LANDKREIS LÜNEBURG
DER LANDRAT

Büro des Landrats		Vorlagenart	Vorlagennummer
Verantwortlich:	Gruppe AfD / dieBasis	**Antrag**	**2023/285**
Datum:	28.08.2023		
		Öffentlichkeitsstatus: öffentlich	

Beratungsgegenstand:

Antrag der AfD-Fraktion vom 26.08.2023 zum Thema "Einrichtung einer Beratungsstelle für die Bürger bei Impfnebenwirkungen und Impffolgeschäden - Offizielle Daten: Covid-Impfstoffe haben 24x mehr Nebenwirkungen als andere Vakzine"

Produkt/e:
111-110 Büro des Landrats

Beratungsfolge

Status	Datum	Gremium
Ö	28.09.2023	Kreistag

Anlage/n:
- Überwachung der Impfstoffsicherheit in Westaustralien – Jahresbericht 2021
- Aufstellung der WHO zu Anzahlen von Impfnebenwirkungen - 12. November 2021

Beschlussvorschlag Antragsteller:
Entsprechend beantragen wir (erneut), der Kreistag möge beschließen:

1. den Landrat zu beauftragen, im Landkreis Lüneburg eine Beratungsstelle einzurichten, an die sich Bürger bei Auftreten von Impfnebenwirkungen und Impffolgeschäden wenden können, sowie

2. diese Stelle durch organisatorische Maßnahmen innerhalb der Verwaltung zu realisieren, um so die Schaffung einer zusätzlichen Stelle zu vermeiden.

3. die Beratungsstelle wird dem Kreistag regelmäßig über die Beratungen bzw. die Erfassung der Impfnebenwirkungen und Impffolgeschäden in unserem Landkreis, auch aus Sicht der die Beratungsstelle Aufsuchenden, berichten

Ergänzend zum Antrag 2022/177 der AFD-Fraktion vom 16.05.2022 (Einrichtung einer Beratungsstelle für die Bürger bei Impfnebenwirkungen und Impffolgeschäden) ist zu berichten, dass nun ein detaillierter Überwachungsbericht zur Impfstoffsicherheit aus Westaustralien vorliegt (s. Anlage), dem zu entnehmen ist, dass Covid-„Impfstoffe“ 24x mehr Nebenwirkungen als andere Vakzine aufweisen:

Demnach wurden in der australischen Provinz im Jahr 2021 knapp über 1,8 Millionen Nicht-Covid-Impfstoffe und rund 3,95 Millionen Covid-„Impfstoffe“ verabreicht. Bei den anderen Impfstoffen wurden dabei 200 Fälle von unerwünschten Nebenwirkungen gemeldet, bei den Covid-„Impfstoffen“ hingegen ganze 10.428.

Das heißt: Von 100.000 Geimpften sonstiger Impfungen erlitten demnach 11,1 Personen solche Nebenwirkungen, doch ganze 264,1 der Covid-„Geimpften“. Wobei anzumerken ist, dass Nebenwirkungen (insbesondere weniger schwere) seltener gemeldet werden als es tatsächlich welche gibt, da der Bürokratieaufwand enorm ist.

Der Impfstoff Spikevax (Moderna) verzeichnete dem Bericht zufolge 281,4 Fälle von Nebenwirkungen pro 100.000 Dosen. Comirnaty (Pfizer) verzeichnete 244,8 Fälle pro 100.000 verabreichten Dosen und der „Impfstoff“ Vaxzevria (AstraZeneca), der aus dem „Impfprogramm“ gestrichen wurde, nachdem Berichte über Blutgerinnsel bei jüngeren Menschen auftauchten, verzeichnete 306 Fälle.

Unerwünschte Ereignisse als Folgen einer Impfung können von milden Erkrankungen wie Armschmerzen bis hin zu schwerwiegenden Erkrankungen wie Anaphylaxie, Thrombose mit Thrombozytopenie-Syndrom (TTS), Guillain-Barré-Syndrom (GBS), Myokarditis und Perikarditis reichen.

Sogar noch Wochen nach den Injektionen wurden bei „Geimpften“ Spike-Proteine, die mit Hilfe der RNA-Anleitung hergestellt wurden, entdeckt. Und dieser Verbleib war mit schweren Multiorganentzündungen und oftmals tödlichen Erkrankungen verbunden.

Da also nicht bekannt ist, wie lange solche Spike-Proteine produziert werden, sind die sich ergebenden Langzeitwirkungen bzw. -schädigungen bis heute nicht absehbar.

Da die Verwaltung unseres Landkreises in Ihrer Stellungnahme vom 19.05.2022 bereits an das Gesundheitsamt verwies, sei ergänzend berichtet, dass bereits im November 2021 WHO-Daten zeigten (s. Anlage), dass die Covid-„Impfung“ deutlich gefährlicher ist, als jede andere Impfung.

Und unser Gesundheitsamt in Lüneburg propagierte dennoch selbst in 2022 die Covid-„Impfung“ sozusagen als Nonplusultra.

Wir halten gerade auch deswegen eine Beratungsstelle unabhängig vom Gesundheitsamt für erforderlich, da diese keine solche, aus unserer Sicht bedenkliche, Vorgeschichte aufweisen würde.

Es ist wichtig, die bisher ziemlich alleingelassenen, betroffenen Bürger unseres Landkreises durch eine neutrale Anlaufstelle im Sinne einer Erstberatung zu unterstützen. Unser Landkreis würde damit auch ein positives Signal an andere Landkreise senden, im Sinne von, seht her, wir lassen unsere Bürger nicht allein und orientieren uns selbstverständlich an den aktuellen Fakten bzw. Zahlen.

Die hohe Anzahl von Nebenwirkungen Betroffener und die Voreingenommenheit Seitens der Behörden in den Corona-Jahren pro Corona-„Impfung“ sprechen eindeutig für solch eine Beratungsstelle in unserem Landkreis.

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

Western Australian Vaccine Safety Surveillance – Annual Report 2021

Produced by the Immunisation Program, Communicable Disease Control Directorate and the COVID-19 Vaccination Program, Department of Health, Western Australia

health.wa.gov.au

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 2021. The format of this Annual Report differs significantly from previous WAVSS Annual Reports, to enable description of the impact of the COVID-19 vaccination program, which was started in February 2021, on WAVSS and other aspects of the state's vaccine surveillance program.

In 2021 a total of 5,756,723 vaccine doses were administered in WA, up from 2,071,167 in 2020. Of this amount, 3,948,673 individual doses of COVID-19 vaccine were recorded in the Australian Immunisation Register (AIR) as being administered to WA residents. The increase in vaccine administration resulted in a significant increase in reports of AEFI, with WAVSS receiving 10,726 individual AEFI reports in 2021, up from 270 in 2020. Of these AEFI, 10,428 (97%) occurred after a COVID-19 vaccine.

Although there was a notable increase in AEFI reports, rates of AEFI across the three COVID-19 vaccines administered in WA in 2021 were similar to national rates reported by the Therapeutic Goods Administration (TGA)[1]. In WA, the total AEFI rate following a COVID-19 vaccine was 264.1 per 100,000 doses. The AEFI rate per brand was: Vaxzevria (AstraZeneca) 306.1 per 100,000 doses, Comirnaty (Pfizer) 244.8 per 100,000 doses and Spikevax (Moderna) 281.4 per 100,000 doses.

These rates were compared to the WAVSS equivalent in the USA; the Vaccine Adverse Event Reporting System (VAERS)[2]. In 2021 the national rate for AEFI following a COVID-19 vaccine was 148.3 per 100,000 doses[3]. The AEFI rates for comparable vaccines in the VAERS program were: Comirnaty (Pfizer) 122.0 per 100,000 doses and Spikevax (Moderna) 187.6 per 100,000 doses. While these AEFI rates are lower than in WA, this likely reflects differences in the sensitivity of passive adverse event reporting systems between the two jurisdictions.

With the onset of the new COVID-19 vaccine program, WAVSS took an active role in identifying potentially serious AEFI. Part of this role included regular collaboration with the TGA, and other state immunisation programs. This report will provide an overview of some of the important AEFI that have been specifically monitored as part of the TGA-coordinated national surveillance vaccine safety program, including anaphylaxis, thrombosis with thrombocytopaenia syndrome (TTS), immune thrombocytopenic purpura (ITP), Guillain-Barré syndrome (GBS), myocarditis, and pericarditis.

Vaccines routinely available on the National Immunisation Program Schedule, and influenza vaccines, contributed 200 individual AEFI reports that were received by WAVSS. This number was lower than the average number of reports received per year for the 2017 - 2020 time period (mean = 275.8). There were 1,808,050 individual doses of non-COVID-19 vaccines recorded in the AIR in 2021, giving a total AEFI rate of 11.1 events per 100,000 doses, which is similar to the reported 2020 rate of 12.4 per 100,000 doses. Expected, minor reactions were common in these reports.

In 2021, there were 1,125 appointments made at the adult vaccine safety clinic at Sir Charles Gairdner Hospital, up from seven in 2020. There were 439 appointments made at the Perth Children's Hospital specialist immunisation clinic, up from 214 in 2020.

[1] Therapeutic Goods Administration Articles https://www.tga.gov.au/resources/article?f[0]=type:189

[2] Vaccine Adverse Event Reporting System (USA) for numerators (number of AEFI reported): https://vaers.hhs.gov/data/datasets.html

[3] Our World in Data COVID-19 dataset for denominators (number of vaccines given): https://github.com/owid/covid-19-data/tree/master/public/data

1. Background

This annual report of adverse events following immunisation (AEFI) in Western Australia (WA) summarises surveillance data received by the Western Australia Vaccine Safety Surveillance (WAVSS) system.[4]

This system is a WA Department of Health (the Department) initiative to monitor vaccine safety that was established in March 2011, in collaboration with the Child and Adolescent Health Service (CAHS) and the Central Immunisation Clinic. It was based on the Victorian Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) model. The system accepts reports of suspected AEFI from health care providers and directly from the public, as well as receiving reports through the active surveillance system administered by AusVaxSafety (SmartVax) and reports received by the Therapeutic Goods Administration (TGA).

Adverse events following immunisation are defined as unwanted or unexpected events following the administration of a vaccine, which could be mild, such as a sore arm, or serious, such as anaphylaxis. AEFI also include conditions that 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, an assessment of causality based on World Health Organization criteria[5] is undertaken by clinical and immunisation experts.

A serious AEFI (SAEFI) is defined[6] as an event that:

- results in death
- is life threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity, or
- results in a congenital anomaly/birth defect

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. A list of AESI for COVID-19 vaccines was determined by the Safety Platform for Emergency Vaccines and the Brighton Collaboration[7] (a global vaccine safety research network). This list was used in addition to AEFI routinely monitored by WAVSS and the Department. Assessment of causality for AESI was also undertaken using the World Health Organization criteria[5].

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 reports by various reporting methods. Passive surveillance includes reports submitted by the person who received the vaccine (the vaccinee) or on their behalf by a health professional (including their immunisation provider), or family member. In WA, there is a statutory requirement for health professionals to report any AEFI to the Department, per the requirements of the Public Health Act 2016[8] and the Public Health Regulations 2017.[9] 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

[4] Western Australian Vaccine Safety Surveillance (WAVSS) system. https://ww2.health.wa.gov.au/Articles/U_Z/Western-Australian-Vaccine-Safety-Surveillance-WAVSS
[5] World Health Organization (2019), Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update
[6] World Health Organisation (2020), Covid-19 vaccines: safety surveillance manual. Geneva: World Health Organization
[7] Safety Platform for Emergency Vaccines (2020), Priority list of COVID-19 Adverse events of special interest
[8] WALW - Public Health Act 2016 - Home Page (legislation.wa.gov.au)
[9] WALW - Public Health Regulations 2017 - Home Page (legislation.wa.gov.au)

'suspected' AEFI that they receive for residents of WA. These reports are triaged to identify serious AEFI and AESI, cross-checked with WAVSS reports, and entered into the WAVSS database where missing. The TGA also provides the Department with daily reports of serious AEFI so they can be entered into WAVSS immediately. Although passive reports of AEFI rarely provide definitive evidence of a causal association between a vaccine and particular outcomes, spontaneous AEFI reporting enables the early detection of signals that can then be more rigorously investigated.

Active surveillance occurs via SmartVax[10] post-vaccination surveys that are distributed directly to the person who received the vaccine with responses reported to the vaccine provider (e.g. general practitioner, pharmacist) or directly to the Department for state run, mass-vaccination clinics. SmartVax is installed in 137 sites (general practitioners, pharmacies and community health clinics) across WA. For the COVID-19 vaccination program, surveys were sent on Day 3, 8 and 42 following vaccination, and reports of medically attended AEFI were reported to WAVSS. Some SmartVax surveys from November and December 2021 were not reported to WAVSS following a decision made in January 2022 to only report medically attended AEFI for adolescents, children, booster doses, and new vaccines. De-identified, aggregated, national active surveillance data from SmartVax is monitored by AusVaxSafety[11], which is an enhanced AEFI surveillance system led by the National Centre for Immunisation Research and Surveillance (NCIRS). In previous years, actively identified adverse events were not included in WAVSS annual reports; however, the number and importance of these reports due to the COVID-19 vaccination program warrant further description. National active surveillance data can be found at https://ausvaxsafety.org.au.

In 2021, WAVSS was expanded to include potential AEFI reports identified through active surveillance via data linkage. The Department has a well-established data linkage branch, with data from over 100 million records from around 50 datasets linked. The COVID-19 Vaccination Linked Data Repository (CVLDR) was established in April 2021; the CVLDR links individual COVID-19 vaccination data in the Australian Immunisation Register (AIR) to emergency department (ED) attendance, hospitalisation and death databases, for identification of potential SAEFI or AESI associated with COVID-19 vaccines. Utilising data linkage mitigates the risk that a healthcare provider or vaccine recipient does not report an AEFI which resulted in an ED or hospital visit, and thus enhances the completeness of the surveillance system. The search criteria for specific medical conditions were modified throughout the course of the COVID-19 vaccination program based on findings from local, national and international vaccine safety surveillance reports, and from the literature. Cases identified through data linkage active surveillance were reviewed by clinicians for eligibility, and if identified as possible SAEFI, entered into the WAVSS database.

In addition to the expansion of active surveillance to include data linkage, the vaccination landscape in WA was significantly different in 2021 compared to previous years. The COVID-19 vaccination program commenced in late February 2021 and introduced three new vaccines over the course of the year with different age groups becoming eligible for vaccination at different timepoints (Figure 1). As a result, the number of vaccine doses administered in WA was significantly higher than in previous years: 5,756,723 doses in 2021 compared to 2,071,167 doses in 2020. Reporting of AEFI also increased significantly from 270 reports in 2020 to 10,628 reports in 2021. In order to manage this substantial increase in workload, a Research Electronic Data Capture (REDCap) project (a web platform for databases) was designed and implemented to assist with triage of reports and case review. The COVID-19 vaccination program attracted considerable public interest and media attention in 2021, almost certainly increasing public

[10] SmartVax http://www.smartvax.com.au/
[11] AusVaxSafety http://ausvaxsafety.org.au/

awareness of vaccine safety. This increase in publicity may have contributed to increased awareness of AEFI and increased reporting of COVID-19 vaccine AEFI to WAVSS.[12]

[12] Varriccio, F et al (2004) Understanding vaccine safety information from the Vaccine Adverse Event Reporting System, The Pediatric Infectious Disease Journal, Volume 23 Issue 4, pp. 287-294

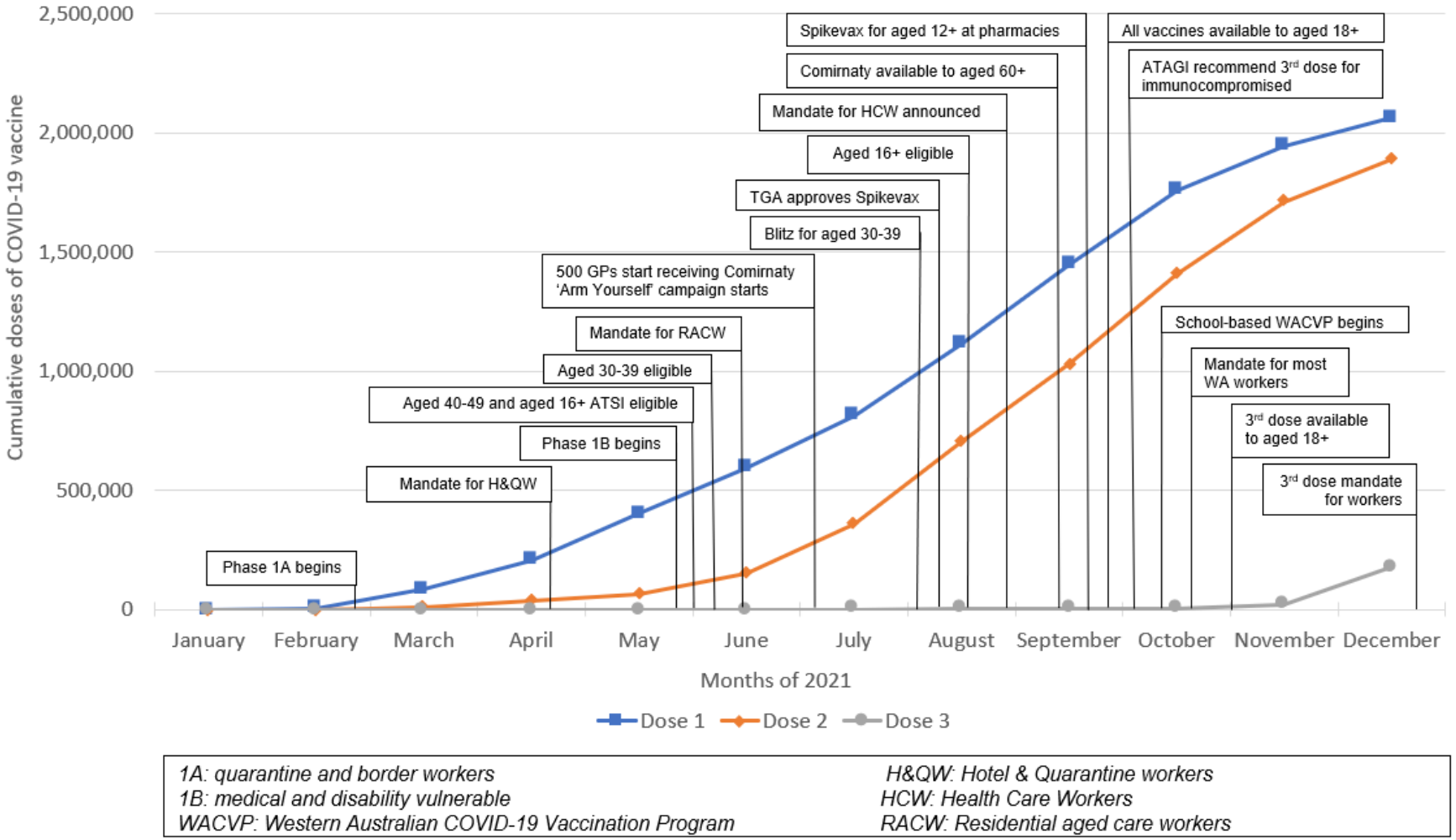


Figure 1. Timeline of COVID-19 vaccine coverage (%) in Western Australia by month in 2021 with significant program time points

2. Method

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

- vaccination was recorded as 'possibly' being the cause of, or contributing to, the reported adverse event. This includes reports where a determination is still pending; and
- the residential address of the individual was recorded as Western Australia; and
- the vaccination occurred between 1 January 2021 and 31 December 2021; and
- the suspected reaction was captured in the state reporting system (WAVSS).

For COVID-19 vaccine AEFI reports:

- AEFI reports were excluded if no vaccination date could be determined;
- AEFI reports were excluded if the reporter provided two separate vaccine doses on separate dates and the reaction-related vaccination date could not be determined;
- AEFI reports were excluded if they were classified as 'not related'; and
- AEFI reports which reported separate reactions to different vaccines on different dates were counted as separate reports.

Important considerations when interpreting the AEFI summary data

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.

Young children often receive multiple vaccines as part of the National Immunisation Program (NIP) schedule[13] during a single health care encounter. In these circumstances, it is usually not possible to attribute a subsequent AEFI to a single vaccine, so all the vaccines administered during the visit are usually listed as 'suspected' of involvement in the AEFI.

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.

Active surveillance data from SmartVax for all routine vaccines was reported to WAVSS based on the immunisation provider's decision to report the SmartVax survey response. For COVID-19 vaccination, SmartVax responses from vaccinees were entered into WAVSS if the vaccinee attended an Emergency Department or was admitted to hospital; these were classified as 'self-reported'. Some SmartVax surveys from November and December 2021 were not reported to WAVSS following a decision made in January 2022 to only report medically attended AEFI for adolescents, children, booster doses, and new vaccines.

The data included in this report were received by WAVSS as of 14 July 2022 (for vaccinations received in 2021) and are subject to change. This date was chosen as a cut-off to enable data validation and timely reporting, and to capture longer-term AEFI. AEFI rates are calculated using the number of doses of a particular vaccine recorded in the Australian Immunisation Register (AIR).

Unlike previous years, the AEFI summary is dominated by the large-scale, predominantly adult COVID-19 vaccination program. The AEFI analysis is therefore broken down into:

- Adverse events following routine vaccines, further separated into
    - Scheduled vaccines (includes all NIP childhood vaccines)
    - Influenza vaccines
- Adverse events following COVID-19 vaccines

[13] Western Australian Immunisation Schedule (health.wa.gov.au)

3. Overview

3.1. Summary of AEFI reports

The number of AEFI reported to WAVSS was significantly higher in 2021 than in previous years (10,726 compared with an average of 276 per year for the 2017-2020 period) due to the introduction of the COVID-19 vaccination program. To allow comparison of AEFI numbers to previous years, Figure 2 presents all AEFI reported to WAVSS for persons vaccinated in 2021, and Figure 3 excludes adverse events following COVID-19 vaccination. The high number of reports in 2021 following COVID-19 vaccination reflects higher uptake of COVID-19 vaccination, and high engagement from the public and health care providers with the monitoring of vaccine safety.

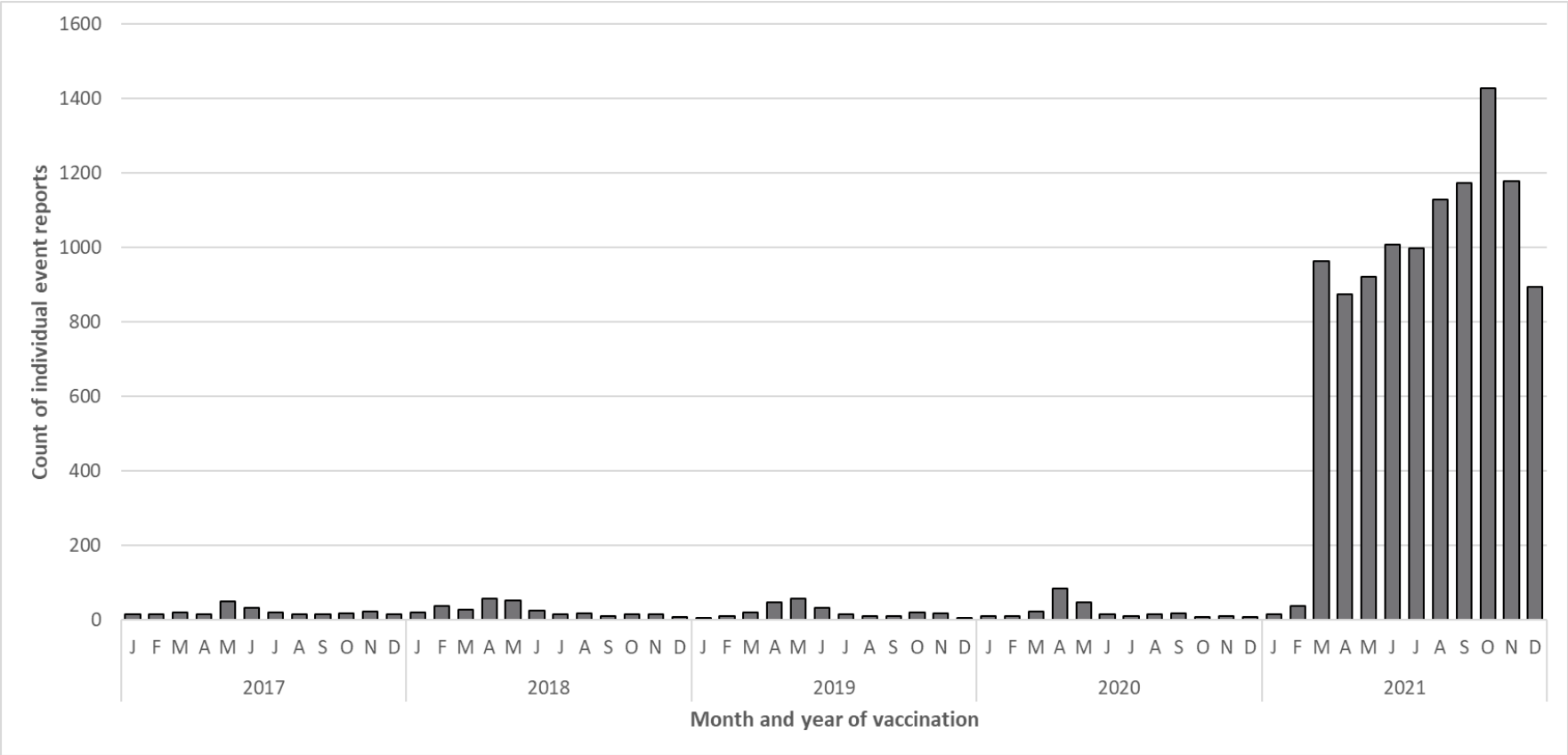


Figure 2: Adverse events following immunisation reported to WAVSS by month, 2017-2021, excluding active surveillance reports for routine vaccination adverse events.

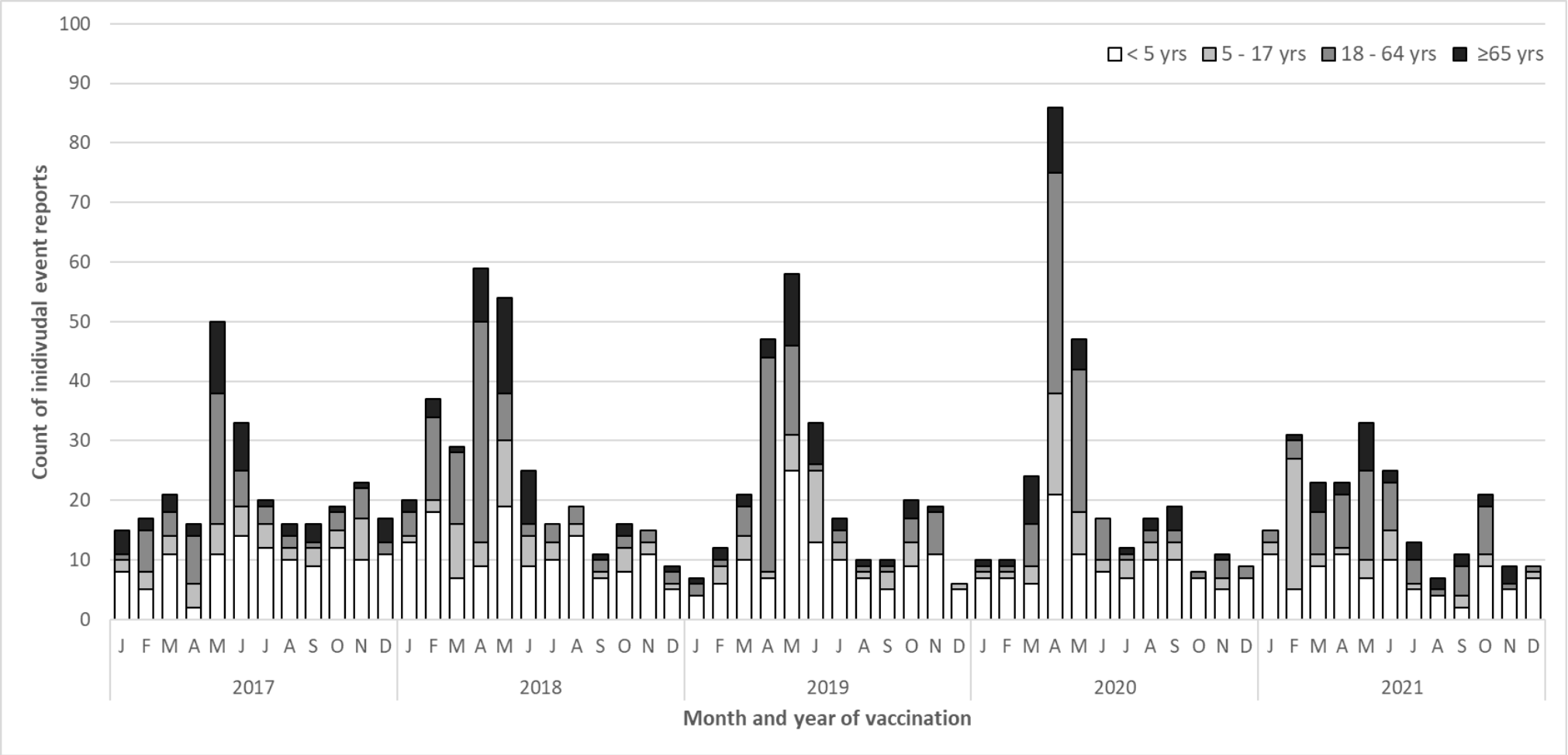


Figure 3: Adverse events following immunisation reported to WAVSS by age group and month, 2017-2021, excluding reports following COVID-19 vaccination and active surveillance of routine vaccines.

3.2. Characteristics of AEFI reports

Figure 4 illustrates how reports were received by WAVSS for vaccinations administered in 2021, as passive surveillance (provider or public reports to WAVSS), active surveillance (reports from SmartVax and data linkage). Despite the large difference in numbers of COVID-19 and routine vaccine AEFI reports, the proportions from surveillance type were similar - 63% and 67% passive surveillance, respectively, 35% and 33% active surveillance, respectively, and 2% data linkage for COVID-19 vaccines.

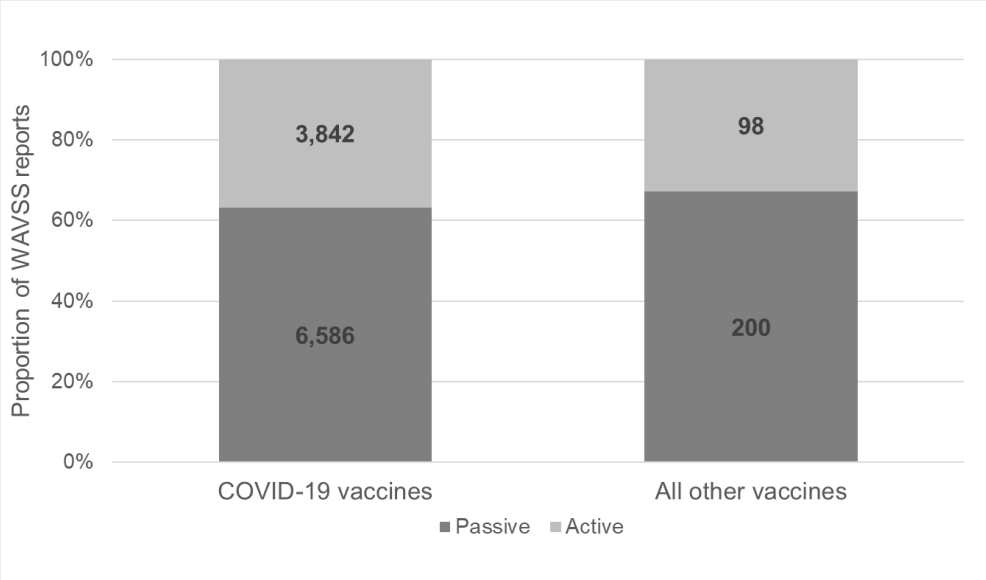


Figure 4. Proportion of adverse events following immunisation reported to WAVSS for vaccinations administered in 2021 by passive and active surveillance.

The characteristics of AEFI reports received from 2017-2021, including demographics of the vaccine recipient, reporter details, and how the AEFI was managed, are presented in Table 1. To allow comparison of AEFI to previous years, only passively reported AEFI are included for routine vaccines. Both passive reporting and active reporting (including data linkage) are included for adverse events following COVID-19 vaccination.

Despite an overall substantial increase in the number of AEFI reported to WAVSS, the number of adverse events following routine vaccines was lower in 2021 than in any of the previous four years. Consistent with previous years, and national-level data[14], more adverse events following routine vaccines were reported for females than for males; however, this difference was most pronounced for COVID-19 vaccine adverse events (64% female; Table 1). For adverse events following routine vaccination, the distribution by age group was similar to previous years, with the majority (54%) occurring in individuals under 18 years of age. The majority (81%) of adverse events following COVID-19 vaccines occurred in the 18-64 years age group.

The reporting of adverse events following COVID-19 vaccines differed from adverse events following routine vaccines in that the majority (58%) were reported by the vaccinee or a family member, whereas the majority (79%) of routine vaccine AEFI were reported by a healthcare provider (Table 1). In 2021, active surveillance in the form of SmartVax surveys accounted for 57% (3,506/6,083) of the self-reported COVID-19 vaccine AEFI (Table 1). The proportion of AEFI with ED attendances following COVID-19 vaccines was over double that of the 2017-2021 routine vaccine AEFI (48% vs 19-23%). This is predominantly due to the inclusion of active surveillance; previous years' data did not include SmartVax survey reports. Of the ED attended AEFI following COVID-19 vaccination, 62% were actively identified via SmartVax surveys.

[14] AusVaxSafety Home | AusVaxSafety

Table 1 Characteristics of adverse events following immunisation reported to WAVSS 2017 – 2021

	2017	2018	2019	2020	2021	
					Routine	COVID-19
Total	263	308	262	270	200	10,428
Sex						
Female	156 (59%)	182 (59%)	158 (60%)	165 (61%)	110 (55%)	6,691 (64%)
Male	107 (41%)	124 (40%)	103 (39%)	105 (39%)	90 (45%)	3,712 (36%)
Unknown	0 (0%)	2 (1%)	1 (<1%)	0 (0%)	0 (0%)	16 (<1%)
Neither	-	-	-	-	-	9 (<1%)
Aboriginality						
Aboriginal/Torres Strait Islander	4 (2%)	13 (4%)	16 (6%)	19 (7%)	10 (5%)	184 (2%)
Non-Aboriginal/Torres Strait Islander	190 (72%)	214 (70%)	195 (74%)	226 (84%)	167 (84%)	9,190 (88%)
Unknown	69 (26%)	81 (26%)	51 (19%)	25 (9%)	23 (12%)	1,054 (10%)
Age group						
< 5 years	115 (44%)	130 (42%)	112 (43%)	106 (39%)	85 (42%)	0 (0%)
5 – 17 years	41 (16%)	45 (15%)	38 (15%)	42 (16%)	21 (11%)	336 (3%)
18 – 64 years	64 (24%)	89 (29%)	77 (29%)	88 (33%)	64 (32%)	8,422 (81%)
≥ 65 years	43 (16%)	44 (14%)	35 (13%)	34 (13%)	30 (15%)	1,602 (15%)
Age not provided	-	-	-	-	-	68 (<1%)^
Reporter Type						
Healthcare Provider	213 (81%)	255 (83%)	217 (83%)	204 (76%)	157 (79%)	3,678 (35%)
Parent/Self^^	41 (16%)	29 (9%)	31 (12%)	33 (12%)	19 (10%)	6,083 (58%)
Pharmacy	3 (1%)	16 (5%)	10 (4%)	25 (9%)	18 (9%)	209 (2%)
Other	6 (2%)	8 (3%)	4 (2%)	8 (3%)	6 (3%)	458 (4%)
Immunisation Provider Type						
Aboriginal Medical Service	1 (0%)	3 (1%)	0 (0%)	2 (1%)	1 (1%)	3 (<1%)
GP	167 (63%)	185 (60%)	134 (51%)	136 (50%)	89 (45%)	1,749 (17%)
Nurse	0 (0%)	0 (0%)	2 (1%)	0 (0%)	0 (0%)	1 (<1%%)
Pharmacy	4 (2%)	9 (3%)	12 (5%)	29 (11%)	15 (8%)	451 (4%)
Workplace	2 (1%)	1 (<1%)	6 (2%)	9 (3%)	4 (2%)	53 (1%)
Hospital	25 (10%)	38 (12%)	27 (10%)	22 (8%)	13 (7%)	1,382 (13%)
Community Clinic	0 (0%)	2 (1%)	4 (2%)	2 (1%)	17 (9%)	2,681 (26%)
Other	47 (18%)	51 (17%)	42 (16%)	27 (10%)	5 (3%)	42 (<1%)
Missing data	17 (6%)	19 (6%)	35 (13%)	43 (16%)	56 (28%)	4,066 (39%)
Managed by						
Emergency department	49 (19%)	63 (20%)	53 (20%)	61 (23%)	40 (20%)	4,957 (48%)
Admitted to hospital	12 (5%)	16 (5%)	23 (9%)	18 (7%)	20 (10%)	961 (9%)
Helpline	7 (3%)	6 (2%)	9 (3%)	10 (4%)	5 (3%)	388 (4%)
Nurse assessment	48 (18%)	70 (23%)	58 (22%)	46 (17%)	33 (17%)	520 (5%)
GP assessment	124 (47%)	141 (46%)	119 (45%)	124 (46%)	77 (39%)	3,082 (30%)

^ 'Age not provided' is from WAVSS reports with no date of birth provided or found.
^^ Parent/Self includes family member

4. Routine vaccines

4.1 Passive surveillance of adverse events following scheduled vaccines

In previous WAVSS annual reports, AEFI have been separated into those following scheduled vaccination (predominantly the childhood NIP vaccines) and those following influenza vaccination. This section includes a breakdown for these two groups for the purposes of historic comparison, with AEFI following COVID-19 vaccines shown in section 5. There were 138 individual AEFI reports received for persons vaccinated in 2021 that were assessed as events possibly related to immunisation from vaccines other than influenza or COVID-19. The AEFI rate for this group of vaccines for 2021 was 14.7 per 100,000 compared to an average of 16.2 per 100,000 between 2017-2020. Figure 5 presents number and rate of reports overall; figures broken down by age group are provided in Appendix 1.

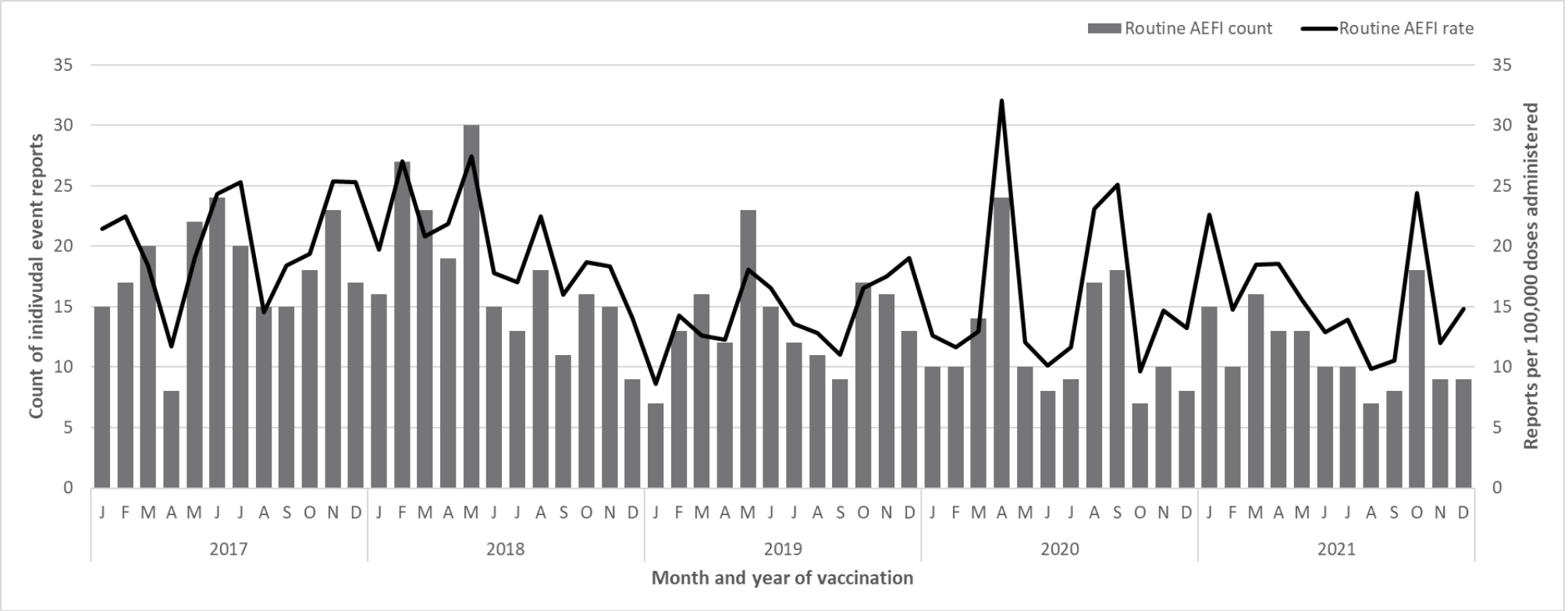


Figure 5: Reports and rates (per 100,000 doses) of adverse events following scheduled immunisation, Western Australia 2017 to 2021, by month of vaccination.

From the 138 reports of AEFI following scheduled vaccinations, 174 reactions were reported. The most common was injection site reaction (minor/common/expected) and the second most common was rash (Figure 6).

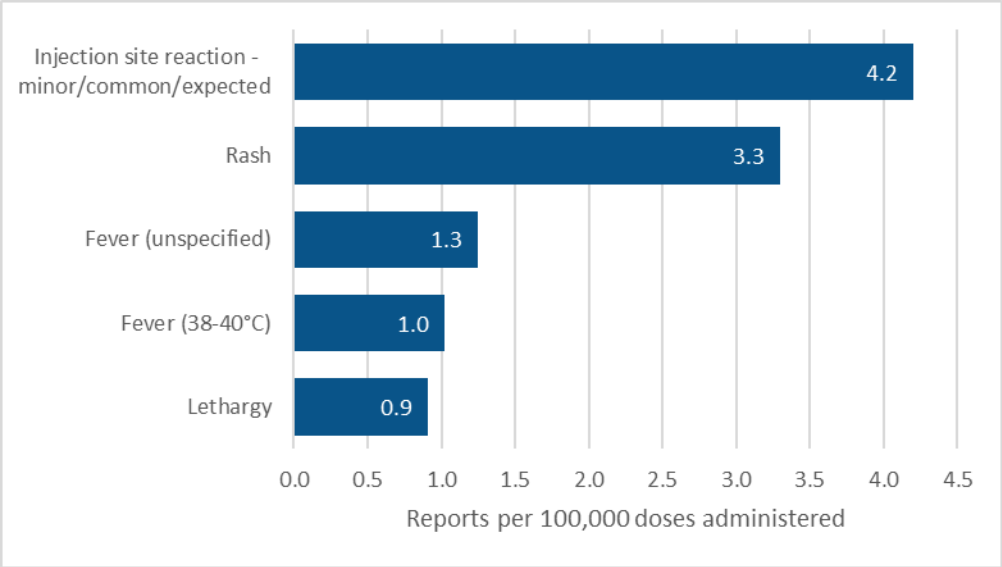


Figure 6: Rates of most frequently reported reactions following scheduled vaccination (any brand) in 2021

The majority (80/138, 58%) of AEFI reports following scheduled vaccination were in those aged <5 years. Of the 80 AEFI for those aged <5 years, 108 reactions were reported. The most common reactions were injection site reaction (minor/common/expected; 25.0%), rash (21.3%), and fever (38-40°C; 6.5%). For vaccines on the childhood immunisation schedule[15], the overall rate of AEFI in children <5 years recorded on the AIR is presented in Table 2. Pneumococcal polysaccharide vaccine (Pneumovax 23) had the highest rate of AEFI reported (16.6 per 10,000 doses). This high rate is possibly due to the small numbers of Pneumovax 23 administered; however, Pneumovax 23 is known to be associated with a high rate of injection site reactions[16]. The two DTPa-IPV vaccines (Quadracel and Infanrix-IPV) had the next highest rates of AEFI (6.85 and 6.02 per 10,000 doses, respectively). The rate of AEFI for all other vaccines was ≤ 3 per 10,000 doses. These rates are within expected ranges based on previous years.

[15] Healthy WA. Childhood Immunisations Schedule https://www.healthywa.wa.gov.au/articles/a_e/childhood-immunisation-schedule

[16] TGA product information for Pneumovax 23 pdf (tga.gov.au)

Table 2: Rate of adverse events following immunisation in children <5 years per 10,000 doses^ administered by vaccine type, 2017 to 2021

Vaccine Type	2017			2018			2019			2020			2021		
	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses	AEFI reported to WAVSS	Doses admin (AIR)	AEFI rate per 10,000 doses
DTPa - Infanrix	11	23,287	4.7	11	28,672	3.8	2	25,373	0.8	3	23,284	1.3	7	25,627	2.7
DTPa -Tripacel	4	11,506	3.5	0	6,026	0.0	2	9,633	2.1	2	9,621	2.1	0	6,809	0.0
DTPa-IPV - Infanrix-IPV	2	5,070	3.9	5	16,231	3.1	6	18,244	3.3	9	20,584	4.4	10	16,607	6.0
DTPa-IPV - Quadracel	27	29,678	9.1	10	16,998	5.9	11	16,508	6.7	9	14,621	6.2	12	17,522	6.9
DTPa-hepB-IPV-Hib - Infanrix hexa	8	103,513	0.8	12	101,880	1.2	12	101,359	1.2	15	97,652	1.5	8	99,269	0.8
Hep A - Vaqta Paediatric	1	5,103	2.0	0	5,128	0.0	0	5,586	0.0	0	3,772	0.0	0	2,524	0.0
Hib – Act-Hib							3	18,902	1.6	3	32,014	0.9	1	31,971	0.3
Seasonal influenza - Fluarix Tetra	1	3,916	2.6	1	3,749	2.7	3	12,348	2.4	1	7,447	1.3	0	3,540	0.0
Seasonal influenza - FluQuadri	1	4,563	2.2	4	10,542	3.8	7	34,160	2.0	2	20,060	1.0	0	4,977	0.0
Seasonal influenza - Vaxigrip Tetra										9	47,741	1.9	5	37,184	1.3
Men ACWY - Nimenrix	3	4,298	7.0	16	59,022	2.7	8	56,203	1.4	5	42,299	1.2	3	38,263	0.8
Men B - Bexsero	18	19,275	9.3	5	20,919	2.4	6	16,832	3.6	8	18,015	4.4	5	22,820	2.2
MMR - MMR II	4	26,897	1.5	7	24,542	2.8	2	19,087	1.0	3	17,560	1.7	2	14,338	1.4
MMR - Priorix	2	11,055	1.8	9	11,557	7.8	4	17,300	2.3	1	16,393	0.6	5	18,015	2.8
MMRV - Priorix-Tetra	2	19,779	1.0	0	17,117	0.0	1	8,454	1.2	1	7,817	1.3	1	8,996	1.1
MMRV - ProQuad	6	15,867	3.8	1	18,006	0.6	3	26,909	1.1	4	25,336	1.6	4	23,620	1.7
Pneumococcal - Prevenar 13	3	106,623	0.3	10	97,029	1.0	9	103,343	0.9	12	99,853	1.2	15	100,316	1.5
Pneumococcal - Pneumovax 23										0	937	0.0	3	1,807	16.6
Rotavirus - Rotarix	2	26,977	0.7	6	63,870	0.9	8	63,861	1.2	9	61,617	1.5	1	63,079	0.2

Events that occur when multiple vaccines are given at a single encounter are ascribed to all vaccines, so there may be multiple vaccines listed for any individual report.
^Rates for this group of vaccines are presented per 10,000 due to the smaller number of doses administered.

4.2 Passive surveillance of adverse events following Influenza vaccines

There were 62 individual AEFI reports received for persons vaccinated with an influenza vaccine in 2021 that were assessed as events possibly or certainly related to vaccination (Figure 7), which is lower than the average of the last four years (n = 92). The pattern of AEFI over the year was different than in previous years, likely related to a combination of earlier uptake of influenza vaccine and the poorer uptake of influenza vaccination overall in 2021 compared to previous years (928,208 doses administered in 2021 compared to 1,138,091 in 2020). The overall rate of influenza vaccine AEFI for 2021 was 6.7 per 100,000 doses.

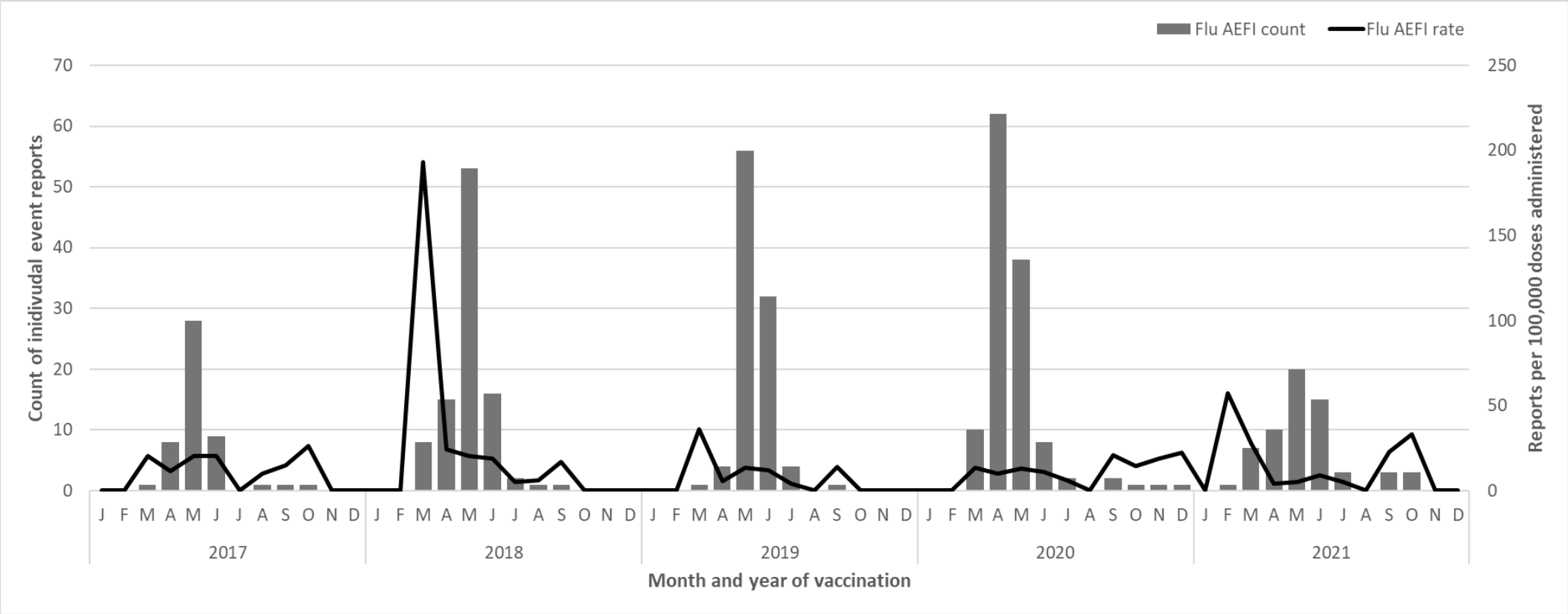


Figure 7: Reports and rates (per 100,000 doses) of adverse events following influenza immunisation, Western Australia 2017 to 2021, by month of vaccination

From the 62 reports following influenza vaccination, a total of 71 reactions were described, with the most common reaction being injection site reaction (minor/common/expected), followed by rash and lethargy (Figure 8).

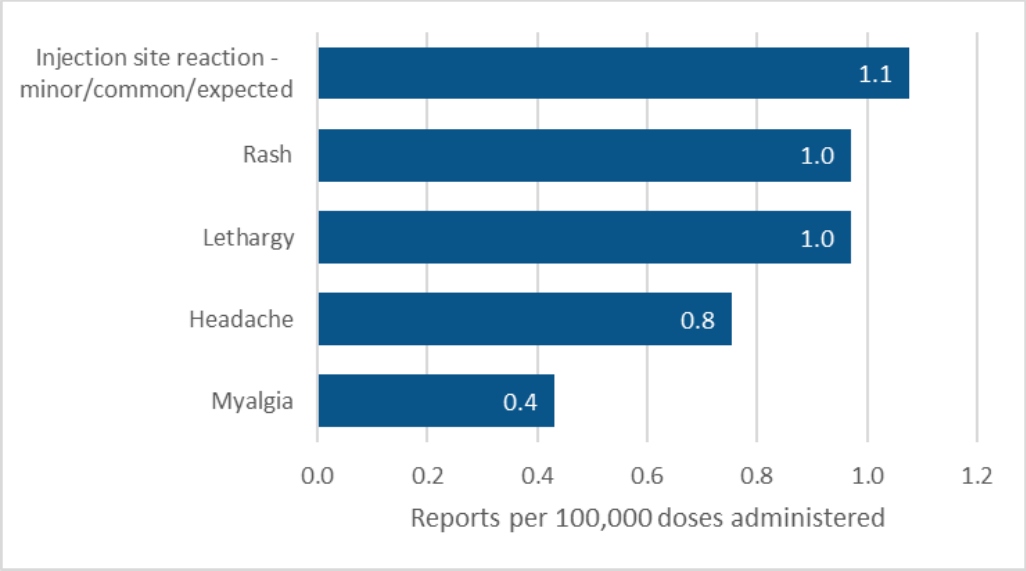


Figure 8: Rates of most frequently reported reactions following influenza vaccination (any brand) in 2021

The majority (39/62, 63%) of AEFI reports related to influenza vaccination occurred in those aged 18-64 years. This group also received the highest number of doses of influenza vaccine (503,189/928,208, 54%). Only five AEFI following influenza vaccination were reported in children aged <5 years in 2021. There were no seizures reported in this age group following influenza vaccination, compared to two in 2020.

4.3 Active surveillance of adverse events following routine vaccines

SmartVax is used for active surveillance following all routine vaccines; AEFI detected used SmartVax are reported to WAVSS following assessment by the patient's immunisation provider.

In 2021, 98 active surveillance reports following all routine vaccines were reported to WAVSS. Of these, 66 (67.3%) were for children aged under five years, and 30 (30.1%) were for children aged six to 17 years. The most common vaccines associated with a report were Infanrix hexa (17 reports), Gardasil (15 reports) and Nimenrix (13 reports). The majority of these AEFI did not require medical assessment; two patients attended an Emergency Department, and three were assessed by a GP.

For the 98 actively identified AEFI reports, 255 reactions were reported. Active surveillance for routine vaccination appears to solicit a greater number of reactions per event than passive surveillance (2.6 reactions per report vs 1.2 for passive surveillance), likely because the active surveillance survey prompts reporters to recall specific symptoms. The most commonly reported reaction was lethargy (16.9% of all reported reactions), followed by fever (38-40°C; 11.4%), pain in limb (11.4%), and rash (10.2%).

5. COVID-19 vaccines

The following COVID-19 vaccine section presents integrated surveillance data which combine passive surveillance (directly reported to WAVSS, including reports to TGA subsequently entered to WAVSS), active surveillance (SmartVax surveys and data linkage). This report will refer to each of the COVID-19 vaccines that were available and administered in WA in 2021 by their brand names: Vaxzevria (AstraZeneca), Comirnaty (Pfizer) and Spikevax (Moderna).

5.1 Total count and rates of adverse events following COVID-19 vaccines

There were 10,428 individual AEFI reports received for persons vaccinated with a COVID-19 vaccine in 2021 that were assessed as events possibly or certainly related to vaccination. Overall, the rate of any COVID-19 vaccine AEFI in 2021 was 264.1 per 100,000 doses, which is similar to the national rate reported by the TGA at the end of 2021 (approximately 230 per 100,000 doses)[17]. Figure 9 shows count and rate of AEFI by month of vaccination categorised by brands Vaxzevria, Comirnaty or Spikevax. The overall rate of AEFI reports per brand was 306.1 per 100,000 doses of Vaxzevria, 281.4 per 100,000 doses of Spikevax, and 244.8 per 100,000 doses of Comirnaty.

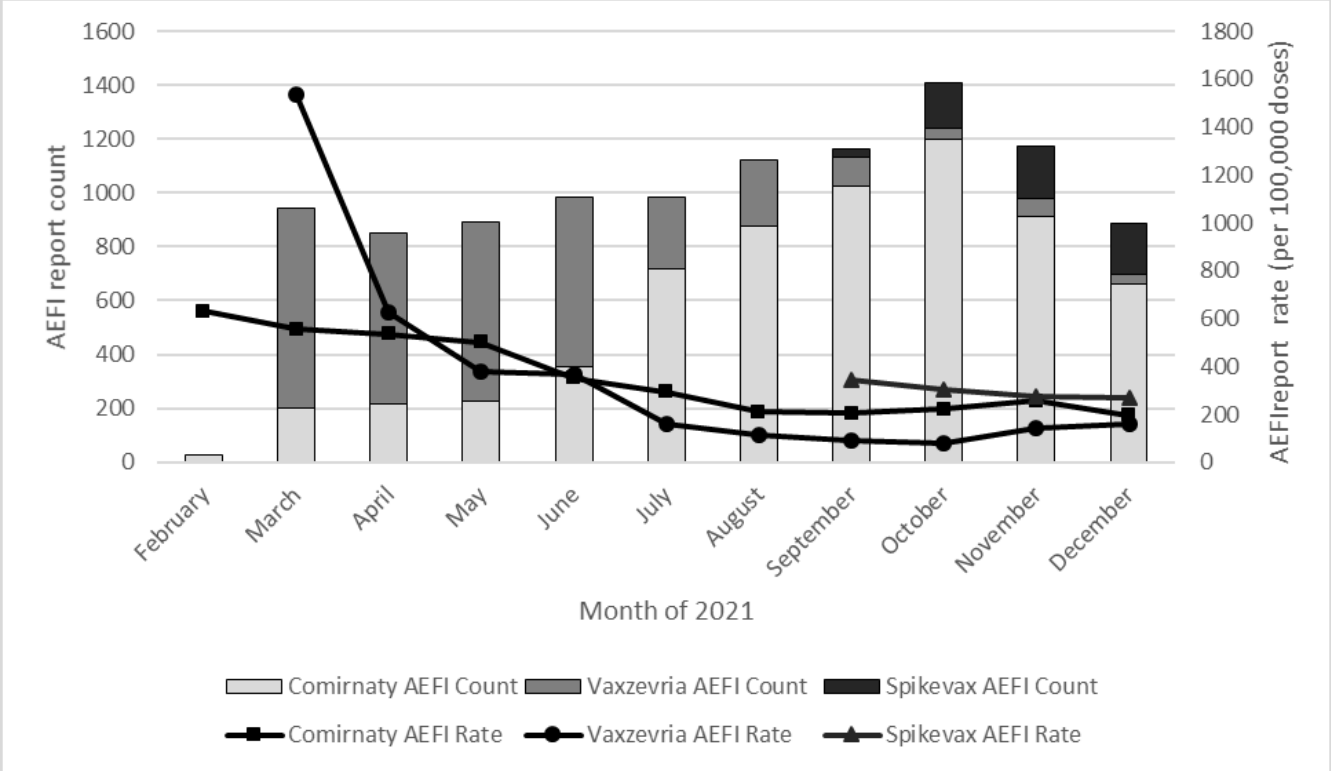


Figure 9 Count and rate (per 100,000 doses) of adverse events following immunisation following COVID-19 vaccines reported to WAVSS by vaccination date.

The vaccination month with the highest number of AEFI reports in 2021 was October (n=1,408), which aligns with the commencement of expanded vaccine eligibility criteria for people aged over 18 years, access to vaccination appointments without booking, and the announcement of a vaccine mandate for the majority of WA workers (Figure 1). The rate of AEFI declined for all brands over time, reflecting increased availability of vaccines, increases in vaccine doses administered, changes to public messaging and Australian Technical Advisory Group on Immunisation (ATAGI) recommendations following the detection of safety signals, and changes in public and healthcare familiarity with AEFI (Figure 1).

[17] TGA Safety report, 06 January 2022. https://webarchive.nla.gov.au/awa/20220604185232/https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-06-01-2022

5.2 Adverse events following COVID-19 vaccines by age group and brand

The rate of adverse events following COVID-19 vaccines per 100,000 doses by age group and brand for 2021 is shown in

Table 3. This excludes Comirnaty age group 5-11 years and Vaxzevria age group 12-17 years, as all reported AEFI for these groups were vaccine administration errors (i.e., administration outside recommendation). The highest AEFI rates were for people aged less than 60 years following Vaxzevria, particularly for those aged 18-24 years (1,031.2 per 100,000 doses) and 40-49 years (1,006.4 per 100,000 doses).

Table 3 Rate of adverse events following COVID-19 immunisation for 2021, by brand and age group in years

	Vaxzevria (AstraZeneca)			Comirnaty (Pfizer)			Spikevax (Moderna)			All COVID-19 vaccines		
Age group (years)	**AEFI Count**	**Doses**	**Rate per 100,000 doses**	**AEFI Count**	**Doses**	**Rate per 100,000 doses**	**AEFI Count**	**Doses**	**Rate per 100,000 doses**	**AEFI Count**	**Doses**	**Rate per 100,000 doses**
12-17	-	-	-	278	212,951	130.5	41	21,811	188.0	319	234,762	135.8
18-24	97	9,407	1,031.2	599	293,141	204.3	50	24,022	208.1	746	326,570	228.4
25-29	108	11,366	950.2	627	248,775	252.0	60	18,682	321.2	795	278,823	285.1
30-39	193	24,051	802.5	1,792	612,676	292.5	156	40,725	383.1	2,141	677,452	316.0
40-49	315	31,299	1,006.4	1,624	589,148	276.7	123	35,475	346.8	2,062	655,922	314.4
50-59	834	203,799	409.2	1,059	414,871	255.3	83	29,313	283.2	1,976	647,983	305.0
60-69	916	393,492	232.8	278	128,332	216.6	41	20,394	201.0	1,235	542,218	227.8
≥70	926	445,196	208.0	125	123,489	101.2	18	16,025	112.3	1,069	584,710	182.9
unknown	24	-	-	35	-	-	9	-	-	68	-	-
All ages	**3,424**	**1,118,610**	**305.1**	**6,417**	**2,623,383**	**244.6**	**581**	**206,447**	**281.4**	**10,411**	**3,948,440**	**263.7**

5.3 Adverse events following COVID-19 vaccines by dose

AEFI reports where a vaccine dose number could be reasonably determined are presented in Table 4. This does not include one AEFI reported for dose 4 and one AEFI for dose 6 (both vaccine administration errors). The highest rate of AEFI was following dose 1 of Vaxzevria (495.1 per 100,000 doses) and dose 1 of Spikevax (355.4 per 100,000 doses). Comirnaty had similar AEFI rates following dose 1 and 2 (250.6 and 257.3 per 100,000 doses respectively).

Table 4. Adverse events following immunisation for COVID-19 vaccines in 2021, by brand and dose.

	Vaxzevria			Comirnaty			Spikevax		
	AEFI	Doses	Rate per 100,000 doses	AEFI	Doses	Rate per 100,000 doses	AEFI	Doses	Rate per 100,000 doses
Dose 1	2,801	565,800	495.1	3,244	1,294,572	250.6	366	102,992	355.4
Dose 2	622	550,656	113.0	3,037	1,180,128	257.3	189	77,721	243.2
Dose 3	1	2,045	48.9	140	147,977	94.6	26	25,612	101.5

5.4 Reactions following COVID-19 vaccines

The 10,428 individual AEFI reports following COVID-19 vaccine for 2021 comprised of 28,211 reactions (a vaccinee may describe multiple AEFI reactions). In 2021, 64 types of adverse reactions were described in 8,704 of the 10,428 reports. A summary of the most frequently reported reactions that met established case definitions is shown in Figure 10.

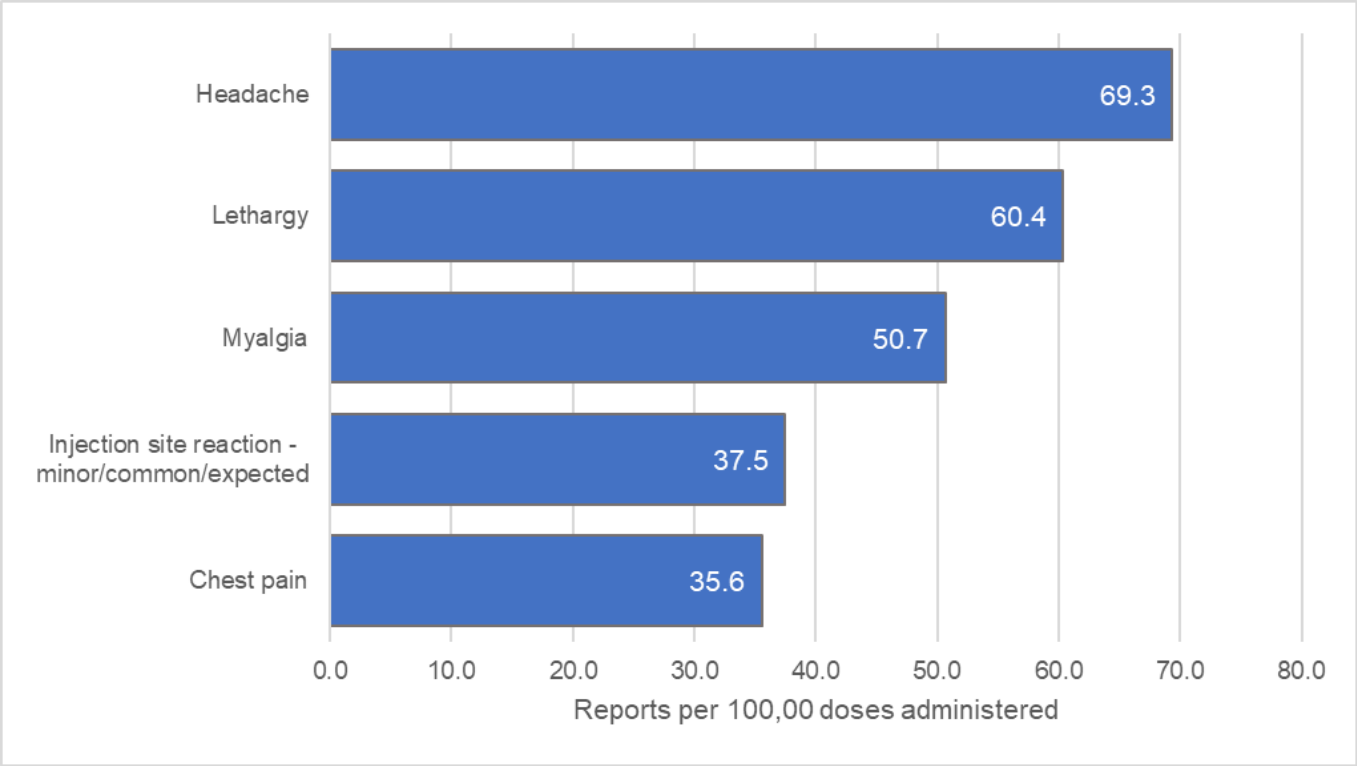


Figure 10. Rates of the five most frequently reported reactions following COVID-19 vaccination (any brand) in 2021.

A further 1,724 reports had an 'other reaction' listed that did not meet one of the 64 adverse reaction types. The most common of these were dizziness (1.9 per 100,000 doses), shingles (1.5 per 100,000 doses), and tinnitus (1.5 per 100,000 doses).

The rates of the most frequently reported reactions by COVID-19 vaccine brand are listed in Table 5. All three brands commonly had headaches, lethargy and injection site reaction reported. More information on nationally reported reactogenicity to COVID-19 vaccines can be found on https://ausvaxsafety.org.au.

Table 5. Rates of the five most frequently reported reactions following COVID-19 vaccination (by brand) in 2021.

Vaxzevria		Comirnaty		Spikevax	
Reaction	**Rate per 100,000 doses**	**Reaction**	**Rate per 100,000 doses**	**Reaction**	**Rate per 100,000 doses**
Headache	91.2	Headache	62.2	Chest pain	59.6
Lethargy	66.5	Lethargy	59.4	Injection site reaction -minor/ common/ expected	43.6
Myalgia	57.9	Myalgia	49.5	Headache	41.7
Fever (unspecified)	42.7	Chest pain	42.8	Lethargy	39.2
Injection site reaction - minor/ common/ expected	34.1	Injection site reaction - minor/ common/ expected	38.5	Shortness of breath	26.6

5.5 COVID-19 vaccines – Adverse events of special interest

Adverse events of special interest (AESI) were monitored by the Department during the COVID-19 vaccination program. AESI that warranted monitoring were determined following expert clinical review by the Department of COVID-19 vaccine safety clinical trials, international adverse event reporting, and AEFI reports to WAVSS. The AESI following COVID-19 vaccines the Department identified as most prevalent during the 2021 rollout of the COVID-19 vaccination program are described below.

5.5.1 Anaphylaxis

Anaphylaxis is a life-threatening allergic reaction that occurs rarely after vaccination, with onset typically within minutes to hours[18].

The WAVSS system received 181 reports of possible anaphylaxis following COVID-19 vaccinations in 2021. The adult vaccine safety clinic at Sir Charles Gairdner Hospital found sufficient evidence to provide a diagnosis of anaphylaxis with a Brighton Collaboration Criteria (BCC) of Level 1, 2 or 3[19] for 49 reports (

Table 6). Of the remaining 132 reports, 47 were reviewed by the adult vaccine safety clinic but received a BCC Level 4 due to insufficient evidence to meet diagnostic certainty; 12 reports were re-diagnosed as immediate allergic reaction; and 73 reports were awaiting clinic review at the time the data were analysed. The rate of confirmed anaphylaxis cases was 1.0 per 100,000 doses

[18] McNeil MM, DeStefano F. Vaccine-associated hypersensitivity. J Allergy Clin Immunol 2018; 141:463–72. PMID PMC6602527.

[19] Law, Barbara. 2021. Safety Platform for Emergency vACcines. SO2 - D2.5.2.1 – AESI Case Definition Companion Guide for 1st Tier AESI – Anaphylaxis. https://brightoncollaboration.us/wp-content/uploads/2021/03/SPEAC_D2.5.2.1_Anaphylaxis-Case-Definition-Companion-Guide_V1.0-12070-1.pdf

of Vaxzevria and 1.5 per 100,000 doses of Comirnaty. There were no confirmed anaphylaxis cases following Spikevax.

Table 6. Count and rates of confirmed anaphylaxis per brand and dose of COVID-19 vaccination, 2021

	Confirmed cases of Anaphylaxis	Doses	Rate per 100,000 doses
Comirnaty			
Dose 1	31	1,294,572	2.4
Dose 2	7	1,180,128	0.6
Vaxzevria			
Dose 1	11	565,800	1.9

5.5.2 Thrombosis with thrombocytopenia syndrome

Thrombosis with thrombocytopenia syndrome (TTS) is a rare but serious side effect of Vaxzevria vaccine identified in 2021. This syndrome presents as blood clots (thrombosis) and low platelet counts (thrombocytopenia), with formal diagnostic criteria established by the Thrombosis and Haemostasis society of Australia and New Zealand[20]. It is also referred to as 'vaccine-induced immune thrombotic thrombocytopenia' (VITT). Information obtained through local, national and international surveillance databases during the COVID-19 vaccination program rollout found that the risk of TTS appeared higher in people aged under 60 years of age. ATAGI issued a preferential recommendation for Comirnaty to people under 60 years of age on 17th June 2021[21].

In 2021, 13 confirmed or probable cases of TTS following Vaxzevria (12 cases following dose 1, one case following dose 2) were reported to WAVSS, resulting in a rate of 1.2 per 100,000 doses. Counts and rates of TTS by age group are summarised in Table 7. In WA, the rate of TTS by age group was 2.1 per 100,000 first doses for people aged less than 60 years of age, 2.1 per 100,000 first doses for people aged 60 years and over, and 0.2 per 100,000 second doses for people aged 60 years and over. National rates of TTS were 2 per 100,000 people vaccinated with Vaxzevria aged 60 years or older and 2 to 3 per 100,000 people vaccinated with Vaxzevria under 60 years of age[21].

Table 7. Count and rates of confirmed or probable thrombosis with thrombocytopenia syndrome[20] per age group of COVID-19 Vaxzevria vaccinations, 2021

Dose & Age Group	Confirmed/ probable cases of TTS	Doses of Vaxzevria	Rate per 100,000 doses
Dose 1			
Aged under 60 years	3	144,816	2.1
Aged 60 years and over	9	420,984	2.1
Dose 2			
Aged under 60 years	-	134,559	-

[20] Thrombosis & Haemostasis society of Australia and New Zealand. THANZ Advisory Statement for Haematologists. 18 December 2021. https://www.thanz.org.au/documents/item/591

[21] Australian Department of Health. Vaxzevria (AstraZeneca) vaccine and thrombosis with thrombocytopenia (TTS) | Australian Government Department of Health and Aged Care. https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance/tts Last updated 25 March 2022.

Aged 60 years and over	1	416,097	0.2
All doses^ & ages	**13**	**1,118,692 ^**	**1.2**

^Includes doses beyond dose 2.

5.5.3 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[22]. In 2021, 30 confirmed cases of ITP were reported to WAVSS following COVID-19 vaccinations. The rate of ITP was 2.4 per 100,000 doses of Vaxzevria, 0.1 per 100,000 doses of Comirnaty, and 1.0 per 100,000 doses of Spikevax. One report of ITP following dose 1 of Vaxzevria resulted in death, and this was confirmed to be linked to their immunisation as determined by the Vaccine Safety Investigation Group authorised by the TGA[23]. The TGA reported a national rate of ITP following Vaxzevria vaccination of <1 per 100,000 but has not provided a rate of ITP following Comirnaty or SpikeVax[17].

Table 8. Count and rates of confirmed or probable Immune Thrombocytopenic Purpura per brand and dose of COVID-19 vaccinations, 2021

	Confirmed cases of Immune Thrombocytopenia Purpura	Doses	Rate per 100,000 doses
Vaxzevria			
Dose 1	20	565,800	3.5
Dose 2	7	550,656	1.3
All doses^	**27**	**1,118,692**	**2.4**
Comirnaty			
Dose 1	1	1,294,572	0.1
Dose 2	1	1,180,128	0.1
All doses^	**2**	**2,623,525**	**0.1**
Spikevax			
Dose 1	2	102,992	1.9

^Includes doses beyond dose 2.

5.5.4 Guillain-Barré syndrome

Guillain-Barré syndrome (GBS) is a rare but sometimes serious immune disorder when nerves are attacked by immune cells resulting in pain, numbness, muscles weakness and/or difficulty walking[17].

In 2021, WAVSS had 14 confirmed cases of GBS following Vaxzevria and Comirnaty COVID-19 vaccinations. Counts and rates of GBS by brand and dose are summarised in Table 9. The rate of GBS was 0.8 per 100,000 doses of Vaxzevria, and 0.2 per 100,000 doses of Comirnaty. The TGA reported the national rate of GBS was 1 per 100,000 people vaccinated with Vaxzevria[17]. The TGA has not reported a national rate of GBS following Comirnaty.

[22] ITP Australia. https://itpaustralia.org.au/about-itp/

[23] Therapeutic Goods Administration Safety Report 8th July 2021. https://webarchive.nla.gov.au/awa/20220603184200/https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-08-07-2021

Table 9. Count and rates of confirmed Guillain Barré syndrome per brand and dose of COVID-19 vaccinations, 2021

	Confirmed cases of GBS	Doses	Rate per 100,000 doses
Vaxzevria			
Dose 1	7	565,800	1.2
Dose 2	2	550,656	0.4
All doses^	**9**	**1,118,692**	**0.8**
Comirnaty			
Dose 1	3	1,294,572	0.2
Dose 2	2	1,180,128	0.2
All doses^	**5**	**2,623,525**	**0.2**

^Includes doses beyond dose 2.

5.5.5 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)[24]. 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[24]. Diagnostic criteria for myocarditis, myopericarditis, and pericarditis have been established by both the United States Centres for Disease Control and Prevention (CDC)[25] and the Brighton Collaboration[26]. Both these classification systems have been applied to cases of possible myocarditis, myopericarditis, and pericarditis that have been reported to WAVSS. For this report, myopericarditis has been grouped together with myocarditis due to its clinical severity, and similar management approach post-vaccination.

In 2021, 138 confirmed cases of myocarditis/myopericarditis following COVID-19 vaccinations were reported to WAVSS. Counts and rates of myocarditis/myopericarditis by brand and dose are summarised in Table 10. The rate of myocarditis/myopericarditis was 0.4 per 100,000 doses of Vaxzevria, 4.5 per 100,000 doses of Comirnaty, and 7.3 per 100,000 doses of Spikevax. Myocarditis/myopericarditis following second dose Spikevax was more than twice the rate of myocarditis/myopericarditis following second dose Comirnaty.

The TGA reported rates of myocarditis/myopericarditis were 1.5 per 100,000 doses of Comirnaty, and 2.2 per 100,000 doses of Spikevax[17]. The TGA has not reported a national rate of myocarditis or myopericarditis following Vaxzevria and reports confirmed cases of myocarditis following internal clinical review.

[24] Australian Department of Health. Last updated 29 April 2022. https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance/myocarditis-pericarditis
[25] Centers for Disease Control and Prevention. 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. 9 July 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm
[26] Brighton Collaboration. Myocarditis/pericarditis Case Definition. 19 November 2021. https://brightoncollaboration.us/myocarditis-case-definition-update/

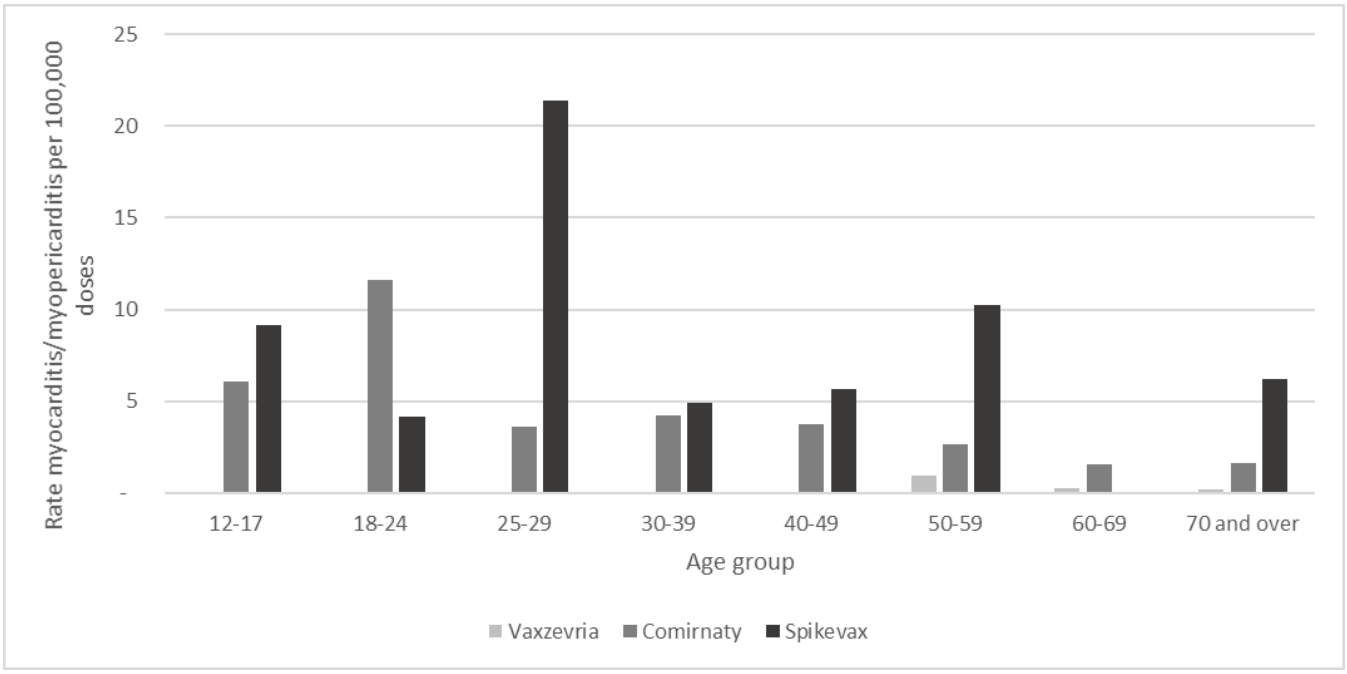
Table 10. Count and rates of confirmed myocarditis/myopericarditis cases per brand and dose of COVID-19 vaccinations, 2021

	Confirmed cases of myocarditis/ myopericarditis	Doses	Rate per 100,000 doses
Vaxzevria			
Dose 1	4	565,800	0.7
Dose 2	0	550,656	-
All doses^	**4**	**1,118,692**	**0.4**
Comirnaty			
Dose 1	40	1,294,572	3.1
Dose 2	74	1,180,128	6.3
Dose 3	5	147,977	3.4
All doses^	**119**	**2,623,525**	**4.5**
Spikevax			
Dose 1	4	102,992	3.9
Dose 2	10	77,721	12.9
Dose 3	1	25,612	3.9
All doses^	**15**	**206,456**	**7.3**

^Includes doses beyond dose 2.

Rates of myocarditis/myopericarditis for 2021 by age group are shown in Figure 11. The highest myocarditis/myopericarditis rates following Spikevax were age groups 25-29 years (21.4 per 100,000 doses), 50-59 years (10.2 per 100,000 doses) and 12-17 years (9.2 per 100,000 doses). The highest myocarditis/myopericarditis rate following Comirnaty were age groups 18-24 years (11.6 per 100,000 doses) and 12-17 years (6.1 per 100,000 doses). Rates of myocarditis/myopericarditis following Vaxzevria by age group were less than 1 per 100,000 doses.

Figure 11. Rates of confirmed myocarditis/myopericarditis cases per brand of COVID-19 vaccinations by age group, 2021.



A total of 365 confirmed cases of pericarditis following COVID-19 vaccinations received in 2021 were reported to WAVSS. Counts and rates of pericarditis by brand and dose are summarised in Table 11. The rate of pericarditis was 1.4 per 100,000 doses of Vaxzevria, and 11.9 per 100,000 doses of Comirnaty, and 18.4 per 100,000 doses of Spikevax. Pericarditis following first and third dose Spikevax was 1.7 times the rate of pericarditis following first and third dose Comirnaty, and pericarditis following second dose Spikevax was 1.4 times the rate of pericarditis following second dose Comirnaty.

National pericarditis rates reported by the TGA were 7.1 per 100,000 doses of Comirnaty, and 8.6 per 100,000 doses of Spikevax[17]. The TGA has not reported a national rate of pericarditis following Vaxzevria and reports confirmed cases of pericarditis following internal clinical review.

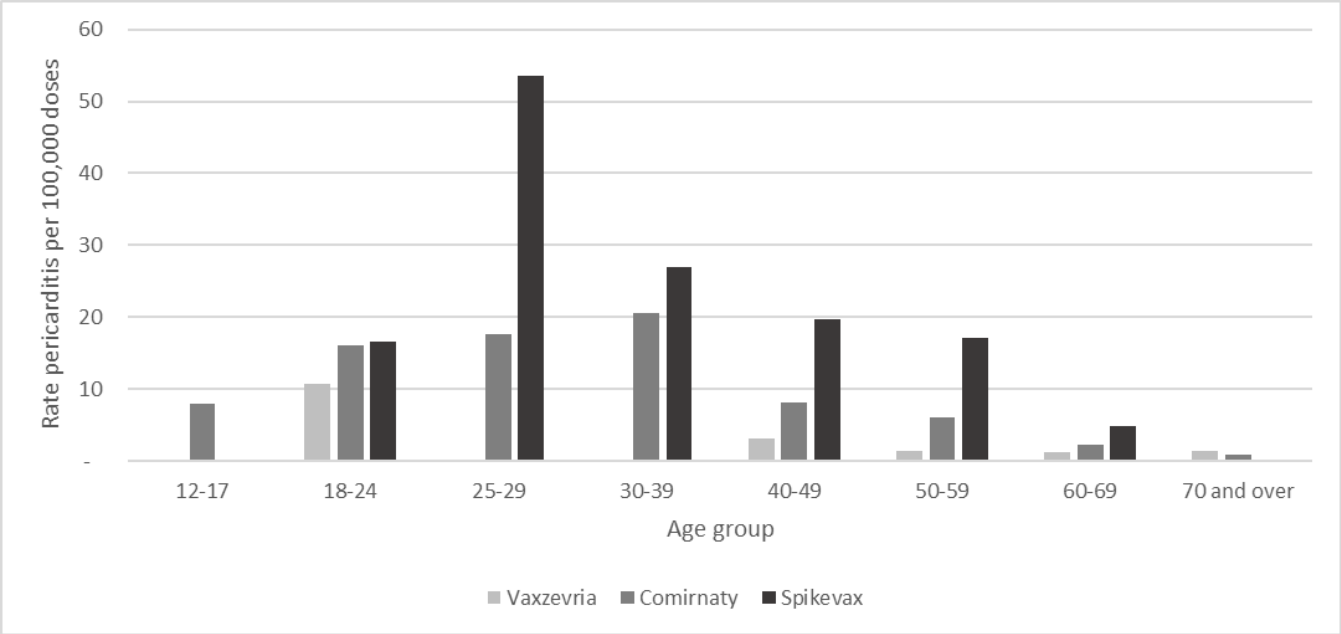
Table 11. Count and rates of confirmed pericarditis cases per brand and dose of COVID-19 vaccinations, 2021

	Confirmed cases of pericarditis	Doses	Rate per 100,000 doses
Vaxzevria			
Dose 1	15	565,800	2.7
Dose 2	1	550,656	0.2
All doses^	**16**	**1,118,692**	**1.4**
Comirnaty			
Dose 1	186	1,294,572	14.4
Dose 2	118	1,180,128	10.0
Dose 3	7	147,977	4.7
All doses^	**311**	**2,623,525**	**11.9**
Spikevax			
Dose 1	25	102,992	24.3
Dose 2	11	77,721	14.2
Dose 3	2	25,612	7.8
All doses^	**38**	**206,456**	**18.4**

^Includes doses beyond dose 2.

Rates of pericarditis for 2021 by age are shown in Figure 12. The highest rates of pericarditis following Spikevax were age groups 25-29 years (53.5 per 100,000 doses) and 30-39 (27.0 per 100,000 doses). The highest rates of pericarditis following Comirnaty were age group 30-39 years (20.6 per 100,000 doses), 25-29 years (17.7 per 100,000 doses) and 18-24 (16.0 per 100,000 doses). The highest rates of pericarditis following Vaxzevria was age group 18-24 years (10.6 per 100,000 doses).

Figure 12. Rates of confirmed pericarditis cases per brand of COVID-19 vaccinations by age group, 2021



The background rate of both myocarditis and pericarditis in the WA population was higher in 2021 than the previous five-year average (Table 12).

Table 12: Background rates (WA) of myocarditis and pericarditis prior to (2016-2020) and after (2021) the introduction of COVID-19 vaccination. Rates calculated based on principal diagnosis for emergency department presentations and hospital inpatients.

Time period	Myocarditis rate (per 10,000 separations*)	Pericarditis rate (per 10,000 separations)
2016-2020	0.556	3.903
2021	0.749	4.892

*A separation refers to a patient being discharged from hospital

5.6 COVID-19 active surveillance - data linkage

In 2021, 230 possible AEFI following COVID-19 vaccinations that had not already been reported to WAVSS were identified using the newly established data linkage active surveillance system. AEFI types identified by data linkage are shown in Table 13 and Appendix 3. Additionally, data linkage identified 40 deaths that occurred within a 21-day window following COVID-19 vaccination and these were reviewed and determined to be not related to vaccination.

Table 13. Adverse events following immunisation identified through data linkage active surveillance following COVID-19 vaccinations, 2021

Reaction	Number of data linkage cases identified
Bell's palsy	18
Chest pain	24
Deep vein thrombosis	11
Guillain Barré syndrome	3
Myocarditis/Myopericarditis	28
Pericarditis	25
Pulmonary embolism	35
Other AESI	46

6. Specialist clinic activity (all vaccines)

6.1. Referrals following COVID-19 vaccine AEFI

A total of 1,200 WAVSS reports following COVID-19 vaccination resulted in a referral to a specialist clinic. Of these, 1,168 (97%) were referred to the adult vaccine safety clinic at Sir Charles Gairdner Hospital, 29 (2%) were referred to the paediatric specialist immunisation clinic (SIC) at Perth Children's Hospital, and three to Sir Charles Gairdner Hospital Haematology Department.

6.2. Adult clinic activity

In 2021, there were 1,125 appointments made at the adult vaccine safety clinic at Sir Charles Gairdner Hospital. Appointments include referrals from non-WAVSS sources, and one patient can have multiple appointments.

Most of the referrals were related to COVID-19 vaccination queries in relation to previous adverse events following immunisation, with a small number (~20) due to complex, medically at-risk cases. By comparison, there were seven adults referred for specialist immunisation care at Sir Charles Gairdner Hospital in 2020.

6.3. Child and adolescent clinic activity

In 2021, there were 439 appointments made at the Perth Children's Hospital SIC, of which 292 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 300 individual children and adolescents attended the SIC and 83 did not attend their appointment. Of those who attended their appointment, 42 (13.7%) were due to possible AEFI, 116 (37.8%) for complex medically-at-risk immunisation requirements, 45 (14.7%) for vaccine hesitancy, 65 (21.1%) for needle phobia and 39 (12.7%) for other immunisation reasons.

This represents a 173% increase in referrals to the Paediatric SIC from 2020, and a 40% increase in appointments.

7. WA Vaccine Safety Advisory Committee (WAVSAC)

In previous years, Western Australia's Vaccine Safety Advisory Committee (WAVSAC) met twice a year to review state vaccine safety. In 2021, this Committee held additional meetings and then continued meeting weekly to review the vaccine safety from the WA COVID-19 vaccination program. The committee met 31 times in 2021. In May 2021, WAVSAC convened a specialist sub-group, the Expert Clinical Review Group (ECRG), to individually review WAVSS reports which required specialist assessment. The ECRG met 34 times in 2021 and reviewed 849 WAVSS reports.

8. Discussion

In 2021, WAVSS provided robust and timely vaccine safety surveillance for all vaccines administered in WA. Building on existing capabilities, WAVSS expanded significantly, demonstrating agility in response to a change in the vaccination landscape and highlighting the sound vaccine safety surveillance methods already employed.

8.1. Vaccine safety surveillance results

A summary of the number of vaccines administered in 2021, the number of adverse events reported, and the rates of adverse events is provided in Table 14.

Table 14: Numbers of vaccines administered, and adverse events reported, with rate of adverse events, for non COVID-19 vaccines and COVID-19 vaccines, 2021.

Vaccine type	Number of vaccines administered in 2021	Number of adverse events reported to WAVSS	Rate of adverse events per 100,000 doses
Non COVID-19	1,808,050	200	11.1
COVID-19	3,948,673	10,428	264.1

The surveillance of routine vaccines was a small – albeit important – component of the WAVSS workload. This report demonstrates that vaccination with scheduled and influenza vaccines continues to be safe, with little change in AEFI rates compared to previous years, and with most reactions being minor, with minimal impact on vaccine recipients. Confidence in the surveillance and safety of vaccines was further strengthened by the inclusion of active surveillance data in 2021.

The most common AEFI reported for COVID-19 and routine vaccinations were similar; headache, lethargy, myalgia and fever, with the exception of chest pain following COVID-19 mRNA vaccines.

The high number of reports following COVID-19 vaccination reflects high engagement from the public and health care providers with the monitoring of vaccine safety. The volume of reports allowed rigorous investigation of adverse events. In combination with national and international data, monitoring of AEFSI by WAVSS (e.g. TTS, myocarditis) affected the recommendations by TGA and ATAGI to provide a safer program.

8.2. Changes to WAVSS in 2021

Prior to 2021, WAVSS had already established sound methods for identifying potential AEFI, that provided an essential basis for monitoring the safety of the COVID-19 vaccines. Due to the considerable increase in volume of AEFI reports received by WAVSS following the introduction of the COVID-19 vaccination program, several WAVSS processes were added to/expanded in 2021 including:

- Direct reporting of AEFI from WAVSS to the TGA. This contributed to national decisions, for example, when reports of TTS following Vaxzevria contributed to changes in ATAGI recommendations for age groups eligible to receive this vaccine.
- Inclusion of reports from SmartVax. SmartVax provided a multi-day survey (on days 3, 8 and 42 post-vaccination) to COVID-19 vaccinees promoting the use of active surveillance in addition to passive surveillance for members of the public. This service enabled longer term safety signals to be detected.

- Referrals to the adult vaccine safety clinic. The capacity of the adult clinic increased significantly in 2021 and was an essential service provided during the COVID-19 vaccination program.

Additionally, changes to vaccine safety surveillance at the Department were introduced in 2021 to manage the exponential increase in AEFI reports including:

- A COVID-19 vaccine safety team was established as part of the vaccination program to:
    - review, enter and validate AEFI reports,
    - manage a REDCap support project designed and implemented to assist WAVSS workflow,
    - support the WA Vaccine Safety Advisory Committee (WAVSAC) and sub-group Expert Clinical Review Group (ECRG).
- The establishment of the ECRG provided clinical oversight of AEFI through individual case review by a group of specialist consultants. The ECRG has continued into 2022 and has been identified as providing an essential service for future vaccine safety surveillance.
- A new data linkage system was established in 2021 as part of the active surveillance for COVID-19 vaccines which proved useful in identifying adverse events of special interest that had otherwise not been reported to WAVSS. Data linkage for non-COVID-19 vaccine safety is intended to be used by the Department in the future.
- AusVaxSafety and the National Centre for Immunisation Research and Surveillance (NCIRS) established a national follow up of TTS and myocarditis following COVID-19 vaccination. De-identified cases in WAVSS have been included in this important study, made possible through ethics and governance approval through the Department, and expanded capacity of WAVSS staff, enabling essential follow up of WA participants.

9. 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
BCC	Brighton Collaboration Criteria
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
ITP	Immune thrombocytopenic purpura
NIP	National Immunisation Program
SAEFI	Serious Adverse Event Following Immunisation
SAEFVIC	Surveillance of Adverse Events Following Vaccination in the Community
SIC	Specialist Immunisation Clinic
TGA	Therapeutic Goods Administration
The Department	WA Department of Health
TTS	Thrombosis with Thrombocytopenia Syndrome
VITT	Vaccine-induced Immune Thrombotic Thrombocytopenia
WAVSAC	Western Australian Vaccine Safety Advisory Committee
WAVSS	Western Australian Vaccine Safety Surveillance

10. Thanks

Recognition and thanks to members of the WA public and others who contributed to the WAVSS systems including the following groups who contributed to vaccine safety surveillance in WA: Western Australian Vaccine Safety Advisory Committee (WAVSAC), WAVSAC Expert Clinical Review Group (ECRG), AusVaxSafety and SmartVax.

Appendix 1

Figures 12-15 present the numbers and rates of AEFI following routine immunisation.

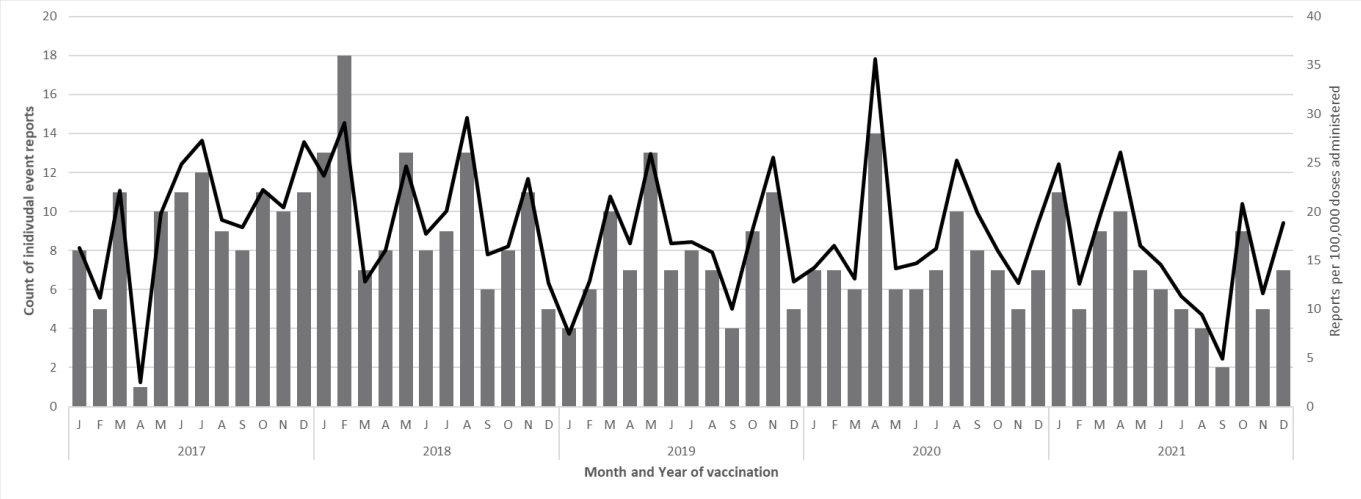


Figure 13: Reports and rates (per 100,000 doses) of routine adverse events following immunisation in <5 years of age, Western Australia 2017 to 2021, by month of vaccination

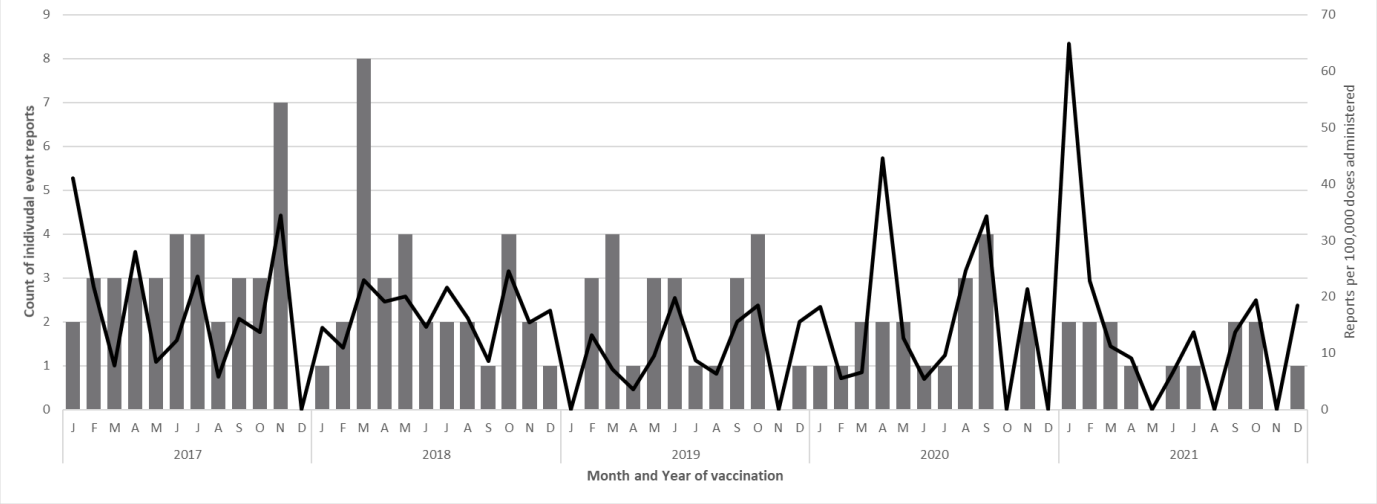


Figure 14: Reports and rates (per 100,000 doses) of routine adverse events following immunisation in 6 - 17 year olds, Western Australia 2017 to 2021, by month of vaccination

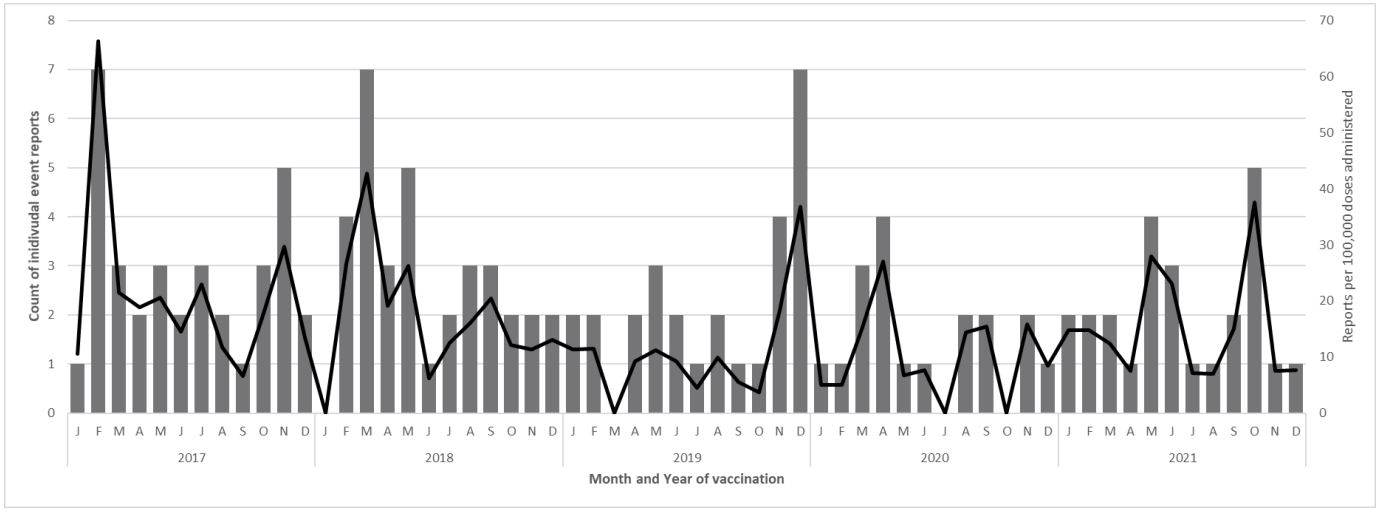


Figure 15: Reports and rates (per 100,000 doses) of routine adverse events following immunisation in 18 - 64-year olds, Western Australia 2017 to 2021, by month of vaccination

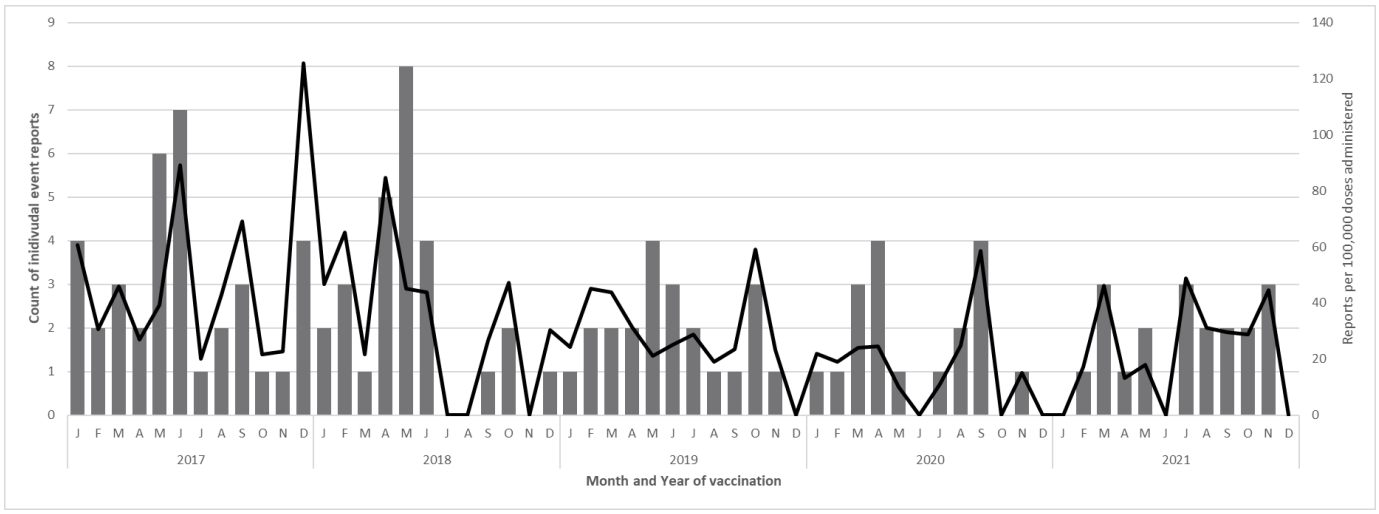


Figure 16: Reports and rates (per 100,000 doses) of routine adverse events following immunisation in >65-year olds, Western Australia 2017 to 2021, by month of vaccination

Appendix 2

Table 15. Reactions reported for adverse events following immunisation for all vaccines in 2021.

Reaction	Non-COVID-19	COVID-19	Reaction	Non-COVID-19	COVID-19
Abdominal pain	1	651	Lymphadenopathy	2	244
Abscess	0	8	Meningitis - aseptic	0	3
Allergic reaction (generalised)	5	273	Myalgia	6	2,001
Anaphylaxis	6	181	Myocarditis	1	98
Angioedema	0	28	Myopericarditis	0	48
Apnoea with bradycardia	0	1	No Reaction	1	14
Arthralgia	2	859	Nodule at injection site	0	3
Arthritis	0	22	Not Related to Vaccine	0	17
Bell's palsy	0	66	Orchitis	0	2
Brachial neuritis	0	1	Pain in limb	3	439
Cellulitis at injection site	3	27	Palpitations	0	396
Chest pain	1	1,404	Paresthesia	2	247
Crying (persistent)	1	1	Parotitis	0	1
Death^ ^^	0	87	Pericarditis	0	402
Deep vein thrombosis	0	118	Pulmonary embolism	1	131
Diarrhoea	2	431	Rash	38	685
Drug error^^^ - incorrect administration	15	286	Reaction undefined	0	11
Fever (≥ 40 ºC)	0	47	Seizure-afebrile	4	40
Fever (≥ 38 <40ºC)	10	354	Seizure-febrile	6	2
Fever (unspecified)	13	1,086	Seizure-syncopal	1	34
Guillain-Barré Syndrome (GBS)	1	16	Sepsis	0	5
Headache	13	2,737	Shortness of breath	6	693
Historic reaction	1	5	Shoulder Injury Related to Vaccine Administration (SIRVA)	0	55
Hypotonic hyporesponsive episode	2	1	SIRVA - suspected	0	4
Influenza-like-illness	2	266	Swelling at or near injection site	0	1
Injection site reaction - minor/common/expected	47	1,480	Thrombocytopenia	1	57
Injection site reaction - severe	4	49	Urticaria/Hives/Allergic Rash	10	122
Intussusception	1	7	Vasovagal episode (syncope, faint)	8	363
Lethargy	17	2,384	Vomiting	8	530

^40 deaths were actively identified via data linkage
^^Only one death was found to be causally associated with vaccination
^^^Includes expired vaccine, incorrect administration and doses given outside recommendation

Appendix 3

Table 16. Other adverse events of special interest detected by data linkage active surveillance reported to WAVSS, 2021

Common minor	***Haematological***
Abdominal pain	Arterial Thrombus
Fever (unspecified and ≥38 <40C)	Splenic Thrombosis
Headache	Thrombocytopenia
Lethargy	Thrombophlebitis
Myalgia	
Nausea	***Respiratory***
Pain in limb	Dyspnoea
Paresthesia	Exacerbation of asthma
Vomiting	Pneumonia
	Shortness of breath
Allergic	
Angioedema	***Cardiological***
Rash	Atrial fibrillation
Urticaria/Hives/Allergic rash	Chest pains
	Heart failure
Immunological	Non-ST-elevation myocardial infarction
Autoimmune encephalitis	Palpitations
Autoimmune hepatitis	Supraventricular tachycardia
Acute pancreatitis	
Transverse Myelitis	***Other***
Reactive arthritis	Acute Kidney Injury
	Conjunctivitis
Neurological	Elevated Creatine Kinase
Altered level of consciousness	Necrotising pancreatitis
Cerebrovascular accident	Rhabdomyolysis
Facial weakness	Syncope & collapse
Fall	Syncope with Viral Illness
Ramsay Hunt Syndrome	
Trigeminal neuralgia	

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World Health Organization

VigiAccess was launched by the World Health Organization (WHO) in 2015 to provide public access to information in VigiBase, the WHO global database of reported potential side effects of medicinal products.

Vaccine or Drug Name	Total ADRs	Years
Mumps vaccine	711	1972-2021
Rubella vaccine	2,621	1971-2021
Ivermectin	5,705	1992-2021
Measles vaccine	5,827	1968-2021
Penicillin nos	6,684	1968-2021
smallpox vaccine	6,891	1968-2021
chloroquine	7,139	1968-2021
tetanus vaccine	15,085	1968-2021
Hydroxychloroquine	32,641	1968-2021
Hepatitis A vaccine	46,773	1989-2021
Benzylpenicillin	51,327	1968-2021
Rotavirus vaccine	68,327	2000-2021
Accutane	70,719	1983-2021
Vancomycin	71,159	1974-2021
Hepatitis B vaccine	104,619	1984-2021
Polio vaccine	121,988	1968-2021
Meningococcal vaccine	126,412	1976-2021
Ibuprofen	166,209	1969-2021
tylenol	169,359	1968-2021
Aspirin	184,481	1968-2021
Pneumococcal vaccine	234,783	1980-2021
Influenza vaccine	272,202	1968-2021
Covid-19 vaccine	2,457,386	2020-2021

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Updated Nov. 12th 2021