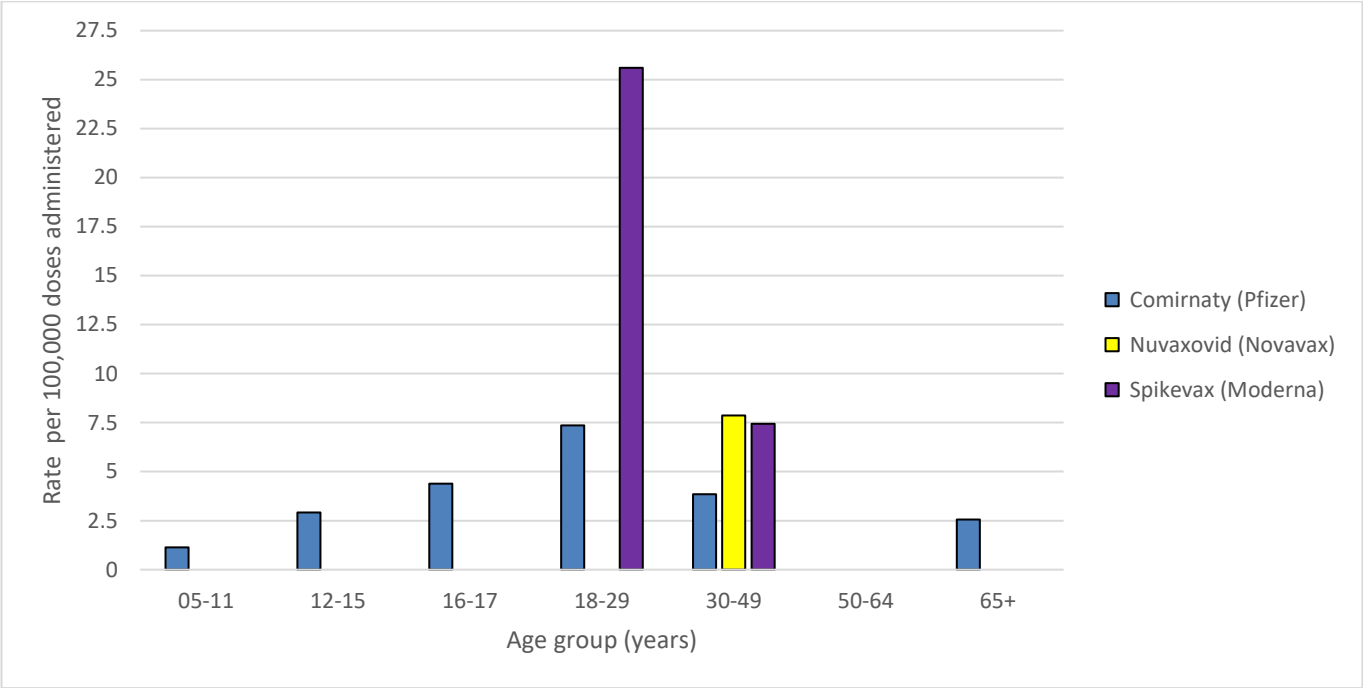

Figure 11: Rate of myocarditis by age group and vaccine brand per 100,000 primary course doses administered of the listed COVID-19 vaccines.

The highest rate of myocarditis following a booster course vaccination was following Spikevax (Moderna) in the 16-17-year age group (Figure 12) with a rate of 41.4 cases per 100,000 booster course Moderna doses administered.

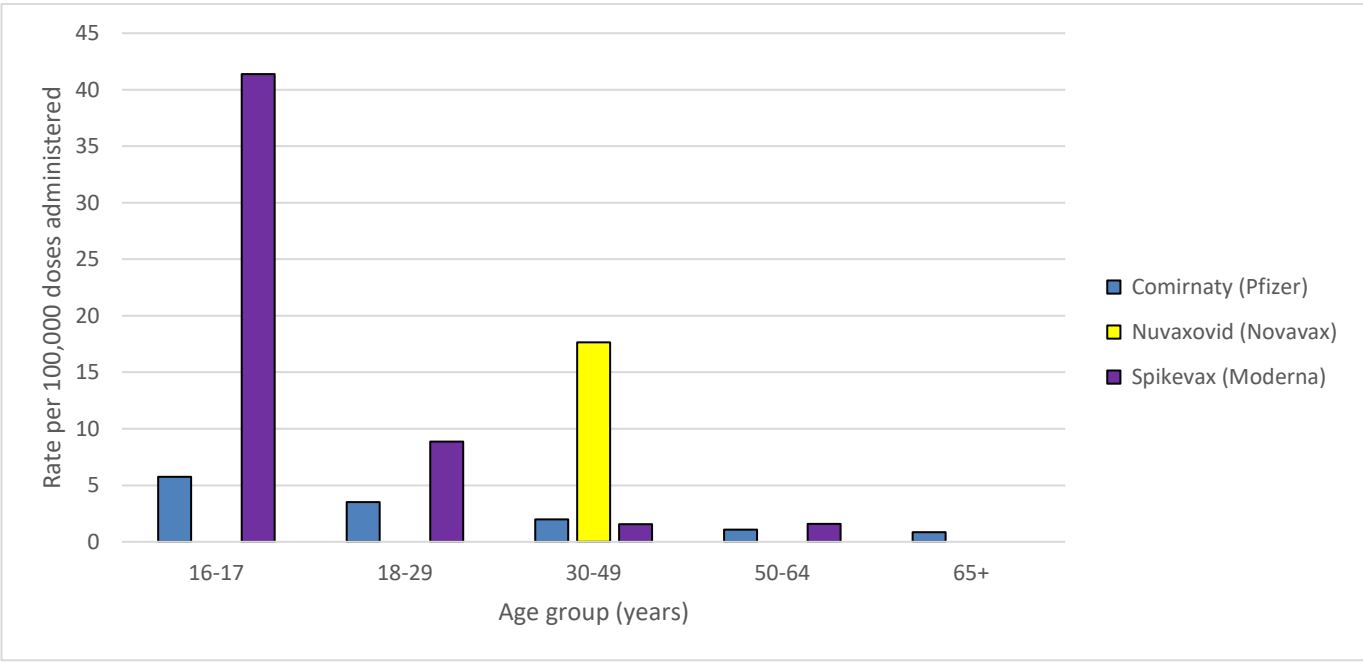

Figure 12: Rate of myocarditis by age group and vaccine brand per 100,000 booster course doses administered of the listed COVID-19 vaccines.

A total of 214 cases of pericarditis following COVID-19 vaccination in 2022 were confirmed by WAVSS, with an overall rate of 7.6 cases per 100,000 COVID-19 doses administered. By course, this rate was 14.7 cases per 100,000 primary course COVID-19 doses administered and 4.7 cases per 100,000 COVID-19 booster course doses administered. The overall rate of confirmed pericarditis following any COVID-19 vaccination was lower than the rate of reaction shown in Figure 10 (8.8 per 100,000 COVID-19 doses administered). This difference is attributable to the fact that not all reported cases of pericarditis are confirmed as cases of pericarditis following clinical review by WAVSS clinicians with assessment against CDC and Brighton Collaboration criteria.

The highest rates of pericarditis following primary course vaccination were in the 18-29 and 30-49-year age groups (Figure 13) with 54.1 cases per 100,000 Nuvaxovid (Novavax) primary course doses administered and 48.4 cases per 100,000 Spikevax (Moderna) primary course doses administered respectively.

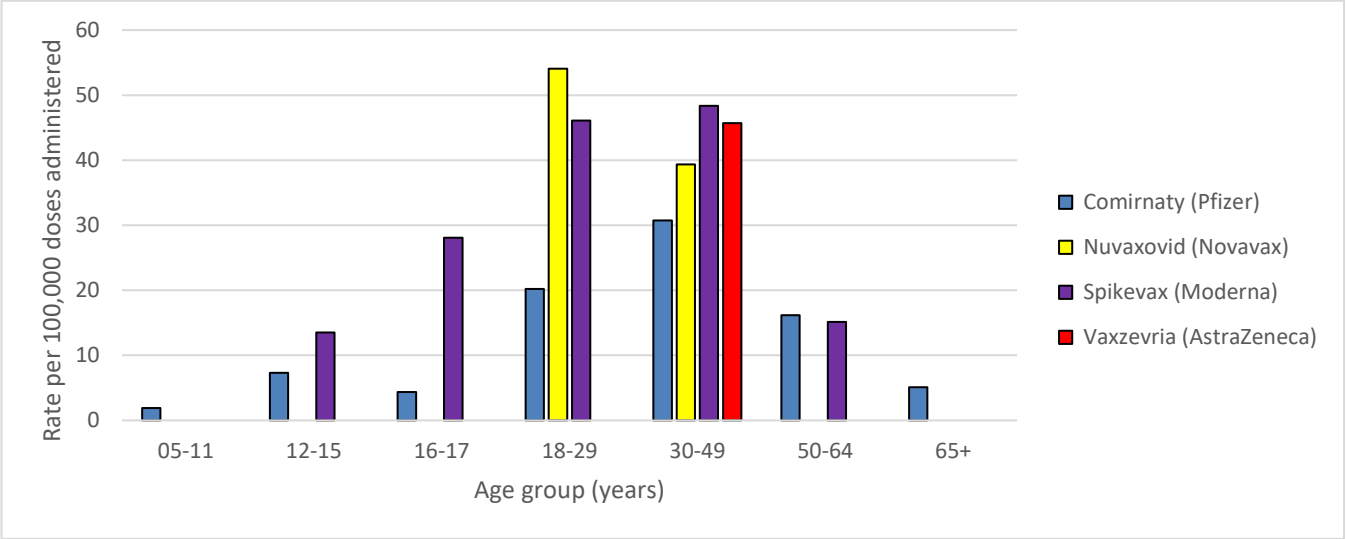

Figure 13: Rate of pericarditis by age group and vaccine brand per 100,000 primary course doses administered of the listed COVID-19 vaccines.

The highest rate of pericarditis following booster course vaccination was in the 18-29 and 65+ years age group following Nuvaxovid (Novavax) (55.2 cases and 43.6 cases per 100,000 Novavax booster course doses administered respectively; Figure 14).

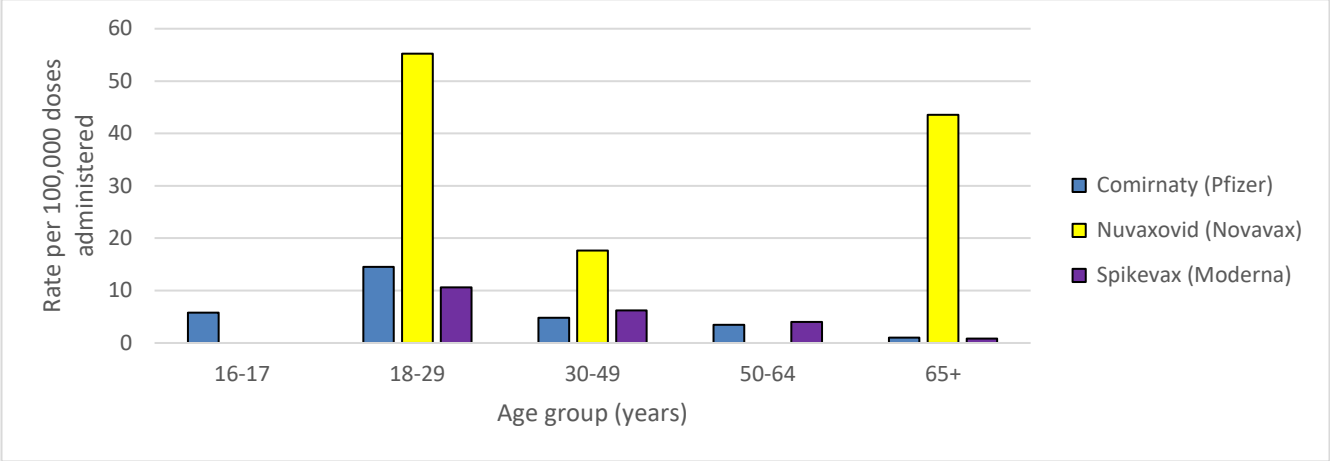

Figure 14: Rate of pericarditis by age group and vaccine brand per 100,000 booster course doses administered of the listed COVID-19 vaccines.

Menstrual disturbance

WAVSS monitored reports of menstrual disturbance following cases emerging in national and international reports. There were 39 cases following COVID-19 vaccines of any reported menstrual abnormalities (1.4 cases per 100,000 doses administered). Investigation by the TGA did not find a causal association between vaccination and menstrual changes; however, the TGA ensured it was added to the Product Information as an adverse reaction that can potentially occur with the mRNA COVID-19 vaccines in February 2023, and continues to monitor it as a listed AESI.[20]

Thrombosis with thrombocytopenia syndrome

Thrombosis with thrombocytopenia syndrome (TTS) is a rare but serious side-effect of Vaxzevria vaccine, first identified in 2021 and continually monitored throughout 2022. No confirmed cases of TTS were reported in 2022, likely attributable to the reduction in Vaxzervria vaccines administered in WA comparative to 2021.

[20] "COVID-19 vaccine safety report – 23-02-2023", Australian Government Department of Health and Aged Care, https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-23-02-2023

10. Clinical review of adverse events

AEFI reports to WAVSS undergo a staged clinical review process determined by the complexity and severity of the reported reaction(s). All AEFI reports receive clinical review at WAVSS. Reports of serious events are determined to require specialist review by either the Expert Clinical Review Group (ECRG) or at a specialist immunisation clinic located at Sir Charles Gairdner Hospital (for adults) or Perth Children's Hospital (for children and adolescents). All reports of SAEFI receiving specialist review are assigned a WHO causality (see Table 7 for classification definitions).

AEFI reports submitted to WAVSS are initially triaged into three categories:

- Possible serious event
- Event
- Non-event

The determination of 'possible serious event' is based on the information provided in the AEFI report to WAVSS regarding the severity of the reported reaction and does not automatically infer causality.

Table 6 presents the breakdown of AEFI reports by triage classification for vaccinations occurring in 2022.

Table 6: Triage classification of AEFI reports by vaccine group

	Vaccine group					
Initial triage	COVID-19	Influenza	Mpox	NIP	Other	**Total**
Event	1,921	182	102	401	18	2,624
Non-event	19	0	0	2	0	21
Possible serious event	445	6	1	8	3	463
Total	2,385	188	103	411	21	3,108

Irrespective of initial triage, further review is still undertaken. At the further review stage, additional information may be identified which leads to further analysis and determination that some of the AEFI reports triaged as 'event' also require specialist review (n = 459 in 2022). These events receive appropriate follow-up and classification. A total of 802 AEFI reports received a WHO causality classification (Table 7).

Table 7: WHO causality classification of AEFI reports by vaccine group

WHO Classification	Vaccine group					**Total**
	COVID-19	Influenza	Mpox	NIP	Other	
A1 (consistent causal association: vaccine product-related reaction)	356	13	2	48	3	422
A3 (consistent causal association: immunisation error-related reaction)	1	0	0	1	0	2
A4 (consistent causal association: immunisation anxiety-related reaction)	4	2	0	6	0	12
B1 (indeterminate: consistent temporal relationship but insufficient evidence for causality)	176	4	6	3	4	193
B2 (indeterminate: conflicting trends of consistency and inconsistency with causality)	39	3	0	8	0	50
C (inconsistent causal association to immunisation [coincidental])	92	2	0	7	0	101
D (ineligible cases and unclassifiable cases)	21	1	0	0	0	22
Clinician reviewed as not serious	1,651	163	95	337	14	2,260
Classification pending	45	0	0	1	0	46
Total	2,385	188	103	411	21	3,108

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 140 deaths that were reported to WAVSS in 2022, 130 (92.9%) were identified via active surveillance through data linkage and 10 (7.1%) through other reporting mechanisms. All cases received specialist review, and where information was sufficient to determine classification (n = 94), none were found to be causally associated with vaccination. Of the outstanding cases that have yet to be formally classified (n = 46, 32.9% of deaths), specialist review has occurred but confirmation of the final cause of death from a death certificate or coroner report is pending. There is no indication that these deaths are likely to be attributed to vaccination based on initial investigation.

Cardiac events identified via data linkage or through other reporting mechanisms were reviewed with 65 events classified as myocarditis or myopericarditis cases, and 215 events classified as pericarditis cases. Of the 65 confirmed myocarditis/myopericarditis cases, 60 were determined to be causally associated with COVID-19 vaccination. Of the 215 confirmed pericarditis cases, 189 were determined to be causally associated with COVID-19 vaccination and one with influenza vaccination.

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 856 AEFI reports resulted in a referral to a specialist clinic (Table 8).

Table 8: Number of reports by triage classification referral destination.

Referral	Initial triage			**Total**
	Event	Possible Serious Event	Non-event	
Not referred to specialist clinic	2,052	200	0	2,252
Referred to PCH	192	22	0	214
Referred to SCGH	380	241	21	642
Total	2,624	463	21	3,108

PCH: Perth Children's Hospital. SCGH: Sir Charles Gairdner Hospital.

11.2. Adult clinic activity

In 2022, the adult vaccine safety clinic at Sir Charles Gairdner Hospital (SCGH) received 1,935 referrals, resulting in 2,527 appointments. Appointments include referrals from non-WAVSS sources, and one patient can have multiple appointments. This represents a 125% increase in appointments from 2021. Almost all referrals were related to AEFI after COVID-19 vaccination.

11.3. Child and adolescent clinic activity

In 2022, there were 504 appointments made at the Perth Children's Hospital Specialist Immunisation Clinic (SIC), of which 316 were new referrals. 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, 437 individual children and adolescents attended the SIC. Of those who attended their appointment, 90 (20.6%) were due to possible AEFI, 116 (26.5%) for complex medically-at-risk immunisation requirements, 45 (10.3%) for vaccine hesitancy, and 186 (42.6%) for needle anxiety.

12. WA Vaccine Safety Advisory Committee (WAVSAC)

Prior to 2021, the Western Australia's Vaccine Safety Advisory Committee (WAVSAC) met twice a year to review state vaccine safety. In 2022, the Committee met 15 times.

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 required specialist assessment. The ECRG met 34 times in 2022 and reviewed over 350 AEFI reports.

13. Summary and Discussion

13.1. Vaccine safety surveillance results

A summary of the past five years of vaccine safety surveillance in WA is presented in Table 9.

Table 9: Doses administered, AEFI reported and AEFI report rate by vaccine group and year(s) of vaccination

Vaccine Group	Course	AEFI Reports 2018-2021	Doses administered 2018-2021	AEFI Report Rate 2018-2021	AEFI Reports 2022	Doses administered 2022	AEFI Report Rate 2022
COVID-19*	Primary	10,228	3,886,914	263.1	1,300	807,373	161.0
COVID-19*	Booster	160	164,309	97.4	1,085	2,028,400	53.5
Influenza		465	3,143,496	14.8	188	1,057,551	17.8
Mpox**					103	3,256	3163.4
NIP		1,289	3,229,985	39.9	411	775,322	53.0
Other		143	430,905	33.2	21	65,873	31.9

*COVID-19 vaccines were only available in WA from 2021 onwards. **Mpox vaccines were not available prior to 2021. AEFI report rates are presented per 100,000 doses administered of the respective dose (and course where applicable).

Relative to 2021, the AEFI report rate for COVID-19 vaccines has decreased. The AEFI report rate for primary course COVID-19 doses administered has decreased by 38.8% from 263.1 to 161.0 per 100,000 doses administered. The AEFI report rate for booster course COVID-19 doses administered has decreased by 45.1% from 97.4 to 53.5 per 100,000 doses administered. The decrease in the AEFI report rate for COVID-19 vaccines likely reflects the WA population's increased understanding of common, minor reactions following these vaccines. This may have also changed the profile of the AEFI reports submitted to WAVSS following COVID-19 vaccination, with a greater proportion of reported AEFI being SAEFI and AESI, compared to 2021. This relative increase also reflects the ongoing active surveillance program, which continued to focus on relevant SAEFI and AESI.

Slight increases were observed in 2022's AEFI report rate for NIP, influenza and 'Other' vaccine groups relative to the previous four-year period. This increase likely reflects the expanding role of active surveillance methods for detecting AEFI in the WA population in the last two years. For example, only 88 distinct AEFI reports submitted in 2020 were via active surveillance, as compared to 898 in 2022, a more than 10-fold increase, and a proportional increase in the contribution of active surveillance by 7%. Greater public awareness of the passive surveillance program following the COVID-19 vaccine roll-out has also likely marginally contributed to this increase in the AEFI report rate. It is expected that the combination of enhanced active surveillance and increased awareness of the passive surveillance program will lead to a higher background AEFI report rate for all vaccines, when compared to historical reporting data in WA prior to 2021.

The high rate of AEFI reports observed in the Mpox vaccine group illustrates how effective active safety surveillance can be in a closely monitored targeted vaccination program. For example, 97.1% of AEFI reports following Mpox vaccination were identified via active surveillance, with most reactions short-lived and resolved without intervention or with simple analgesia.

13.2. Continued improvements to vaccine safety surveillance

In 2022, WAVSS continued to provide robust, reliable and timely vaccine safety surveillance of all vaccines administered in WA. WAVSS has adapted well to significant changes over the past

two years and has been able to refine its processes as it returns to a business-as-usual model following the COVID-19 vaccine rollout. Ensuring the State's immunisation program is safe, and that public confidence is maintained in the program is critical, as high vaccination coverage remains essential to reducing rates of vaccine-preventable diseases in WA.

Data linkage

Both WAVSS and the department were able to consolidate key surveillance measures, particularly through improvements to data linkage active surveillance processes. The data linkage process instituted by the department and WAVSS has proven to be one of the most comprehensive systems for vaccine safety surveillance in Australia. Significant benefits have included the ability to rapidly identify SAEFI and AESI, which has enabled more comprehensive clinical assessment of patients, and enhanced safety signal feedback to the TGA. Challenges have included the dependency on accurate clinical coding data, and appropriateness of targeted conditions of interest. Improvements in understanding of clinical coding, better collaboration with State and international vaccine safety experts and improved efficiencies to the process since its introduction, has allowed better utilisation of the data linkage capability. These strengths were seen through the Mpox surveillance program, where data linkage was quickly adapted to provide effective and timely safety assessment of a new short-term vaccination program. WAVSS expects to be able to use a similar approach to assess adjustments in the immunisation program in the future.

The current data linkage process contributes to higher reported rates of AEFI, specifically compared to other surveillance methods. This active surveillance approach is likely a more accurate reflection of AEFI rates, and thus can only enhance safety signal identification and thus better inform the overall immunisation program. In 2022, our local data has affirmed the safety of the current immunisation program.

Specialist oversight

WAVSS continues to be well-supported by specialists with expertise in vaccine safety, and clinicians with expertise in assessing and managing SAEFI and AESI.

The year 2022 saw the continued expansion of the SCGH adult vaccine safety clinic. Consolidation of this service is key to ensuring the vaccine safety surveillance program is supported by appropriate patient-facing clinical assessment and advice. Whilst this clinic has primarily been established to provide clinical assessment of AEFI, it has also expanded to review adults with complex medical problems who have additional vaccination requirements. The clinic has also seen an increase in patients who had not maintained an 'up to date' vaccination status due to previous AEFI. The paediatric SIC at PCH continues to provide support to children who have issues affecting immunisation, including AEFI, complex vaccination requirements, vaccine hesitancy, and needle anxiety.

WAVSAC and its sub-committee, ECRG, continue to provide support to WAVSS, with a particular focus on SAEFI and AESI. Members of these groups also regularly collaborate with other vaccine safety experts nationally and internationally, and provide regular feedback to the TGA and ATAGI.

Research, education, data analysis and reporting

WAVSS has been involved in important research on vaccine safety, contributing to several national collaborative projects that have been published in the international medical literature.[21,22] These processes are important to improve our understanding of vaccine safety, and to guide

[21] Tran HA et al. "The clinicopathological features of thrombosis with thrombocytopenia syndrome following ChAdOx1-S (AZD1222) vaccination and case outcomes in Australia: a population-based study", *Lancet* 100894, vol. 40 (2023). doi: 10.1016/j.lanwpc.2023.100894

[22] Shivarev A et al. "Adverse event reports of anaphylaxis after Comirnaty and Vaxzevria COVID-19 vaccinations, Western Australia, 22 February to 30 June 2021", *Intern. Med. J.* doi: 10.1111/imj.16001

future advice regarding local, national and international vaccination programs. In addition, ECRG and WAVSAC representatives have participated in numerous education sessions to immunisation providers to improve awareness and understanding of vaccine safety processes and AESI.

The staff dedicated to vaccine safety surveillance constantly improve data capture, data cleaning and data analysis techniques, leading to yearly improvements in consistency, transparency and accuracy of reporting.

14. 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 Services
COVID-19	Coronavirus Disease 2019 (illness caused by SARS-CoV-2)
CVLDR	COVID-19 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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