FREEDOM OF INFORMATION ACT, 1991
YOUR RIGHTS TO REVIEW AND APPEAL

1. INTERNAL REVIEW

If you are dissatisfied or "aggrieved" with certain decisions or "determinations" of an agency/council/university (regarding access to documents or amendment of records), under S.29 and S.38 of the Freedom of Information Act (SA), 1991, you can apply to the agency/council/university concerned for an internal review of its determination.

To apply for an internal review of a determination you must write a letter addressed to the Principal Officer or lodge an internal review application form with the same agency/council/university as made the determination. This also must be addressed to the Principal Officer. The application must be accompanied by the appropriate fee (if applicable). The application should be lodged within 30 days of the original determination.

The agency/council/university will undertake its internal review and advise you of its decision within 14 days of receipt of the application.

There is no right to an internal review of a determination made by a Minister or Principal Officer of an agency/council/university.

2. INVESTIGATION BY THE OMBUDSMAN

After an internal review has been completed, if you are still dissatisfied with the agency/council/university's determination, you can request an external review by the Ombudsman SA of the determination. The Ombudsman is empowered to investigate the conduct of any person or body in relation to a determination made by an agency/council/university under this Act.

You may also request an external review by the Ombudsman if you have no right to an internal review.

The application for review by the Ombudsman should be lodged within 30 days after the date of a determination. However, the Ombudsman can extend this time limit at their discretion.

Investigations by the Ombudsman are free. Further information is available from the Office of the Ombudsman.

3. REVIEW BY SOUTH AUSTRALIAN CIVIL AND ADMINISTRATIVE TRIBUNAL

You have a right to apply for a review by SACAT if you are unhappy with:

- a determination not subject to Internal Review
- an Internal Review determination, or
- the outcome of a review by the Ombudsman SA.

You must exercise your right of review with SACAT within 30 calendar days after being advised of the above types of determinations or the results of a review. Any costs will be determined by SACAT, where applicable.

For more information contact SACAT - Phone: 1800 723 767 Email: sacat@sacat.sa.gov.au

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 1

Date 11 March 2021

Report from 22 Feb 2021 to 10 March 2021

Government of South Australia
SA Health

Introduction

South Australia's COVID-19 vaccination program commenced on 22 February 2021 with Pfizer's Comirnaty vaccine, and on 5 March 2021 with AstraZeneca's COVID-19 vaccine.

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.

Adverse reactions definitions and the TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines are listed in Appendix 1.

As part of the vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program, reports are received and analysed by the South Australian Vaccine Safety Surveillance System (SAVSSS). Each report is automatically uploaded to the TGA. Any report requiring follow up is analysed by the COVID-19 Vaccination Program - Immunisation Coordination Unit and reported to the COVID-19 Vaccine Safety Committee for review.

This report provides a record of all reports received into SAVSSS on Table 1.

Details of AEFIs and AESIs received following Pfizer's COVID-19 Comirnaty vaccine and AstraZeneca vaccines administered are recorded on Table 2 and Table 3. These will be reviewed by the Committee on weekly basis. The report will be tabled up to 24 hours prior to the Committee meeting.

Table 4 will outlines the Therapeutic Goods Administration COVID-19 vaccine weekly safety report.

Table 1: Summary of all COVID-19 vaccine AEFI report received into SAVSSS as 10/03/2021 16:28

All Reports	Number of Reports		25
	Gender	Male	4
		Female	15
	Indigenous	No	18
	Injection Site Reaction	Total number of reports	4
		Rash	1
		Pain	3
		Other	2
	General Reaction	Total number of reports	11
		Nausea	3
		Headache	2
		Hypertension	2
		Asthma	1
		Chills	1
		Conjunctivitis	1
		Dizziness - see vertigo	1
		Eye irritation	1
		Fever mild	1
		Hypotension	1
		Itching	1
		Light headedness	1
		Oedema	1
		Peripheral edema	1
		Rash	1
		Rash unspecified	1
		Tachycardia	1
		Vasovagal episode (syncope, faint) +/-tonic clonic movements	1
		Vertigo	1
		Vomiting	1
	Symptom Classification	Common	6
	Individual Brands	Pfizer Comirnaty	23
		AstraZeneca COVID 19 vaccine	2
	Combo Brands	Pfizer Comirnaty	23
		AstraZeneca COVID 19 vaccine	2

Table 1: Details of serious adverse events received following Pfizer's COVID-19 Comirnaty vaccine administered

ID Number	Age	Incident details	Recommendation from Committee
[redacted]	93	Date vaccinated [redacted] Dose number :1 [redacted]	[redacted]
[redacted]	59	Date vaccinated [redacted] Dose number :1 [redacted] [redacted] [redacted]nic	[redacted]
[redacted]	31	Date vaccinated [redacted] Dose number : 1 [redacted] [redacted]:	[redacted]
[redacted]	[redacted]	Date vaccinated: [redacted] Dose number : 1 Details of Incident: [redacted] [redacted]	[redacted]
[redacted]	54	Date vaccinated: [redacted] Dose number :1 [redacted]	[redacted]

		[redacted]	
[redacted]	45 [redacted]	Date vaccinated: [redacted] Dose number :1 [redacted]	[redacted]

Table 2: Details of serious adverse events received following AstraZeneca's COVID-19 Vaccine administered

ID Number	Age	Incident details	Recommendation for Committee
[redacted]	42 [redacted]	Date vaccinated: [redacted] Dose number :1 Details of Incident: [redacted]	[redacted]

Table 4: Summary of the TGA COVID-19 vaccine weekly safety report

COVID-19 vaccine weekly safety report #1 - 03-03-2021

Total adverse event following immunisation (AEFI) reports received up to 28 February 2021

Gathering reports of suspected side effects following vaccination is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

2.3	79	33,702
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

Reports by jurisdiction

Australian Capital Territory	2
New South Wales	34
Northern Territory	3
Queensland	4
South Australia	5
Tasmania	2
Victoria	28
Western Australia	0
Not reported	1

The most common reactions reported in the first week were:

- Feeling faint
- Dizziness
- Headache
- Nausea
- Sweating

Evaluation of these reports is ongoing.

Adverse events reported to the TGA may not be caused by the vaccine. Not all adverse events are reported, especially for minor and well-known side effects.

The information the TGA receives in reports reflects the view of the reporter. As analysis of these reports is ongoing, the information may change as the data quality are reviewed or further information is provided. Total numbers may also change as duplicate reports are identified.

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)

- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 1 -Table 1: Adverse reactions from Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 1 - Table 2: Adverse reactions from COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACCINE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

References:

1. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au.

Document 2

OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 8

Meeting date: 29 April 2021

Report period: 22 April 2021 to 28 April 2021

Government of South Australia

SA Health

List of Tables

Summary

Vaccination recorded to the Australian Immunisation Register as at 28 April 2021*

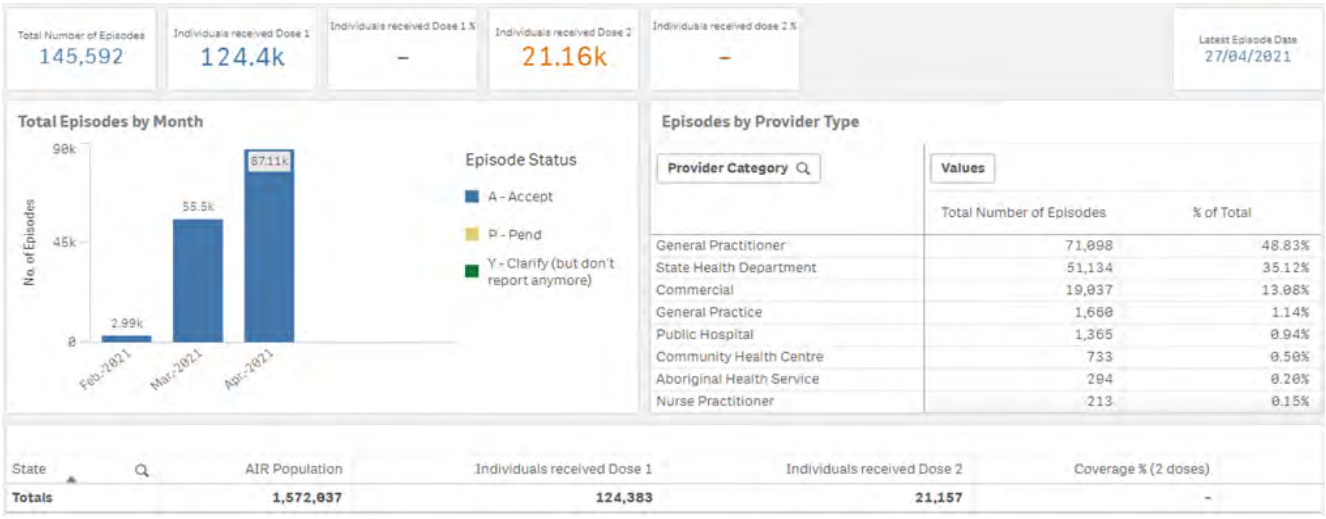
Total doses/episodes: 145,592

Individuals received dose 1 = 124,400

Individuals received dose 2 = 21,160

Pfizer doses = 57,280

AstraZeneca = 88,312



*Latest available data from Australian Immunisation Regsiter report

Background

South Australia's COVID-19 vaccination program commenced on 22 February 2021 with Pfizer's Comirnaty vaccine and on 5 March 2021 with AstraZeneca's COVID-19 vaccine.

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.

Adverse reactions definitions and the TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines are listed in Appendix 1.

As part of the vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program, reports are received and analysed by the South Australian Vaccine Safety Surveillance System (SAVSSS). Each report is automatically uploaded to the TGA. Any report requiring follow up is analysed by the COVID-19 Vaccination Program - Immunisation Coordination Unit and reported to the COVID-19 Vaccine Safety Committee for review.

This report provides a record of all reports received into SAVSSS on Table 1.

Details of AEFIs and AESIs received following Pfizer's COVID-19 Comirnaty vaccine and AstraZeneca vaccines administered are recorded on Table 2 and Table 3 respectively. These will be reviewed by the Committee on weekly basis.

The report will be tabled up to 24 hours prior to the Committee meeting.

Table 4 will outlines the Therapeutic Goods Administration COVID-19 vaccine weekly safety report.

Table 1: Summary of all COVID-19 vaccine AEFI report received into SAVSSS as 07/04/2021

Number of Reports		666
Gender	Male	151
	Female	508
Indigenous	Yes	10
	No	606
	Unknown	28

General reactions	
Total number of reports	604
Headache	200
Myalgia	171
Nausea	108
Fever not recorded	101
Chills	86
Lethargy	76
Fatigue	63
Arthralgia	54
Fever mild	46
Vomiting	34
Dizziness - see vertigo	29
Dyspnoea	29
Injection-site pain	27
Rash	25
Abdominal Pain	21
Fever high	19
Malaise	19
Tachycardia	19
Diarrhoea	18
Hypertension	17
Confusion	16
Lymphadenopathy	16
Clot	15
Flushing	15
Rash unspecified	15
Chest Pain	14
Light headedness	13
Pain	13
Rigors	13
Urticaria	13
Coughing	12

Visual disturbance	12
Injection site pain restricting limb mobility	11
Death	10
Dysgeusia	10
Insomnia	10
Migraine	10
Paresthesia	10
Vasovagal episode (syncope, faint) +/-tonic clonic movements	10
Vertigo	10

Individual Brands	AstraZeneca COVID 19 vaccine	450
	Pfizer Comirnaty	216

Table 2: Events received following Pfizer's COVID-19 Comirnaty vaccine

Event ID Number	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted] 24	**Date and time Vaccinated:** [redacted] **Vaccine Dose: 1** [redacted]	[redacted]
[redacted]	[redacted] 32	**Date and time Vaccinated:** [redacted] **Vaccine Dose: 1** [redacted]	[redacted]
[redacted]	[redacted] 22	**Date and time Vaccinated:** [redacted] **Vaccine Dose: 1** [redacted]	[redacted]
[redacted]	[redacted] 35	**Date and time Vaccinated:** [redacted] **Vaccine Dose: 1** [redacted]	[redacted]

Table 3: Events received following AstraZeneca's Vaccine

Event ID Number	Age and Gender	Incident details	Recommendation from Committee
[redacted]	80[redacted]	**Date and time Vaccinated**: 31/3/21 **Vaccine Dose: 1** **Details:** [redacted] **Treatment**: [redacted] **Medical History:** [redacted]	[redacted]
[redacted]	74[redacted]	**Date and time Vaccinated**: 6/4/21 18:40pm **Vaccine Dose: 1** **Details:** [redacted] **Treatment**: [redacted] **Medical History:** [redacted]	[redacted]
[redacted]	65[redacted]	**Date and time Vaccinated**: 24/3/21 **Vaccine Dose: 1** [redacted]	[redacted]

[redacted]	[redacted] 77	**Date and time Vaccinated**: 12/4/21 – 12:50pm **Vaccine Dose: 1** [redacted]	[redacted]
[redacted]	[redacted] 63	**Date and time Vaccinated**: 10/4/21 **Vaccine Dose: 1** [redacted]	[redacted]
[redacted]	[redacted] 35	**Date and time Vaccinated**: 15/4/21 @ 15:14 **Vaccine Dose: 1** [redacted]	[redacted]
[redacted]	[redacted] 75	**Date and time Vaccinated**: 31/3/21 **Vaccine Dose: 1** [redacted]	[redacted]

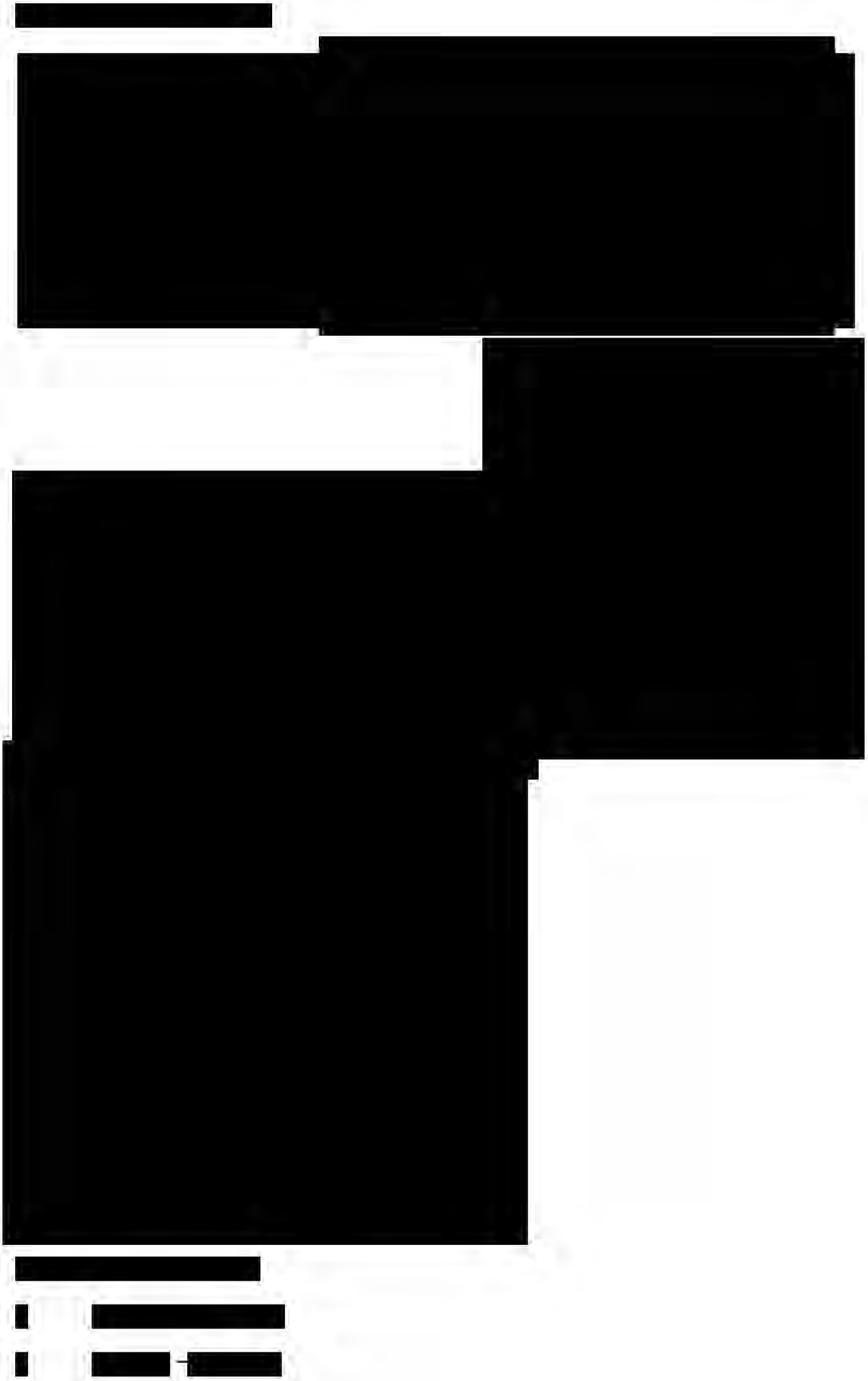


Table 4: Summary of the TGA COVID-19 vaccine AEFI/AESI update

Total adverse event following immunisation (AEFI) reports received up to 25 April 2021

6.6	12,694	1,937,300
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.7	New South Wales	4.2
Northern Territory	6.4	Queensland	5.7
South Australia	5.3	Tasmania	8.3
Victoria	11.1	Western Australia	4.6

A number of factors influence reporting behaviour and reporting rates. Differences in reporting rates do not indicate any safety concerns specific to particular jurisdictions.

Last week, the TGA received a total of 1942 AEFI reports for COVID-19 vaccines, including 518 for the Comirnaty vaccine, 1400 for the AstraZeneca COVID-19 vaccine, and 24 reports where the vaccine tradename was not reported. The most common adverse events reported for COVID-19 vaccines during this period were:

- Headache
- Muscle pain
- Fever
- Injection site reactions
- Lethargy

Adverse events of special interest reported for the Comirnaty vaccine were:

- Anaphylaxis (52 reports)
- Bleeding disorder (27 reports)
- Seizure (13 reports)
- Facial weakness (11 reports)
- Loss of sense of taste or smell (9 reports)
- Cardiac event (5 reports)

Adverse events of special interest reported for the AstraZeneca COVID-19 vaccine include:

- Bleeding disorder (97 reports)
- Anaphylaxis (59 reports)
- Seizure (27 reports)
- Cardiac Event (15 reports)
- Loss of sense of taste or smell (12 reports)
- Low platelets (12 reports)
- Facial weakness (10 reports)
- Liver injury (4 reports)
- Guillian-Barre Syndrome (1 report)

Close monitoring of adverse events involving blood clots with low platelets.
The TGA received 73 reports of venous thromboembolism for the AstraZeneca COVID-19 vaccine in Australia during the reporting period to 18 April 2021, including 51 reports in the week from 12-18 April. These reports were of blood clots in the veins or arteries (including venous thrombosis or venous thromboembolism).

The overall number of reports received is no higher than the expected background rate for the more common type of blood clots in Australia, which occur in around 50 Australians every day irrespective of their vaccination status.

The increase in cases of blood clots submitted to the TGA appears to be due to reporting of coincidental blood clots unrelated to vaccination, due to increased awareness of investigations into a rare and unusual clotting syndrome involving thrombosis (blood clots) with thrombocytopenia (low blood platelet count) following the AstraZeneca COVID-19 vaccine.

Published safety information:

The TGA has published the following COVID-19 safety-related information:

AstraZeneca ChAdOx1-S COVID-19 vaccine: Three additional Australian cases of TTS likely linked to vaccine – 23 April 2021

A Vaccine Safety Investigation Group (VSIG) was convened by the TGA, has concluded that three recently reported cases of thrombosis with thrombocytopenia are likely to be linked to vaccination. All three patients are clinically stable, have responded well to treatment and are recovering. Whilst meeting the international and UK criteria, two of the three cases appear to be milder forms of the syndrome that were recognised very early by the treating health professionals and are responding well to treatment.
There are now six Australian reports of cases of thrombosis with thrombocytopenia following the AstraZeneca COVID-19 vaccine. Five cases are in people aged less than 50 years, who were vaccinated prior to the decision by the Australian Technical Advisory Group on Immunisation (ATAGI) and the announcement by Government on 8 April 2021 that the Pfizer vaccine was preferred for patients under 50 years old.
To 22 April there have been about 1.1 million doses of AstraZeneca COVID-19 vaccine administered in Australia.

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 9

Meeting date: 6th May 2021

Report period: 29/04/2021 to 05/05/2021

List of Tables

Summary

Vaccination recorded to the Australian Immunisation Register as at 04 May 2021*

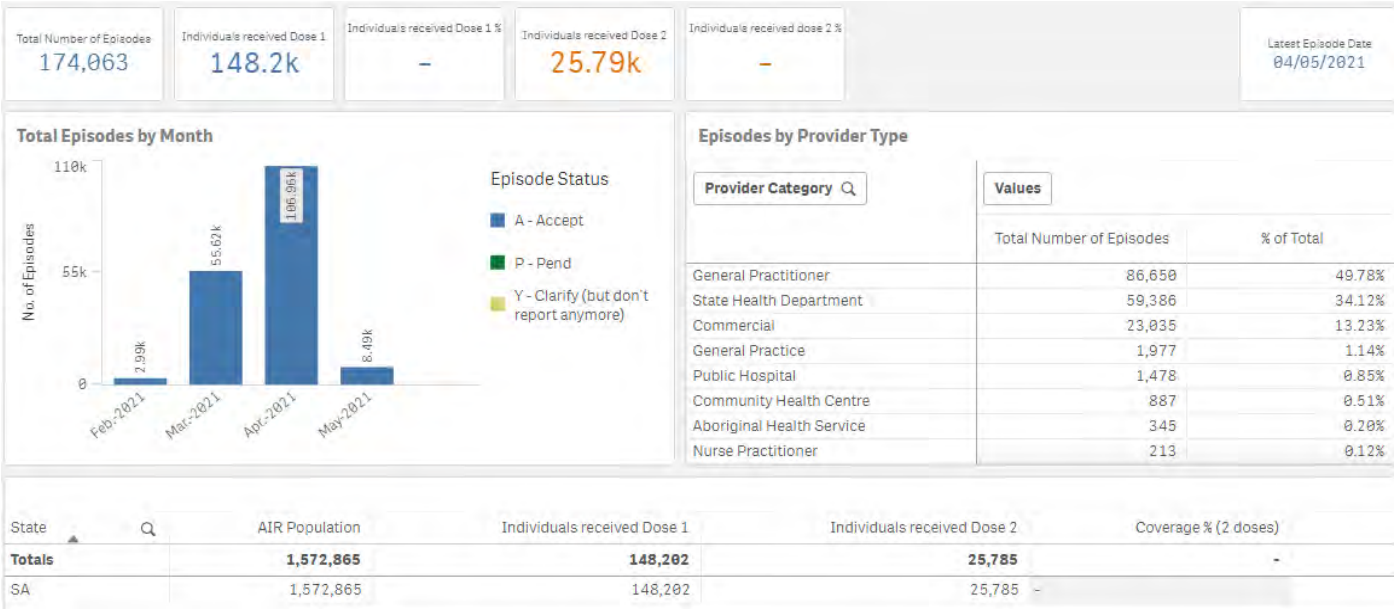
Total doses/episodes: 174,063

Individuals received dose = 148,200

Individuals received dose 2 = 25,790

Pfizer doses = 67,446

AstraZeneca = 106,617



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The report will be tabled up to 24 hours prior to the Committee meeting.

Table 4 will outlines the Therapeutic Goods Administration COVID-19 vaccine weekly safety report.

Table 1: Summary of all COVID-19 vaccine AEFI report received into SAVSSS as 05/05/2021

Number of Reports		
Gender	Male	196
	Female	599
Indigenous	Yes	13
	No	725
	Unknown	36

General reactions	Total number of reports
Headache	240
Myalgia	194
Nausea	131
Fever not recorded	114
Chills	102
Lethargy	86
Fatigue	69
Arthralgia	62
Fever mild	50
Vomiting	42
Dizziness - see vertigo	33
Rash	33
Dyspnoea	32
Abdominal Pain	30
Injection-site pain	28
Tachycardia	24
Hypertension	23
Diarrhoea	22
Malaise	21
Rigors	21

Individual Brands	AstraZeneca COVID 19 vaccine	556
	Pfizer Comirnaty	253

Table 2: Events received following Pfizer's Comirnaty vaccine

Event ID Number	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted] 51	**Date and time vaccinated**: 28/4/21 @ 09:47 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted] 62	**Date and time vaccinated**: 23/4/21 **Dose number: 1** [redacted]	[redacted]
		Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review
		Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review

Table 3: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted] 51	**Date and time Vaccinated**: 13/4/21 @ 09.04 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted] 65	**Date and time vaccinated**: 16/4/21 @ 15.35 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted] 66	**Date and time vaccinated**: 14/4/21 @ 13:44 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted] 67	**Date and time vaccinated**: 28/4/21 @11.45 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]85	**Date and time vaccinated**: 23/4/21 @ 11.43 **Dose number: 1** [redacted] **Treatment**: [redacted]	[redacted]

[redacted]	[redacted] 36	**Date and time vaccinated**: 31/3/21 @ 14:00 **Dose number: 1** **Details:** [redacted] – refer to Image below	[redacted]
[redacted]	[redacted] 44	**Date and time vaccinated**: 31/3/21 @ 12:30 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]	**Date and time vaccinated**: 13/4/21 @ 15:16 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]	**Date and time vaccinated**: 27/4/21 @ 09:00 **Dose number: 1** [redacted]	[redacted]

		[redacted]	
		Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	[redacted]

Images

23 [redacted]

[redacted]

Special Interest Topics

- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

Table 4: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website 25 April 2021 as 5 May 2021 15:30 Total adverse event following immunisation (AEFI) reports received up to 25 April 2021.

This data was presented in Vaccine Safety Surveillance Committee Report 8.

Once data is updated this report will be included in retrospectively.

Document 4

OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 10

Meeting date: 13 May 2021

Report period: 06/05/2021 to 12/05/2021

Government of South Australia

SA Health

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Appendices

Summary

Vaccination recorded to the Australian Immunisation Register as at 12 May 2021*

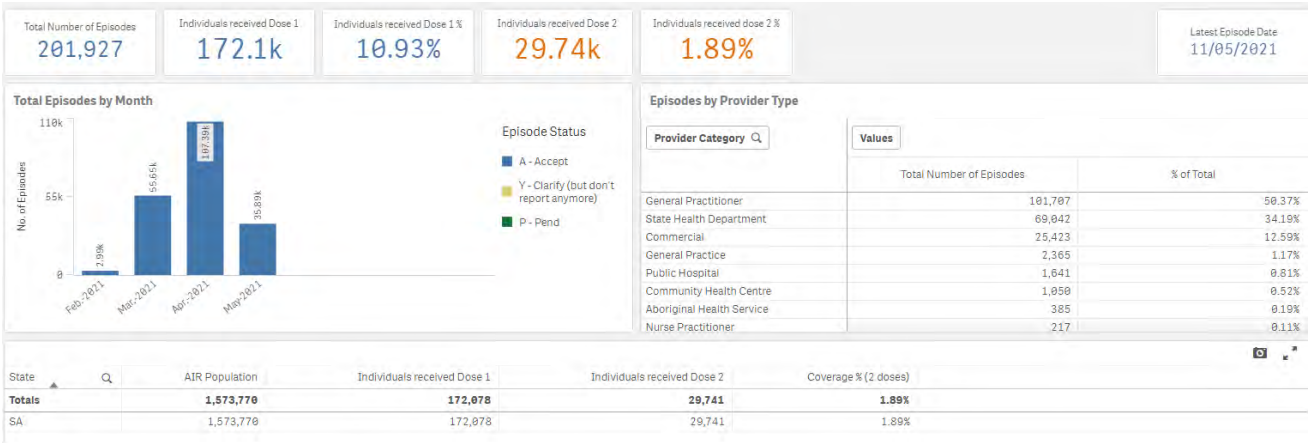
Total doses/episodes: 201,927

Individuals received dose 1 = 172.078

Individuals received dose 2 = 29,741

Pfizer doses = 76,291

AstraZeneca = 125,636



*Latest available data from Australian Immunisation Regsiter report

Background

South Australia's COVID-19 vaccination program commenced on 22 February 2021 with Pfizer's Comirnaty vaccine and on 5 March 2021 with AstraZeneca's COVID-19 vaccine.

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.

Adverse reactions definitions and the TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines are listed in Appendix 1.

As part of the vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program, reports are received and analysed by the South Australian Vaccine Safety Surveillance System (SAVSSS). Each report is automatically uploaded to the TGA. Any report requiring follow up is analysed by the COVID-19 Vaccination Program - Immunisation Coordination Unit and reported to the COVID-19 Vaccine Safety Committee for review.

This report provides a record of all reports received into SAVSSS on Table 1.

Details of AEFIs and AESIs received following Pfizer's COVID-19 Comirnaty vaccine and AstraZeneca vaccines administered are recorded on Table 2 and Table 3 respectively. These will be reviewed by the Committee on weekly basis.

The report will be tabled up to 24 hours prior to the Committee meeting.

Table 5 will outlines the Therapeutic Goods Administration COVID-19 vaccine weekly safety report.

Table 1: Summary of COVID-19 vaccine AEFI report SAVSSS as at 12/05/2021

Total Number of Reports		910
Gender	Male	226
	Female	679
Indigenous	Yes	14
	No	827
	Unknown	42

Injection Site Reactions Total Number of Reports	229

General reactions	
Total number of reports	839
Headache	273
Myalgia	216
Nausea	147
Fever not recorded	126
Chills	114
Lethargy	92
Fatigue	85
Arthralgia	69
Fever mild	52
Vomiting	46
Dizziness - see vertigo	41
Rash	36
Dyspnoea	35
Abdominal Pain	34
Injection-site pain	31
Chest Pain	28
Hypertension	28
Pain	28
Tachycardia	27
Diarrhoea	26
Light headedness	25
Clot	24
Lymphadenopathy	23
Rash unspecified	23
Vertigo	22
Confusion	21
Malaise	21
Paresthesia	21
Rigors	21
Fever high	20

Individual Brands	AstraZeneca COVID 19 vaccine	614
	Pfizer Comirnaty	306

Table 2: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review

Table 3: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	[redacted] 71	**Date and time vaccinated**: 16/4/21 **Dose number:** Dose 1 [redacted] **Treatment:** **Medical History:** [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 81	**Date and time vaccinated**: 04/05/21 @ 12:05 **Dose number:** Dose 1 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 48	**Date and time vaccinated**: 14/4/21 **Dose number:** Dose 1 [redacted]	[redacted]
[redacted]		[redacted] 62	**Date and time vaccinated**: 9/4/21 @ 12:59 **Dose number:** Dose 1 [redacted]	[redacted]

			[redacted]	

Table 4: Special Interest AEFI Topics:

	YTD	Week 10
Total Number of reports	354	45
Myalgia	303	35
Arthralgia	131	19
Abdominal Pain (pancreatitis)	54 (2 pancreatitis)	8 (1 pancreatitis)
Chest Pain (chest tightness, angina)	46	13
Pain	38	18
Clot	33	10
Visual disturbance	17	2
Epistaxis	16	4
Death	15	0
Stroke	9	1
Atrial fibrillation	8	0
Cellulitis at the injection site	5	3
Thrombocytopenia	3	2
Hyperglycaemia	2	1
Miscarriage	1	1
Pericaditis	4	3

TGA unmatched reports x 4

- [redacted]
- [redacted]
- [redacted]

Table 5: Summary of the TGA COVID-19 vaccine update

Last data reported available on TGA website 6 May 2021

https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-06-05-2021

Total adverse event following immunisation (AEFI) reports received up to 2 May 2021

Gathering reports of suspected side effects following vaccination is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

The following results include AEFI reports received by the TGA and entered into our adverse event database. Responses to AusVaxSafety surveys are not included (see 'Active surveillance' section below).

6.6	15,017	2,260,615
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	5.2	New South Wales	4.6
Northern Territory	7.1	Queensland	5.7
South Australia	5.6	Tasmania	8.6
Victoria	10.5	Western Australia	4.8

Appendix 1: TGA listed AEFI and AESI definitions COVID-19 vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published AEFI definitions Pfizer COVID-19 vaccine

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COV D-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccine *

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

Product information for AusPAR - COV D-19 VACCINE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 F NAL 15 February 2021

Document 5

OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 16

Meeting date: 24 June 2021

Report period: 16 June 2021 to 23 June 2021

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 23/06/2021*

Total doses/episodes: **500,299**
Individuals received dose 1 = **409,598**
Individuals received dose 2 = **89,382**
Pfizer doses = **191,453** (Dose 1: 124,369 – Dose 2: 66,968)
AstraZeneca doses = **308,846** (Dose 1:285,350 – Dose 2: 22,417)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 23 June 2021 YTD

Number of Reports		**1,655**
Gender	Male	419
	Female	1,232
Indigenous	Yes	21
	No	1,539
	Unknown	64
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**408**
General reactions Total number of COVID-19 Vaccines Reports		**1,532**

Astra Zeneca **Total General Reactions:**	**1,023**	**% of Total AZ vaccine administered**
Headache	392	0.13
Myalgia	262	0.08
Chills	205	0.07
Nausea	182	0.06
Fever not recorded	172	0.06
Fatigue	115	0.04
Arthralgia	111	0.04
Lethargy	110	0.04
Vomiting	62	0.02
Diarrhoea	52	0.02
Fever mild	50	0.02
Abdominal Pain	49	0.02
Dizziness - see vertigo	48	0.02
Rash	41	0.01
Dyspnoea	38	0.01
Malaise	37	0.01
Pain	37	0.01
Chest Pain	36	0.01
Injection-site pain	34	0.01
Vertigo	33	0.01
Clot	31	0.01
Rigors	31	0.01
Tachycardia	31	0.01
Coughing	25	0.01
Fever high	25	0.01
Light headedness	25	0.01
Hypertension	21	0.01
Influenza-like illness	21	0.01
Sweating	21	0.01

Visual disturbance	21	0.01
Confusion	20	0.01
Deep vein thrombosis	19	0.01
Paresthesia	19	0.01
Flushing	18	0.01
Rash unspecified	17	0.01
Urticaria	17	0.01
Injection site pain restricting limb mobility	16	0.01
Insomnia	16	0.01
Migraine	15	0.00
Shivering	15	0.00
Anorexia	14	0.00
Death	12	0.00
Pain in extremity	12	0.00
Palpitations	12	0.00
Cramps	11	0.00
Dysgeusia	11	0.00
Epistaxis	11	0.00
Herpes zoster	11	0.00
Lymphadenopathy	11	0.00
Vasovagal episode (syncope, faint) +/-tonic clonic movements	11	0.00
Pruritus	10	0.00
Pulmonary embolism	10	0.00

Pfizer **Total General Reactions**	**509**	**% of Total Pfizer vaccine administered**
Headache	148	0.08
Myalgia	95	0.05
Nausea	79	0.04
Fatigue	58	0.03
Chills	50	0.03
Lymphadenopathy	49	0.03
Lethargy	44	0.02
Fever not recorded	42	0.02
Arthralgia	41	0.02
Paresthesia	32	0.02
Chest Pain	29	0.02
Dizziness - see vertigo	26	0.01
Vomiting	26	0.01
Light headedness	25	0.01
Pain	25	0.01
Rash	25	0.01
Coughing	23	0.01

Hypertension	23	0.01
Abdominal Pain	22	0.01
Diarrhoea	21	0.01
Rash unspecified	20	0.01
Tachycardia	20	0.01
Urticaria	20	0.01
Vertigo	19	0.01
Fever mild	18	0.01
Flushing	17	0.01
Injection-site pain	17	0.01
Dyspnoea	16	0.01
Death	14	0.01
Sweating	14	0.01
Menstrual Irregularity	13	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	12	0.01
Itching	11	0.01
Throat soreness	11	0.01
Visual disturbance	11	0.01
Numbness	10	0.01

Table 2: Special Interest AEFI Topics as at 23 June 2021 YTD:

Astra Zeneca	YTD		Week 16	
Total Number of reports	543	% of Total AZ vacc admin.	38	% of YTD AESI reported
Myalgia	381	0.12	24	6.30
Arthralgia	205	0.07	17	8.29
Abdominal Pain	81	0.03	5	6.17
Chest Pain	59	0.02	3	5.08
Clot	44	0.01	0	0.00
Pain	46	0.01	6	13.04
Vertigo	45	0.01	3	6.67
Visual disturbance	31	0.01	0	0.00
Hypertension	30	0.01	1	3.33
Epistaxis	20	0.01	0	0.00
Deep vein thrombosis	23	0.01	3	13.04
Death	16	0.01	0	0.00
Herpes zoster	13	0.004	1	7.69
Pulmonary embolism	12	0.004	2	16.67
Atrial fibrillation	10	0.003	1	10.00
Hyperglycemia	9	0.003	0	0.00
Cellulitis at the injection site	5	0.002	0	0.00
Cerebral vascular accident see Stroke	5	0.002	0	0.00
Stroke	5	0.002	0	0.00
Thrombocytopenia	4	0.001	0	0.00
Bells Palsy	3	0.001	0	0.00
Anaphylaxis	2	0.001	0	0.00
Angina pectoris	2	0.001	0	0.00
Pericaditis	2	0.001	0	0.00
Arthritis	1	0.000	0	0.00
Menstrual Irregularity	1	0.000	0	0.00
Varicella-like rash (general)	1	0.000	0	0.00
Guillain Barré syndrome	1	0.000	1	100.00

Myocarditis	0	0.000	0	0

Pfizer	YTD		Week 16	
Total Number of reports	223	% of Total Pfizer vacc admin.	18	% of YTD AESI reported
Myalgia	158	0.08	12	7.59
Arthralgia	86	0.04	11	12.79
Chest Pain	47	0.02	4	8.51
Pain	42	0.02	3	7.14
Abdominal Pain	35	0.02	0	0.00
Hypertension	33	0.02	6	18.18
Vertigo	25	0.01	7	28.00
Menstrual Irregularity	18	0.01	1	5.56
Death	16	0.01	0	0.00
Visual disturbance	15	0.01	0	0.00
Clot	8	0.004	0	0.00
Stroke	7	0.004	0	0.00
Epistaxis	4	0.002	0	0.00
Pericaditis	4	0.002	0	0.00
Arthritis	3	0.002	0	0.00
Atrial fibrillation	3	0.002	0	0.00
Anaphylaxis	2	0.001	0	0.00
Bells Palsy	2	0.001	0	0.00
Herpes zoster	2	0.001	1	50.00
Hyperglycemia	1	0.001	0	0.00
Miscarriage	1	0.001	0	0.00
Pulmonary embolism	1	0.001	0	0.00
Thrombocytopenia	1	0.001	0	0.00
Varicella-like rash (general)	1	0.001	0	0.00
Deep vein thrombosis	1	0.001	1	100.00
Myocarditis	0	0.000	0	0

Table 3: TGA reported TTS Summary as at 23 June 2021 YTD:

Confirmed	Probable (deemed to meet criteria*, awaiting TGA determination)	Possible	Unlikely	Unclassified on TGA listing	Total
2	3	4	2	2	13

Summary of cases:

[redacted]	Age [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	70 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	26 [redacted]	[redacted]	[redacted]	Astra Zeneca-1	[redacted]
[redacted]	47 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca -1	[redacted]

	58			Astra Zeneca – 1	
	89			Astra Zeneca 1	
	73			Astra Zeneca -1	
	71			Astra Zeneca 1	
	91			Astra Zeneca 1	-
	65			Astra Zeneca 1	-

Table 4: TGA unmatched AEFI reports as at 23 June 2021:

Number unmatched reports: 2 *Reporter contacted to submit SAVSS report	81
	76 *

Table 5: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	58 [redacted]	**Date and time vaccinated:** 29/04/2021 11:00 **Dose number:** 2 [redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	79[redacted]	**Date and time vaccinated**: 15/5/21 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	58[redacted]	**Date and time vaccinated**: 21/5/21 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	61[redacted]	**Date and time vaccinated**: 27/5/21 @15:10 **Dose number:** 1 [redacted]	[redacted]

[redacted]	[redacted]	65[redacted]	**Date and time vaccinated:** 4/6/21 @ 16:00 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	53[redacted]	**Date and time vaccinated**: 10/3/21 @ 12:15 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	92[redacted]	**Date and time vaccinated**: 20/5/21 @ 10:49 **Dose number:** 1 [redacted]	[redacted]

[redacted]	[redacted]	58 [redacted] AZ	**Date and time vaccinated:-** 21/05/2021 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]	70 [redacted] AZ	**Date and Time Vaccinated:** 07/04/2021 @ [redacted] **Dosage number: 1** **Details:** [redacted] **Treatment:** [redacted] **Medical history:** [redacted]	[redacted]
[redacted]	[redacted]	71 [redacted]	**Date and Time Vaccinated:** [redacted] **Dosage: 1** [redacted]	[redacted]
[redacted]	[redacted]	53 [redacted] AZ	**Date and time vaccinated** [redacted] **Dose number**: 1 [redacted]	[redacted]

Table 7: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 17 June 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-17-06-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Twelve additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. The increase in the number of cases correlates with an increase in the number of doses of AstraZeneca vaccine administered during the reporting period.
- This brings the total number of confirmed and probable TTS cases in Australia to 60. Seven of the 12 new cases occurred in individuals in aged between 50 and 59 years. When assessed using the United Kingdom (UK) case definition, three cases were confirmed and nine were deemed probable TTS.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 7-13 June 2021, we received 2106 AEFI reports for COVID-19 vaccines.

To 13 June 2021, we received 303 reports of death following vaccination for COVID-19 vaccines.

By chance, some people will experience new illnesses or die from a pre-existing condition shortly after vaccination, especially if they are elderly. We review all deaths reported after vaccination and compare the expected natural death rates in a similar case group to observed death rates following immunisation to distinguish between possible side effects of the vaccines and coincidental events.

For reports of death other than TTS, our review of cases and analysis of reporting patterns does not suggest that the vaccine caused these deaths.

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Total adverse event reports to 13 June 2021

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.4	New South Wales	3.7
Northern Territory	4.8	Queensland	5.1
South Australia	4.6	Tasmania	6.8
Victoria	6.3	Western Australia	4.2

Most commonly reported vaccine side effects

The AEFI most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally. They include headache, muscle and joint pain, fever and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 7-13 June 2021 were headache, fever, muscle pain, chills and nausea.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 7-13 June 2021 were headache, muscle pain, injection site reactions, nausea and lethargy.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

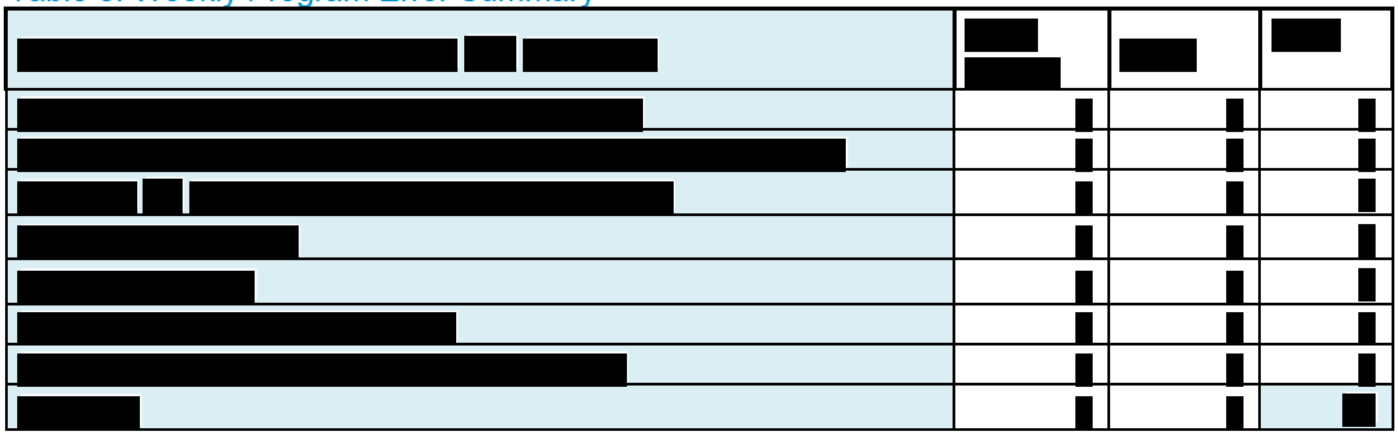
They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

Non-Critical Errors

- [redacted]
- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine#

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COV D-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

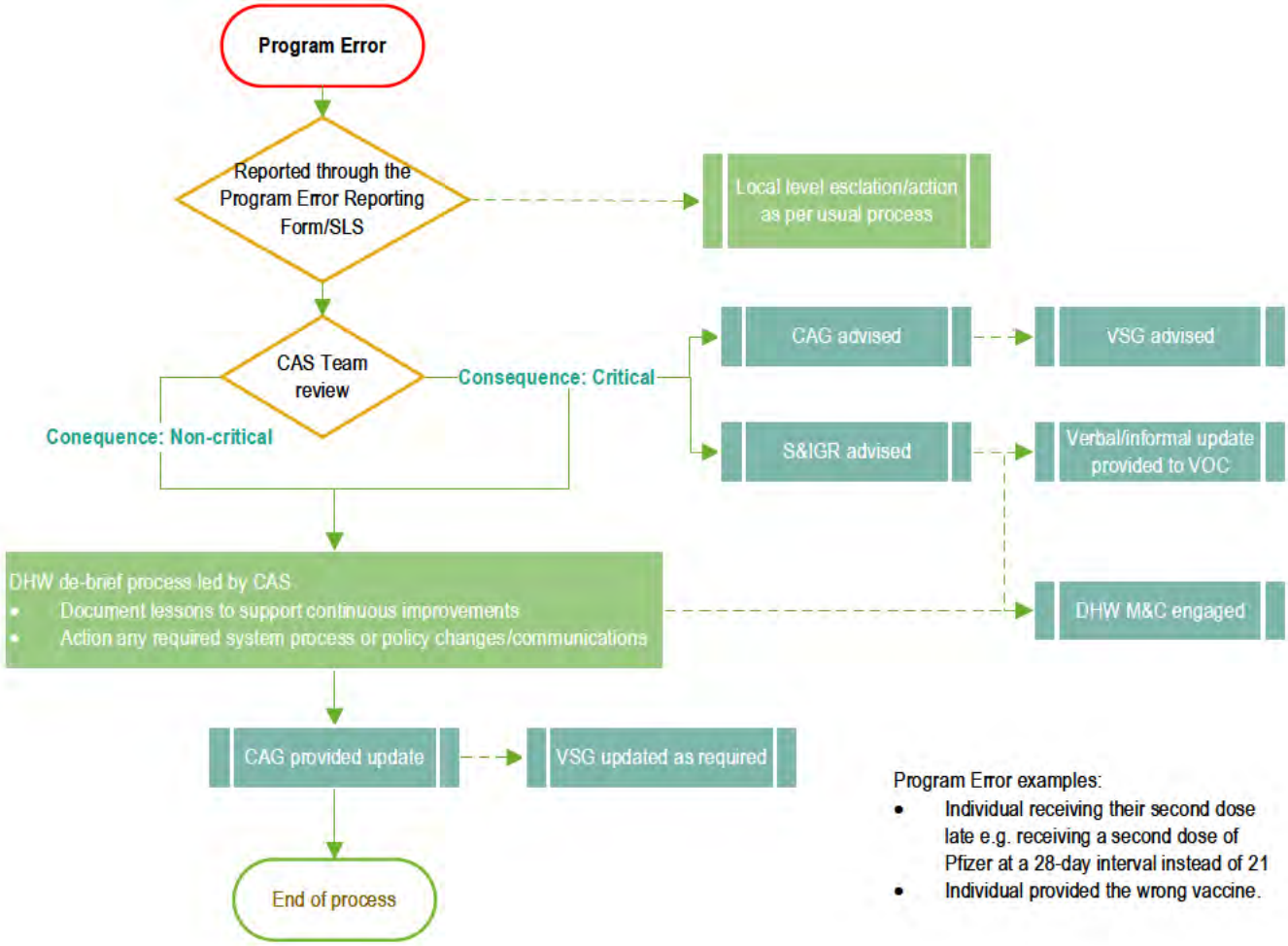
[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

Appendix 4.

INCIDENT ESCALATION AND COMMUNICATION PROCESS FLOW - CLINICAL



Program Error examples:

- Individual receiving their second dose late e.g. receiving a second dose of Pfizer at a 28-day interval instead of 21
- Individual provided the wrong vaccine.

DHW: Department for Health and Wellbeing
VOC: Vaccine Operations Centre
CAS: Clinical Advisory Service Team
CAG: Clinical Advisory Group

M&C: Media and Communications team
S&IGR: Strategy and Intergovernment Relations team
VSG: Vaccine Strategy Group
SLS: Safety Learning System

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 17

Meeting date: 1 July 2021

Report period: 23 June 2021 to 30 June 2021

Government of South Australia
SA Health

Contents

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 30/06/2021*

Total doses/episodes: 547,277
Individuals received dose 1 = 438,501
Individuals received dose 2 = 108,436
Pfizer doses = 217,315 (Dose 1: 141,188 – Dose 2: 76,008)
AstraZeneca doses = 329,962 (Dose 1: 297,460 – Dose 2: 32,431)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 30 June 2021 YTD

Number of Reports		**1,793**
Gender	Male	451
	Female	1.336
Indigenous	Yes	22
	No	1,666
	Unknown	71
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**447**
General reactions Total number of COVID-19 Vaccines Reports		**1,655**

Astra Zeneca **Total General Reactions:**	**1,099**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	414	37.67	0.13
Myalgia	280	25.48	0.08
Chills	216	19.65	0.07
Nausea	190	17.29	0.06
Fever not recorded	180	16.38	0.05
Fatigue	122	11.10	0.04
Lethargy	121	11.01	0.04
Arthralgia	116	10.56	0.04
Vomiting	65	5.91	0.02
Diarrhoea	57	5.19	0.02
Abdominal Pain	55	5.00	0.02
Fever mild	52	4.73	0.02
Dizziness - see vertigo	50	4.55	0.02
Rash	44	4.00	0.01
Malaise	42	3.82	0.01
Pain	42	3.82	0.01
Chest Pain	40	3.64	0.01
Dyspnoea	39	3.55	0.01
Injection-site pain	35	3.18	0.01
Vertigo	35	3.18	0.01
Rigors	33	3.00	0.01
Tachycardia	33	3.00	0.01
Clot	31	2.82	0.01
Light headedness	27	2.46	0.01
Coughing	26	2.37	0.01
Fever high	26	2.37	0.01
Paresthesia	23	2.09	0.01
Sweating	23	2.09	0.01
Hypertension	22	2.00	0.01

Influenza-like illness	22	2.00	0.01
Rash unspecified	22	2.00	0.01
Confusion	21	1.91	0.01
Urticaria	21	1.91	0.01
Visual disturbance	21	1.91	0.01
Deep vein thrombosis	20	1.82	0.01
Shivering	19	1.73	0.01
Flushing	18	1.64	0.01
Injection site pain restricting limb mobility	18	1.64	0.01
Insomnia	17	1.55	0.01
Anorexia	16	1.46	0.005
Migraine	16	1.46	0.005
Pain in extremity	16	1.46	0.005
Palpitations	16	1.46	0.005
Lymphadenopathy	14	1.27	0.004
Epistaxis	13	1.18	0.004
Herpes zoster	13	1.18	0.004
Death	12	1.09	0.004
Pruritus	12	1.09	0.004
Pulmonary embolism	12	1.09	0.004
Vasovagal episode (syncope, faint) +/-tonic clonic movements	12	1.09	0.004
Cramps	11	1.00	0.003
Dysgeusia	11	1.00	0.003

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**556**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	167	30.04	0.08
Myalgia	110	19.78	0.05
Nausea	94	16.91	0.04
Fatigue	66	11.87	0.03
Lymphadenopathy	53	9.53	0.02
Chills	51	9.17	0.02
Lethargy	50	8.99	0.02
Fever not recorded	46	8.27	0.02
Arthralgia	43	7.73	0.02
Chest Pain	37	6.65	0.02
Paresthesia	35	6.29	0.02
Light headedness	31	5.58	0.01
Rash	30	5.40	0.01
Vomiting	30	5.40	0.01
Dizziness - see vertigo	29	5.22	0.01
Hypertension	26	4.68	0.01
Coughing	25	4.50	0.01

Pain	25	4.50	0.01
Urticaria	25	4.50	0.01
Abdominal Pain	23	4.14	0.01
Diarrhoea	22	3.96	0.01
Rash unspecified	20	3.60	0.01
Tachycardia	20	3.60	0.01
Vertigo	20	3.60	0.01
Dyspnoea	18	3.24	0.01
Fever mild	18	3.24	0.01
Flushing	18	3.24	0.01
Injection-site pain	18	3.24	0.01
Death	14	2.52	0.01
Menstrual Irregularity	14	2.52	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	14	2.52	0.01
Sweating	12	2.16	0.01
Visual disturbance	12	2.16	0.01
Itching	11	1.98	0.01
Numbness	11	1.98	0.01
Throat soreness	11	1.98	0.01
Injection-site swelling	10	1.80	0.005
Oedema	10	1.80	0.005
Pruritus	10	1.80	0.005
Shivering	10	1.80	0.005
Deep vein thrombosis	1	0.18	0.0005

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 30 June 2021 YTD:

Astra Zeneca	YTD		Week 17		
Total Number of reports	**1,099**	**% of Total AZ vacc admin***	**73**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Myalgia	280	0.08	17	6.07	0.0052
Arthralgia	116	0.04	5	4.31	0.0015
Abdominal Pain	55	0.02	6	10.91	0.0018
Chest Pain	40	0.01	4	10.00	0.0012
Clot	31	0.01	0	0.00	0.00
Pain	42	0.01	4	9.52	0.0012
Vertigo	35	0.01	2	5.71	0.0006
Visual disturbance	21	0.01	0	0.00	0.00
Hypertension	22	0.01	1	4.55	0.0003
Epistaxis	13	0.004	2	15.38	0.0006
Deep vein thrombosis	20	0.01	1	5.00	0.0003
Death	12	0.004	0	0.00	0.00
Herpes zoster	13	0.004	2	15.38	0.0006
Pulmonary embolism	12	0.004	2	16.67	0.0006
Atrial fibrillation	8	0.002	0	0.00	0.00
Hyperglycemia	5	0.002	0	0.00	0.00
Cellulitis at the injection site	3	0.001	0	0.00	0.0000
Cerebral vascular accident see Stroke	3	0.001	2	66.67	0.0006
Stroke	6	0.002	1	16.67	0.0003
Thrombocytopenia	4	0.001	1	25.00	0.0003
Bells Palsy	3	0.001	0	0.00	0.00
Anaphylaxis	2	0.001	0	0.00	0.00
Angina pectoris	1	0.0003	0	0.00	0.00
Pericaditis	1	0.0003	0	0.00	0.00
Arthritis	1	0.0003	0	0.00	0.00
Menstrual Irregularity	2	0.001	1	50.00	0.0003
Varicella-like rash (general)	1	0.0003	0	0.00	0.00
Guillain Barré syndrome	1	0.0003	0	0.00	0.00

Myocarditis	0	0.00	0	0	0.00
Thrombosis with thrombocytopenia syndrome TTS	2	0.001	0	0.00	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 17**		
Total Number of reports	**556**	**% of Total Pfizer vacc admin.***	**44**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Myalgia	110	0.05	13	11.82	0.006
Arthralgia	43	0.02	2	4.65	0.001
Chest Pain	37	0.02	7	18.92	0.003
Pain	25	0.01	0	0.00	0.00
Abdominal Pain	23	0.01	1	4.35	0.0005
Hypertension	26	0.01	3	11.54	0.001
Vertigo	20	0.01	1	5.00	0.0005
Menstrual Irregularity	14	0.01	1	7.14	0.0005
Death	14	0.01	0	0.00	0.00
Visual disturbance	12	0.01	1	8.33	0.0005
Clot	6	0.003	0	0.00	0.00
Stroke	4	0.002	0	0.00	0.00
Epistaxis	3	0.001	0	0.00	0.00
Pericaditis	4	0.002	2	50.00	0.001
Arthritis	3	0.001	0	0.00	0.00
Atrial fibrillation	1	0.0005	0	0.00	0.00
Anaphylaxis	3	0.001	1	33.33	0.0005
Bells Palsy	1	0.0005	0	0.00	0.00
Herpes zoster	3	0.001	1	33.33	0.0005
Hyperglycemia	1	0.0005	0	0.00	0.00
Miscarriage	1	0.0005	0	0.00	0.00
Pulmonary embolism	2	0.001	1	50.00	0.0005
Thrombocytopenia	1	0.0005	0	0.00	0.00
Varicella-like rash (general)	1	0.0005	0	0.00	0.00
Deep vein thrombosis	1	0.0005	0	0.00	0.00

Myocarditis	0	0.00	0	0	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 30 June 2021 YTD:

Confirmed	Possible	Probable	Unlikely	Unclassified on TGA listing	Removed from TTS listing 30/6/2021	Total
2	3	4	2	1	1	13

Summary of cases:

[redacted]	Age [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	70 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	26 [redacted]	[redacted]	[redacted]	Astra Zeneca-1	[redacted]
[redacted]	47 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca -1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	89 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	73 [redacted]	[redacted]	[redacted]	Astra Zeneca -1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	-
[redacted]	91 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 30 June 2021:

Number unmatched reports: 2 *Reporter contacted to submit SAVSS report	81 [redacted]*
	76 [redacted]*

Table 5: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	50[redacted]	**Date and time vaccinated:** 20/06/21 - 1610hrs **Dose number**: 1 [redacted]	[redacted]
[redacted]	[redacted]	54[redacted]	**Date and time vaccinated** 23/06/2021 @ 1358 **Dose number**: 1 [redacted]	[redacted]
[redacted]	[redacted]	29[redacted]	**Date and time vaccinated 13/04/2021 Dose 1, 17/5/21 Dose 2** **Dose number**: 1 & 2 [redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	69 [redacted]	**Date and time vaccinated 17/06/2021 @ 1830** **Dose number**: 1 [redacted]	[redacted]
[redacted]	[redacted]	89 [redacted]	**Date and time vaccinated: 23/05/2021 @ 1300** **Dose number**: 1 [redacted]	[redacted]
[redacted]	[redacted]	80 [redacted]	**Date and time vaccinated:** 14/04/2021 **Dosage number**: 1 [redacted]	[redacted]
3[redacted]	[redacted]	76 [redacted]	**Date and time vaccinated: 18/6/21** **Dose number**: 1 [redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	73 [redacted]	**Date and time vaccinated** 08/04/2021 **Dose number**: 1 [redacted]	[redacted]
[redacted]	[redacted]	66 [redacted]	**Date and time vaccinated** 25/03/2021 **Dose number**: 1 [redacted]	[redacted]
[redacted]	[redacted]	61 [redacted]	**Date and Time vaccinated:** 25/5/2021 **Dose: 1** [redacted]	[redacted]

[redacted]	[redacted]	55[redacted]	**Date and time vaccinated:** 14/05/2021 **Dose number**: 1st Dose of Astra Zeneca [redacted]	[redacted]
[redacted]	[redacted]	81[redacted]	**Date and time vaccinated:** 14/5/2021 **Dose number**: 1 [redacted]	[redacted]
[redacted]	[redacted]	70[redacted]	**Date and time vaccinated:** 9/6/21 **Dose number**: 1 [redacted]	[redacted]

Table 7: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 24June 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-24-06-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Five additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the UK case definition, three were confirmed and two were deemed probable TTS. However, following reassessment of a previously reported case as being unlikely to be TTS, there is only a net increase of four cases. This brings the total number of cases of TTS to 64.
- We are also monitoring reports of suspected myocarditis and pericarditis following vaccination with Comirnaty and suspected Guillain-Barre Syndrome following vaccination with the AstraZeneca vaccine. No causal association with either vaccine has been established at this stage.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 14-20 June 2021 we received 2,018 AEFI reports for COVID-19 vaccines.

Since the beginning of the vaccine rollout to 20 June 2021, the TGA has received 318 reports of death in people who have recently been vaccinated.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported after vaccination and monitors signals that may relate to vaccine safety. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths. To date, our review of cases and analysis of reporting patterns does not suggest that the vaccine caused these deaths, other than for the TTS cases.

Total adverse event reports to 20 June 2021

4.8	31,641	6,590,741
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

2,1799	9,592	253
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.1	New South Wales	3.5
Northern Territory	4.5	Queensland	4.7
South Australia	4.3	Tasmania	6.9
Victoria	6.1	Western Australia	4.1

Most commonly reported vaccine side effects

The AEFI most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally. They include headache, muscle and joint pain, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 14-20 June 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 14-20 June 2021 were headache, muscle pain, dizziness, fatigue and nausea.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

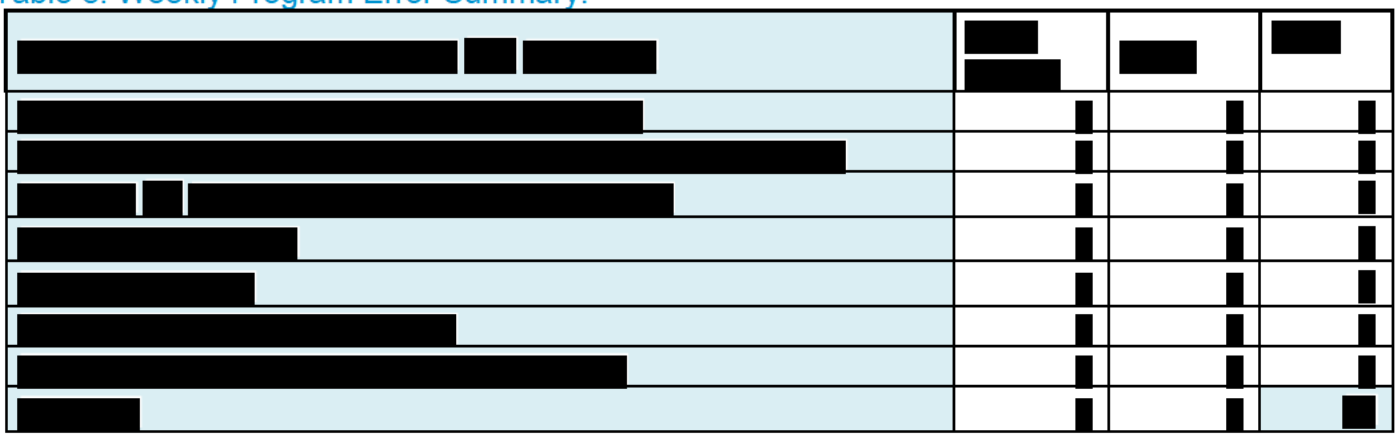
They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

Non-Critical Errors

-

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine#

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COV D-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

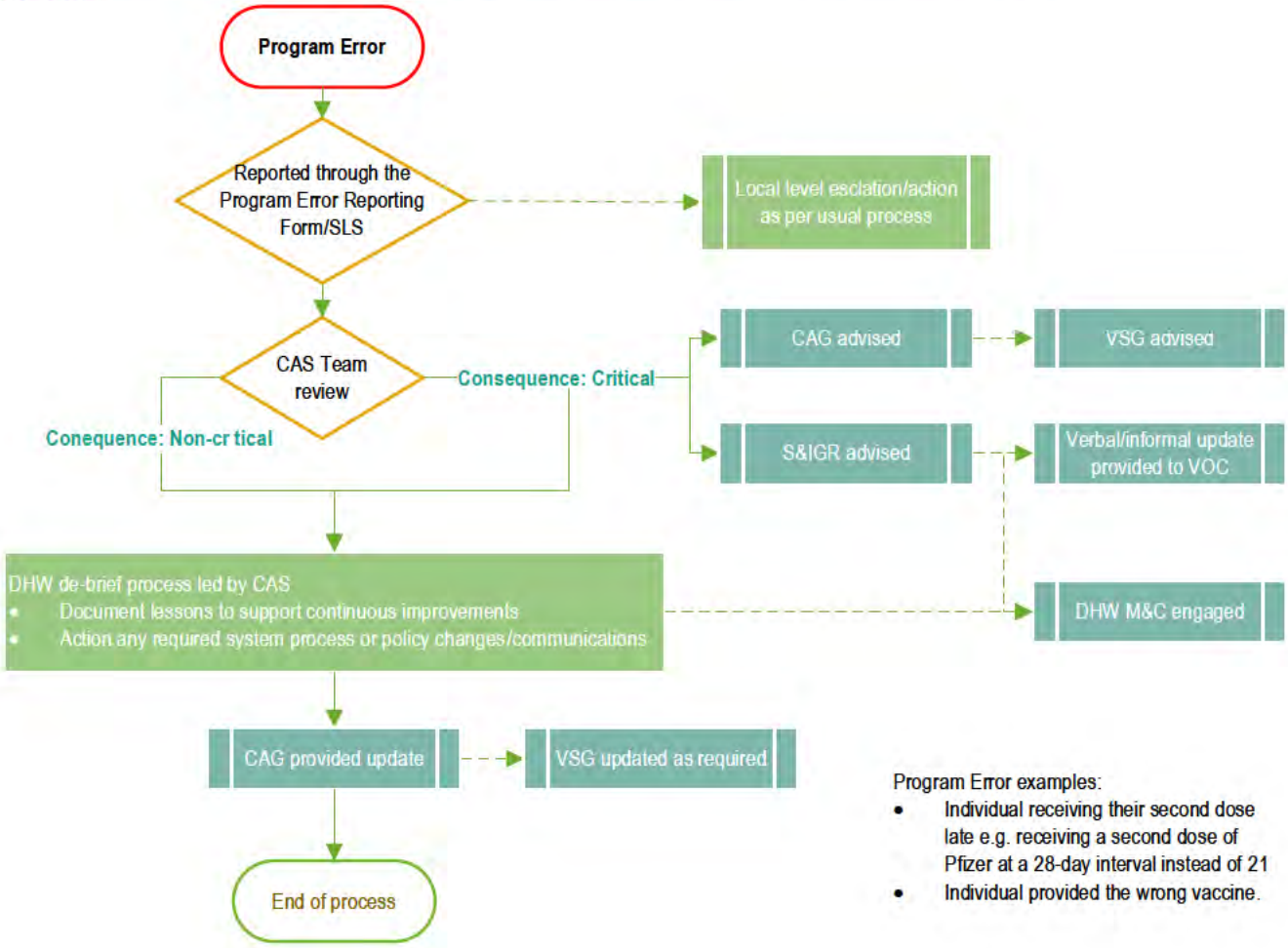
[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

Appendix 4.

INCIDENT ESCALATION AND COMMUNICATION PROCESS FLOW - CLINICAL



Program Error examples:

- Individual receiving their second dose late e.g. receiving a second dose of Pfizer at a 28-day interval instead of 21
- Individual provided the wrong vaccine.

DHW: Department for Health and Wellbeing
VOC: Vaccine Operations Centre
CAS: Clinical Advisory Service Team
CAG: Clinical Advisory Group

M&C: Media and Communications team
S&IGR: Strategy and Intergovernment Relations team
VSG: Vaccine Strategy Group
SLS: Safety Learning System

Document 7

OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 18

Meeting date: 08 July 2021

Report period: 30 June 2021 to 07 July 2021

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 07/07/2021*

Total doses/episodes: 625, 748
Individuals received dose 1 = 477,266
Individuals received dose 2 = 148,482
Pfizer doses = 256,108 (Dose 1: 164,013 – Dose 2: 92,095)
AstraZeneca doses = 369,842 (Dose 1: 313,450 – Dose 2: 56,392)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 07/07/2021 YTD

Number of Reports		**1,892**
Gender	Male	488
	Female	1,399
Indigenous	Yes	25
	No	1,756
	Unknown	79
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**480**
General reactions Total number of COVID-19 Vaccines Reports		**1,781**

Astra Zeneca **Total General Reactions:**	**1,174**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	441	37.56	0.12
Myalgia	293	24.96	0.08
Chills	224	19.08	0.06
Nausea	197	16.78	0.05
Fever not recorded	188	16.01	0.05
Fatigue	132	11.24	0.04
Lethargy	122	10.39	0.03
Arthralgia	120	10.22	0.03
Vomiting	69	5.88	0.02
Abdominal Pain	60	5.11	0.02
Diarrhoea	59	5.03	0.02
Fever mild	55	4.68	0.01
Dizziness - see vertigo	52	4.43	0.01
Rash	47	4.00	0.01
Malaise	45	3.83	0.01
Pain	45	3.83	0.01
Chest Pain	44	3.75	0.01
Dyspnoea	44	3.75	0.01
Vertigo	37	3.15	0.01
Rigors	36	3.07	0.01
Injection-site pain	35	2.98	0.01
Tachycardia	35	2.98	0.01
Clot	31	2.64	0.01
Light headedness	30	2.56	0.01
Coughing	29	2.47	0.01
Paresthesia	27	2.30	0.01
Fever high	26	2.21	0.01
Sweating	26	2.21	0.01
Deep vein thrombosis	25	2.13	0.01

Hypertension	23	1.96	0.01
Influenza-like illness	23	1.96	0.01
Urticaria	23	1.96	0.01
Rash unspecified	22	1.87	0.01
Shivering	22	1.87	0.01
Confusion	21	1.79	0.01
Visual disturbance	21	1.79	0.01
Pulmonary embolism	19	1.62	0.01
Flushing	18	1.53	0.00
Injection site pain restricting limb mobility	18	1.53	0.00
Lymphadenopathy	18	1.53	0.00
Migraine	18	1.53	0.00
Insomnia	17	1.45	0.00
Pain in extremity	17	1.45	0.00
Palpitations	17	1.45	0.00
Anorexia	16	1.36	0.00
Death	15	1.28	0.00
Epistaxis	15	1.28	0.00
Pruritus	14	1.19	0.00
Herpes zoster	13	1.11	0.00
Vasovagal episode (syncope, faint) +/- tonic clonic movements	13	1.11	0.00
Cramps	12	1.02	0.00
Dysgeusia	12	1.02	0.00
Altered breathing	10	0.85	0.00
Angioedema	10	0.85	0.00
Throat soreness	10	0.85	0.00
Tremor	10	0.85	0.00
Thrombosis with thrombocytopenia syndrome TTS	3	0.26	0.00

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**607**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	183	30.15	0.07
Myalgia	118	19.44	0.05
Nausea	100	16.47	0.04
Fatigue	78	12.85	0.03
Lymphadenopathy	59	9.72	0.02
Chills	54	8.90	0.02
Lethargy	53	8.73	0.02
Fever not recorded	51	8.40	0.02
Arthralgia	48	7.91	0.02
Chest Pain	41	6.75	0.02
Paresthesia	39	6.43	0.02

Light headedness	33	5.44	0.01
Rash	33	5.44	0.01
Dizziness - see vertigo	32	5.27	0.01
Vomiting	32	5.27	0.01
Pain	31	5.11	0.01
Coughing	30	4.94	0.01
Urticaria	27	4.45	0.01
Hypertension	26	4.28	0.01
Diarrhoea	25	4.12	0.01
Abdominal Pain	24	3.95	0.01
Vertigo	22	3.62	0.01
Dyspnoea	21	3.46	0.01
Rash unspecified	21	3.46	0.01
Tachycardia	20	3.29	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	20	3.29	0.01
Death	14	2.31	0.01
Pericaditis	5	0.82	0.00

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 07/07/2021 YTD:

Astra Zeneca	**YTD**		**Week 18**		
Total Number of reports	**1,099**	**% of Total AZ vacc admin***	**73**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	60	0.02	4	6.67	0.0011
Chest Pain	44	0.01	0	0.00	0.00
Clot	31	0.01	0	0.00	0.00
Vertigo	37	0.01	2	5.41	0.0005
Visual disturbance	21	0.01	0	0.00	0.00
Hypertension	23	0.01	1	4.35	0.0003
Epistaxis	15	0.00	2	13.33	0.0005
Deep vein thrombosis	25	0.01	3	12.00	0.0008
Death	15	0.00	3	20.00	0.0008
Herpes zoster	13	0.00	0	0.00	0.00
Pulmonary embolism	19	0.01	6	31.58	0.0016
Atrial fibrillation	9	0.00	1	11.11	0.0003
Hyperglycemia	6	0.002	1	16.67	0.0003

Cerebral vascular accident see Stroke	4	0.001	0	0.00	0.00
Stroke	6	0.002	0	0.00	0.00
Thrombocytopenia	5	0.001	1	20.00	0.0003
Bells Palsy	3	0.001	0	0.00	0.00
Anaphylaxis	2	0.001	0	0.00	0.00
Angina pectoris	2	0.001	1	50.00	0.0003
Pericaditis	1	0.000	0	0.00	0.00
Arthritis	1	0.000	0	0.00	0.00
Menstrual Irregularity	2	0.001	0	0.00	0.00
Guillain Barré syndrome	1	0.000	1	100.00	0.0003
Myocarditis	0	0.000	0	0.00	0.00
Exacebation of existing medical condition	4	0.001	0	0.00	0.00
Thrombosis with thrombocytopenia syndrome TTS	3	0.001	1	33.33	0.0003
Cerebral Venous Sinus Thrombosis	2	0.001	1	50.00	0.0003
Dyskinesia	2	0.001	2	100.00	0.0005
Idiopathic thrombocytopenic purpura	1	0.000	0	0.00	0.00
Multiple sclerosis	1	0.000	0	0.00	0.00
Pancreatitis	1	0.000	0	0.00	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 18**		
Total Number of reports	**556**	**% of Total Pfizer vacc admin.***	**44**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	24	0.01	0	0.00	0.00
Chest Pain	42	0.02	3	7.14	0.0012
Clot	7	0.00	1	14.29	0.0004
Vertigo	22	0.01	1	4.55	0.0004
Visual disturbance	12	0.00	0	0.00	0.00
Hypertension	26	0.01	0	0.00	0.00
Epistaxis	3	0.00	0	0.00	0.00
Deep vein thrombosis	1	0.00	0	0.00	0.00

Death	14	0.01	0	0.00	0.00
Herpes zoster	3	0.00	0	0.00	0.00
Pulmonary embolism	3	0.001	1	33.33	0.0004
Atrial fibrillation	1	0.000	0	0.00	0.00
Hyperglycaemia	2	0.001	1	50.00	0.0004
Cerebral vascular accident see Stroke	0	0.000	0	0.00	0.00
Stroke	4	0.002	0	0.00	0.000
Thrombocytopenia	1	0.000	0	0.00	0.00
Bells Palsy	1	0.000	0	0.00	0.00
Anaphylaxis	3	0.001	0	0.00	0.00
Angina pectoris	0	0.000	0	0.00	0.00
Pericarditis	6	0.002	2	33.33	0.0008
Arthritis	4	0.002	0	0.00	0.00
Menstrual Irregularity	14	0.005	0	0.00	0.00
Exacerbation of existing medical condition	4	0.000	0	0.00	0.00
Miscarriage	1	0.000	0	0.00	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 7 July 2021 YTD:

Confirmed	Probable	Unclassified on TGA listing	Removed from TTS listing 6/7/21	Total
3	1	1 *removed from list 30/6/21 & added back to list 6/7/21	8	13

Summary of cases: # indicates the case is also for AEFI discussion in Table 5

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	-
[redacted]	91 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 07/07/2021 YTD:

Number unmatched reports: 2 *Reporter contacted to submit SAVSS report	56 [redacted]
	76 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	19[redacted]	**Date and time vaccinated:** 28/06/2021 **Dose number:** 2 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	47[redacted]	**Date and time vaccinated:** 2/07/2021 [redacted] **Dose number:** 2 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	48[redacted]	**Date and time vaccinated:** 5/06/2021 **Dose number:** 2 [redacted]	[redacted]	[redacted]

			[redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP** [redacted]**:**		
[redacted]	[redacted]	40[redacted]	**Date and time vaccinated:** 29/06/2021 **Dose number:** 1 [redacted] **:**	[redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	61[redacted]	**Date and time vaccinated:** 26/05/2021 @ [redacted] **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	66[redacted]	**Date and time vaccinated:** 25/05/2021 @ [redacted] **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	80[redacted]	**Date and time vaccinated:** 09/04/2021 **Dosage number:** 1 [redacted]	[redacted]	[redacted]

[redacted]	[redacted]	84[redacted]	**Date and time vaccinated:** 22/06/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	52 F	**Date and time vaccinated:** 24/06/2021 **Dose number:** 2 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	79[redacted]	**Date and time vaccinated:** 05/05/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	72[redacted]	**Date and time Vaccinated:** 24/06/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	68[redacted]	**Date and time vaccinated:** 16/06/2021 **Dose number:** 1	[redacted]	[redacted]

			- :		:
		73	**Date and time vaccinated:** 19/06/2021 **Dose number:** 1 :		
		65	**Date and time Vaccinated:** 18/06/2021 @ **Dose Number:** 1 :	)	:
			Date and time Vaccinated:14/05/2021 **Dose:** 1		
		76	**Date and time Vaccinated:** 25/06/2021 **Dose:** 1 :		:
		68	**Date and time Vaccinated:** 25/05/2021 **Dose:**1		

			[redacted]		

Table 7: Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 01 July 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-01-07-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Five additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, two were confirmed and three were deemed probable TTS. This brings the total number of cases of TTS to 69 out of 4.8 million doses to date.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 21-27 June 2021 we received 1459 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination and monitors signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 27 June 2021, there have been over 7.3 million doses of COVID-19 vaccines administered. The TGA has received and reviewed 335 reports of deaths in people who have recently been vaccinated and found that two were definitely linked to vaccination. These were both TTS cases related to the AstraZeneca vaccine.

Total adverse event reports to 27 June 2021

4.6	33,807	7,374,666
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

23,235	10,314	263
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.0	New South Wales	3.4
Northern Territory	4.4	Queensland	4.4
South Australia	4.1	Tasmania	6.6
Victoria	5.8	Western Australia	4.0

Most commonly reported vaccine side effects

The most common adverse effects following immunisation (AEFI) reported to the TGA are predictable and have been observed with vaccines generally. They include headache, muscle and joint pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 21-27 June 2021 were headache, muscle pain, fever, nausea and fatigue.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 21-27 June 2021 were headache, dizziness, nausea, muscle pain, and lethargy.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary:

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

- [redacted]

[redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine#

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COV D-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 19

Meeting date: 15 July 2021

Report period: 7 July 2021 to 14 July 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 13/07/2021*

Total doses/episodes: 667,858
Individuals received dose 1 = 495,800
Individuals received dose 2 = 172,058
AstraZeneca doses = 387,883 (Dose 1: 320,287 – Dose 2: 67,596)
Pfizer doses = 280,181 (Dose 1: 175,714 – Dose 2: 104,467)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 14/07/2021 YTD

Number of Reports		**2036**
Gender	Male	524
	Female	1,506
Indigenous	Yes	25
	No	1,900
	Unknown	79
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**506**
General reactions Total number of COVID-19 Vaccines Reports		**1887**

Astra Zeneca **Total General Reactions:**	**1228**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	450	36.64	0.12
Myalgia	299	24.35	0.08
Chills	230	18.73	0.06
Nausea	202	16.45	0.05
Fever not recorded	192	15.64	0.05
Fatigue	138	11.24	0.04
Lethargy	123	10.02	0.03
Arthralgia	122	9.93	0.03
Vomiting	71	5.78	0.02
Abdominal Pain	63	5.13	0.02
Diarrhoea	60	4.89	0.02
Fever mild	56	4.56	0.01
Dizziness - see vertigo	53	4.32	0.01
Rash	53	4.32	0.01
Pain	48	3.91	0.01
Dyspnoea	47	3.83	0.01
Malaise	46	3.75	0.01
Chest Pain	45	3.66	0.01
Vertigo	38	3.09	0.01
Tachycardia	37	3.01	0.01
Rigors	36	2.93	0.01
Injection-site pain	35	2.85	0.01
Light headedness	33	2.69	0.01
Clot	31	2.52	0.01
Coughing	31	2.52	0.01
Deep vein thrombosis	27	2.20	0.01
Paresthesia	27	2.20	0.01
Sweating	27	2.20	0.01
Urticaria	27	2.20	0.01

Fever high	26	2.12	0.01
Hypertension	24	1.95	0.01
Influenza-like illness	24	1.95	0.01
Pulmonary embolism	23	1.87	0.01
Shivering	23	1.87	0.01
Confusion	22	1.79	0.01
Rash unspecified	22	1.79	0.01
Visual disturbance	21	1.71	0.01
Thrombosis with thrombocytopenia syndrome TTS	3	0.24	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**659**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	200	30.35	0.07
Myalgia	131	19.88	0.05
Nausea	107	16.24	0.04
Fatigue	86	13.05	0.03
Lymphadenopathy	65	9.86	0.02
Chills	60	9.10	0.02
Arthralgia	56	8.50	0.02
Fever not recorded	55	8.35	0.02
Lethargy	55	8.35	0.02
Chest Pain	46	6.98	0.02
Paresthesia	42	6.37	0.01
Rash	38	5.77	0.01
Light headedness	37	5.61	0.01
Dizziness - see vertigo	35	5.31	0.01
Vomiting	34	5.16	0.01
Pain	33	5.01	0.01
Coughing	32	4.86	0.01
Urticaria	29	4.40	0.01
Diarrhoea	27	4.10	0.01
Hypertension	26	3.95	0.01
Abdominal Pain	25	3.79	0.01
Dyspnoea	23	3.49	0.01
Vertigo	23	3.49	0.01
Fever mild	21	3.19	0.01
Rash unspecified	21	3.19	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	21	3.19	0.01
Flushing	20	3.03	0.01
Injection-site pain	20	3.03	0.01
Pericarditis	7	1.06	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 14/07/2021 YTD:

Astra Zeneca	YTD		Week 18		
Total Number of reports	**1,304**	**% of Total AZ vacc admin***	**51**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	63	0.016	2	3.175	0.0005
Chest Pain	45	0.012	1	2.222	0.0003
Clot	31	0.008	0	0.0000	0.0000
Vertigo	38	0.010	1	2.632	0.0003
Visual disturbance	21	0.005	0	0.000	0.0000
Hypertension	24	0.006	1	4.167	0.0003
Epistaxis	16	0.004	1	6.250	0.0003
Deep vein thrombosis	27	0.007	3	11.111	0.0008
Death	15	0.004	0	0.0000	0.0000
Herpes zoster	16	0.004	3	18.750	0.0008
Pulmonary embolism	23	0.006	4	17.391	0.0011
Atrial fibrillation	9	0.002	0	0.0000	0.0000
Hyperglycaemia	6	0.002	0	0.0000	0.0000
Cerebral vascular accident see Stroke	4	0.001	0	0.0000	0.0000
Stroke	6	0.002	0	0.0000	0.0000
Thrombocytopenia	5	0.001	0	0.0000	0.0000
Bells Palsy	3	0.001	0	0.0000	0.0000
Anaphylaxis	3	0.001	1	33.333	0.0003
Angina pectoris	2	0.001	0	0.0000	0.0000
Pericarditis	1	0.000	0	0.0000	0.0000
Arthritis	1	0.000	0	0.0000	0.0000
Menstrual Irregularity	2	0.001	0	0.0000	0.0000
Guillain Barré syndrome	2	0.001	1	50.000	0.0003
Myocarditis	0	0.000	0	0.0000	0.0000
Exacerbation of existing medical condition	6	0.002	2	33.333	0.0005
Thrombosis with thrombocytopenia syndrome TTS	3	0.001	0	0.0000	0.0000
Cerebral Venous Sinus Thrombosis	2	0.001	0	0.0000	0.0000

Dyskinesia	2	0.001	0	0.0000	0.0000
Idiopathic thrombocytopenic purpura	1	0.0003	0	0.0000	0.0000
Multiple sclerosis	1	0.0003	0	0.0000	0.0000
Pancreatitis	1	0.0003	0	0.0000	0.0000
Purpura	6	0.002	1	16.667	0.0003
Ecchymosis	5	0.001	0	0.0000	0.0000
Dysgeusia	14	0.004	2	14.286	0.0005

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 18**		
Total Number of reports	**660**	**% of Total Pfizer vacc admin.***	**52**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	25	0.009	1	4.000	0.0004
Chest Pain	46	0.016	4	8.696	0.0016
Clot	7	0.002	0	0.000	0.0000
Vertigo	23	0.008	1	4.348	0.0004
Visual disturbance	12	0.004	0	0.000	0.0000
Hypertension	26	0.009	0	0.000	0.0000
Epistaxis	3	0.001	0	0.000	0.0000
Deep vein thrombosis	1	0.000	0	0.000	0.0000
Death	14	0.005	0	0.000	0.0000
Herpes zoster	4	0.001	1	25.000	0.0004
Pulmonary embolism	3	0.001	0	0.000	0.0000
Atrial fibrillation	3	0.001	2	66.667	0.0008
Hyperglycaemia	2	0.001	1	50.000	0.0004
Cerebral vascular accident see Stroke	0	0.000	0	0.000	0.0000
Stroke	4	0.001	0	0.000	0.0000
Thrombocytopenia	1	0.000	0	0.000	0.0000
Bells Palsy	1	0.000	0	0.000	0.0000
Anaphylaxis	3	0.001	0	0.000	0.0000
Angina pectoris	0	0.000	0	0.000	0.0000

Pericarditis	7	0.002	1	14.286	0.0004
Arthritis	4	0.001	0	0.000	0.0000
Menstrual Irregularity	16	0.006	2	12.500	0.0008
Exacerbation of existing medical condition	5	0.002	1	0.000	0.0004
Miscarriage	1	0.000	0	0.000	0.0000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 14 July 2021 YTD:

Confirmed	Probable	Unlikely	Unclassified	Removed from TTS listing 13/7/21	Total
3	3	1	1	7 (*1 removed from list 30/6/21 & added back to list 6/7/21 & removed 13/7/21)	15

Summary of cases: # indicates the case is also for AEFI discussion in Table 5

SAVSS / TGA No.	Age / Gender	Site of Thrombosis	Location	Vaccine	TTS Status
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	59 [redacted]	[redacted] /	[redacted]	Astra Zeneca – 1	[redacted]

[redacted]		[redacted]	[redacted]		
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	-
[redacted]	91 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 14/07/2021 YTD:

Number unmatched reports: 6 *Reporter contacted to submit SAVSS report	56 [redacted] *
	76 [redacted] *
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	48 [redacted]	**Date and time vaccinated:** 07/06/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	48 [redacted]	**Date and time vaccinated:** 8/7/2021 **Dose number:** 2 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	51 [redacted]	**Date and time vaccinated:** 01/07/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	46 [redacted]	**Date and time vaccinated:** 5/7/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	59 [redacted]	**Date and time vaccinated:** 23/03/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	59 [redacted]	**Date and time vaccinated:** 28/05/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	64 [redacted]	**Date and time vaccinated:** 04/06/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

[redacted]	[redacted]	53 [redacted]	**Date and time vaccinated**: 29/05/2021 **Dose number: 1** [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	64 [redacted]	**Date and time vaccinated**: 10/06/2021 **Dose number: 1** [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	57 [redacted]	**Date and time vaccinated: 26/06/2021** **Dose: 2** [redacted]	[redacted]	[redacted]

Table 7: Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 08 July 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-08-07-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- An external Vaccine Safety Investigation Group (VSIG), convened by the TGA on 2 July 2021, concluded that a very rare but fatal case of immune thrombocytopenia (ITP) in a 61-year-old woman who had received the AstraZeneca vaccine was likely to be related to immunisation.
- Seven additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, three were confirmed TTS and four were deemed probable TTS. This brings the total number of cases of TTS to 76 out of five million doses to date.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 28 June - 4 July 2021 we received 1,646 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination. We also monitor signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 4 July 2021, over 8.2 million doses of COVID-19 vaccines have been given. The TGA has received and reviewed 355 reports of deaths in people who have recently been vaccinated and found that only three were linked to immunisation. These deaths were all related to the first dose of the AstraZeneca vaccine – two were TTS cases and one was a case of ITP (reported below).

Total adverse event reports to 4 July 2021

4.4	36,387	8,255,473
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

24,795	11,321	276
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.8	New South Wales	3.2
Northern Territory	4.2	Queensland	4.1
South Australia	4.0	Tasmania	6.6
Victoria	5.7	Western Australia	3.9

Most commonly reported vaccine side effects

The most common adverse effects following immunisation reported to the TGA are predictable and have been observed with vaccines generally. They include headache, muscle pain, fever, chills, nausea and injection site reactions.

The most common reactions reported for the AstraZeneca vaccine in the week 28 June – 4 July 2021 were headache, fatigue, muscle pain, fever and nausea.

The most common reactions reported for the Comirnaty (Pfizer) vaccine in the week of 28 June – 4 July 2021 were headache, muscle pain, lethargy, fever and nausea.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

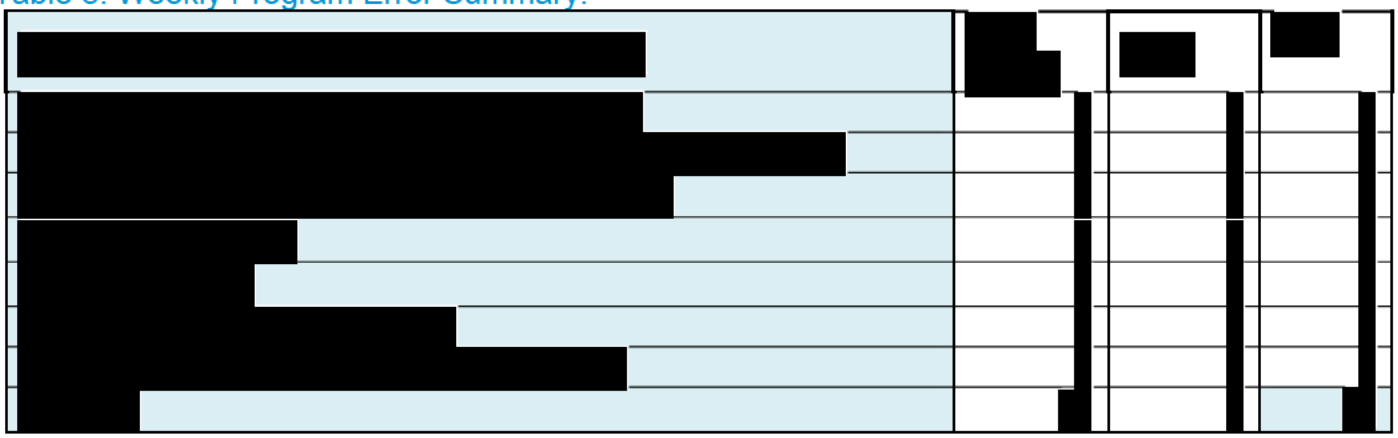
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 20

Meeting date: 22 July 2021

Report period: 14 July 2021 to 20 July 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 20/07/2021*

Total doses/episodes: 734,717
Individuals received dose 1 = 526,673
Individuals received dose 2 = 208,044
AstraZeneca doses = 413,831 (Dose 1: 329,536 – Dose 2: 84,295)
Pfizer doses = 321,130 (Dose 1: 197,375 – Dose 2: 123,755)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 20/07/2021 YTD

Number of Reports		**2,153**
Gender	Male	555
	Female	1,593
Indigenous	Yes	27
	No	2,009
	Unknown	84
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**531**
General reactions Total number of COVID-19 Vaccines Reports		**2,000**

Astra Zeneca **Total General Reactions:**	**1283**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	463	36.09	0.11
Myalgia	306	23.85	0.07
Chills	233	18.16	0.06
Nausea	206	16.06	0.05
Fever not recorded	194	15.12	0.05
Fatigue	145	11.30	0.04
Lethargy	128	9.98	0.03
Arthralgia	124	9.66	0.03
Vomiting	74	5.77	0.02
Abdominal Pain	69	5.38	0.02
Diarrhoea	62	4.83	0.01
Fever mild	57	4.44	0.01
Dizziness - see vertigo	55	4.29	0.01
Rash	55	4.29	0.01
Pain	49	3.82	0.01
Dyspnoea	48	3.74	0.01
Malaise	48	3.74	0.01
Chest Pain	47	3.66	0.01
Vertigo	40	3.12	0.01
Tachycardia	38	2.96	0.01
Rigors	37	2.88	0.01
Injection-site pain	35	2.73	0.01
Light headedness	34	2.65	0.01
Coughing	33	2.57	0.01
Clot	31	2.42	0.01
Deep vein thrombosis	29	2.26	0.01
Fever high	28	2.18	0.01
Sweating	28	2.18	0.01
Urticaria	28	2.18	0.01

Paresthesia	27	2.10	0.01
Hypertension	25	1.95	0.01
Influenza-like illness	25	1.95	0.01
Pulmonary embolism	25	1.95	0.01
Shivering	25	1.95	0.01
Visual disturbance	25	1.95	0.01
Confusion	23	1.79	0.01
Rash unspecified	22	1.71	0.01
Epistaxis	20	1.56	0.005
Flushing	20	1.56	0.005
Migraine	20	1.56	0.005
Thrombosis with thrombocytopenia syndrome TTS	3	0.23	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**717**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	216	30.13	0.07
Myalgia	136	18.97	0.04
Nausea	116	16.18	0.04
Fatigue	95	13.25	0.03
Lymphadenopathy	75	10.46	0.02
Chills	65	9.07	0.02
Fever not recorded	64	8.93	0.02
Arthralgia	61	8.51	0.02
Lethargy	58	8.09	0.02
Chest Pain	54	7.53	0.02
Paresthesia	47	6.56	0.01
Rash	44	6.14	0.01
Dizziness - see vertigo	42	5.86	0.01
Light headedness	37	5.16	0.01
Coughing	35	4.88	0.01
Pain	35	4.88	0.01
Vomiting	35	4.88	0.01
Diarrhoea	31	4.32	0.01
Urticaria	29	4.04	0.01
Abdominal Pain	27	3.77	0.01
Hypertension	27	3.77	0.01
Dyspnoea	26	3.63	0.01
Fever mild	24	3.35	0.01
Vertigo	23	3.21	0.01
Sweating	22	3.07	0.01
Tachycardia	22	3.07	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	22	3.07	0.01
Injection-site pain	21	2.93	0.01

Rash unspecified	21	2.93	0.007
Flushing	20	2.79	0.006
Pericarditis	7	0.98	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 20/07/2021 YTD:

Astra Zeneca	**YTD**		**Week 18**		
Total Number of reports	**1,362**	**% of Total AZ vacc admin***	**50**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	69	0.017	5	7.25	0.0012
Chest Pain	47	0.011	2	4.26	0.0005
Clot	31	0.007	0	0.00	0.0000
Vertigo	40	0.010	2	5.00	0.0005
Visual disturbance	25	0.006	4	16.00	0.0010
Hypertension	25	0.006	1	4.00	0.0002
Epistaxis	20	0.005	4	20.00	0.0010
Deep vein thrombosis	30	0.007	1	3.33	0.0002
Death	15	0.004	0	0.00	0.0000
Herpes zoster	16	0.004	0	0.00	0.0000
Pulmonary embolism	25	0.006	2	8.00	0.0005
Atrial fibrillation	10	0.002	1	10.00	0.0002
Hyperglycaemia	8	0.002	2	25.00	0.0005
Cerebral vascular accident see Stroke	4	0.001	0	0.00	0.0000
Stroke	7	0.002	1	14.29	0.0002
Thrombocytopenia	5	0.001	0	0.000	0.0000
Bells Palsy	3	0.001	0	0.000	0.0000
Anaphylaxis	3	0.001	0	0.000	0.0000
Angina pectoris	2	0.000	0	0.000	0.0000
Pericarditis	1	0.000	0	0.000	0.0000
Arthritis	1	0.000	0	0.000	0.0000
Menstrual Irregularity	2	0.000	0	0.000	0.0000
Guillain Barré syndrome	2	0.000	0	0.000	0.0000
Myocarditis	0	0.000	0	0.000	0.0000

Exacerbation of existing medical condition	11	0.003	5	45.45	0.0012
Thrombosis with thrombocytopenia syndrome TTS	3	0.001	0	0.00	0.0000
Cerebral Venous Sinus Thrombosis	2	0.000	0	0.00	0.0000
Dyskinesia	2	0.000	1	50.00	0.0002
Idiopathic thrombocytopenic purpura	1	0.0002	0	0.000	0.0000
Multiple sclerosis	1	0.0002	0	0.000	0.0000
Pancreatitis	1	0.0002	0	0.000	0.0000
Purpura	7	0.002	1	14.29	0.0002
Ecchymosis	6	0.001	1	16.67	0.0002
Dysgeusia	14	0.003	0	0.000	0.0000
Thrombophlebitis	7	0.002	3	42.86	0.0007

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 18**		
Total Number of reports	**795**	**% of Total Pfizer vacc admin.***	**52**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	27	0.0084	0	0.000	0.0000
Chest Pain	54	0.0168	8	14.815	0.0025
Clot	7	0.0022	0	0.000	0.0000
Vertigo	23	0.0072	0	0.000	0.0000
Visual disturbance	12	0.0037	0	0.000	0.0000
Hypertension	27	0.0084	0	0.000	0.0000
Epistaxis	3	0.0009	0	0.000	0.0000
Deep vein thrombosis	1	0.0003	0	0.000	0.0000
Death	14	0.0044	0	0.000	0.0000
Herpes zoster	5	0.0016	1	20.000	0.0003
Pulmonary embolism	3	0.0009	0	0.000	0.0000
Atrial fibrillation	3	0.0009	0	0.000	0.0000
Hyperglycaemia	2	0.0006	0	0.000	0.0000
Cerebral vascular accident see Stroke	0	0.0000	0	0.000	0.0000
Stroke	4	0.0012	0	0.000	0.0000

Thrombocytopenia	1	0.0003	0	0.000	0.0000
Bells Palsy	1	0.0003	0	0.000	0.0000
Anaphylaxis	4	0.0012	1	25.000	0.0003
Angina pectoris	0	0.0000	0	0.000	0.0000
Pericarditis	7	0.0022	0	0.000	0.0000
Arthritis	4	0.0012	0	0.000	0.0000
Menstrual Irregularity	16	0.0050	0	0.000	0.0000
Exacerbation of existing medical condition	10	0.0031	3	0.000	0.0009
Miscarriage	1	0.0003	0	0.000	0.0000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 20 July 2021 YTD:

Confirmed	Probable	Unlikely	Unclassified	Removed from TTS listing 13/7/21	Total
3	3	1	1	7 (*1 removed from list 30/6/21 & added back to list 6/7/21 & removed 13/7/21)	15

Summary of cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87[redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]

[redacted]	58 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	59 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	-
[redacted]	91 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 20/07/2021 YTD:

Number unmatched reports: 6 *Reporter contacted to submit SAVSS report	56 [redacted]*
	76 [redacted]*
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	54[redacted]	**Date and time vaccinated**: 19/7/21 **Dose number:** 2 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	24[redacted]	**Date and time vaccinated**: 06/07/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	32[redacted]	**Date and time vaccinated**: 07/07/2021 **Dose number**: 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	73[redacted]	**Date and time vaccinated**: 17/06/2021 **Dose number**: 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	60[redacted]	**Date and time vaccinated**: 31/05/2021 **Dose number**: 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	75[redacted]	**Date and time vaccinated**: 28/04/2021 **Dose number**: 1 [redacted]	[redacted]	[redacted]

[redacted]	[redacted]	51[redacted]	**Date and time vaccinated**: 02/06/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

[redacted]	[redacted]	56[redacted]	**Date and time vaccinated**: 15/5/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	65[redacted]	**Date and time vaccinated**: 10/6/21 **Dose number:** 1 [redacted]	[redacted]	[redacted]

Table 7: Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 15 July 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-15-07-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- As reported by South Australian Health authorities on 12 July 2021, sadly a 72-year-old woman from South Australia has died from TTS following vaccination with a first dose of the AstraZeneca vaccine. This case was confirmed to be linked to the vaccine and was reported in last weeks' report.
- Seven additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, four were confirmed and three were deemed probable TTS. This brings the total number of cases of TTS to 83 from 5.4 million doses administered to date.
- We continue to closely monitor reports of immune thrombocytopenia (ITP) and Guillain-Barre Syndrome (GBS) following vaccination with the AstraZeneca vaccine and myocarditis and pericarditis with the Comirnaty vaccine.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 5-11 July 2021 we received 1,705 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination. We also monitor signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 11 July 2021, over 9.1 million doses of COVID-19 vaccines have been given. The TGA has received and reviewed 377 reports of deaths in people who have recently been vaccinated and found that four were linked to immunisation. These deaths were all related to the first dose of the AstraZeneca vaccine – three were TTS cases and one was a case of ITP.

Total adverse event reports to 11 July 2021

4.3	39,077	9,149,817
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

26,302	12,495	288
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.5	New South Wales	3.1
Northern Territory	3.9	Queensland	4.0
South Australia	3.8	Tasmania	6.6
Victoria	5.6	Western Australia	3.8

Most commonly reported vaccine side effects

The most common adverse effects following immunisation reported to the TGA are predictable and have been observed with vaccines generally. They include headache, muscle pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 5-11 July 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 5-11 July 2021 were headache, muscle pain, lethargy, injection site reactions and nausea.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

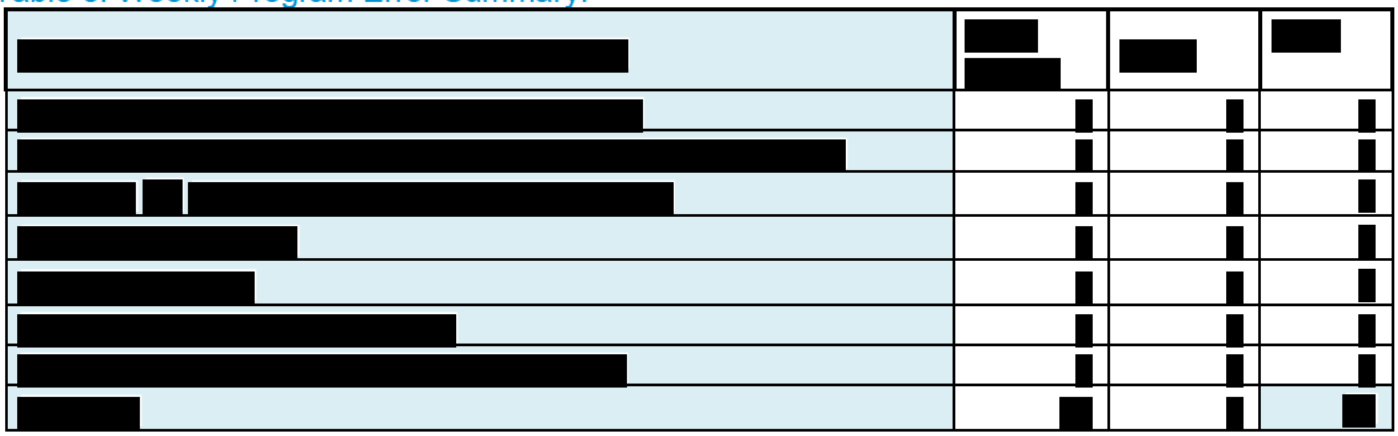
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

Non-Critical Errors

-

[redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)

- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine#

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COV D-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 21

Meeting date: 29 July 2021

Report period: 21 July 2021 to 27 July 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 21/07/2021*

Total doses/episodes: 813,474
Individuals received dose 1 = 566,724
Individuals received dose 2 = 246,750
AstraZeneca doses = 444,333 (Dose 1: 340,920 – Dose 2: 103,413)
Pfizer doses = 369,440 (Dose 1: 226,096 – Dose 2: 143,344)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 27/07/2021 YTD

Number of Reports		**2,276**
Gender	Male	586
	Female	1,685
Indigenous	Yes	29
	No	2,124
	Unknown	89
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**563**
General reactions Total number of COVID-19 Vaccines Reports		**2,110**

Astra Zeneca **Total General Reactions:**	**1328**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	477	35.92	0.11
Myalgia	314	23.64	0.07
Chills	240	18.07	0.05
Nausea	211	15.89	0.05
Fever not recorded	199	14.98	0.04
Fatigue	151	11.37	0.03
Lethargy	132	9.94	0.03
Arthralgia	127	9.56	0.03
Vomiting	77	5.80	0.02
Abdominal Pain	72	5.42	0.02
Diarrhoea	65	4.89	0.01
Rash	60	4.52	0.01
Fever mild	58	4.37	0.01
Dizziness - see vertigo	56	4.22	0.01
Chest Pain	51	3.84	0.01
Pain	51	3.84	0.01
Malaise	49	3.69	0.01
Dyspnoea	48	3.61	0.01
Vertigo	41	3.09	0.01
Rigors	39	2.94	0.01
Tachycardia	39	2.94	0.01
Injection-site pain	35	2.64	0.01
Coughing	34	2.56	0.01
Light headedness	34	2.56	0.01
Sweating	32	2.41	0.01
Clot	31	2.33	0.01
Urticaria	31	2.33	0.01
Deep vein thrombosis	30	2.26	0.01
Fever high	29	2.18	0.01

Paresthesia	29	2.18	0.01
Influenza-like illness	28	2.11	0.01
Hypertension	27	2.03	0.01
Pulmonary embolism	26	1.96	0.01
Shivering	26	1.96	0.01
Visual disturbance	25	1.88	0.01
Confusion	23	1.73	0.01
Rash unspecified	23	1.73	0.01
Migraine	22	1.66	0.005
Flushing	21	1.58	0.005
Epistaxis	20	1.51	0.005
Pain in extremity	20	1.51	0.005
Palpitations	20	1.51	0.005
Thrombosis with thrombocytopenia syndrome TTS	3	0.23	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**782**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	233	29.80	0.06
Myalgia	156	19.95	0.04
Nausea	128	16.37	0.03
Fatigue	114	14.58	0.03
Lymphadenopathy	83	10.61	0.02
Chills	71	9.08	0.02
Arthralgia	68	8.70	0.02
Fever not recorded	67	8.57	0.02
Lethargy	65	8.31	0.02
Chest Pain	61	7.80	0.02
Rash	50	6.39	0.01
Paresthesia	49	6.27	0.01
Dizziness - see vertigo	48	6.14	0.01
Vomiting	41	5.24	0.01
Light headedness	40	5.12	0.01
Pain	38	4.86	0.01
Coughing	37	4.73	0.01
Diarrhoea	35	4.48	0.01
Abdominal Pain	33	4.22	0.01
Urticaria	31	3.96	0.01
Fever mild	29	3.71	0.01
Hypertension	29	3.71	0.01
Dyspnoea	28	3.58	0.01
Sweating	25	3.20	0.01
Vertigo	25	3.20	0.01
Rash unspecified	22	2.81	0.01

Tachycardia	22	2.81	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	22	2.81	0.01
Injection-site pain	21	2.69	0.006
Flushing	20	2.56	0.005
Menstrual Irregularity	20	2.56	0.005
Throat soreness	20	2.56	0.005
Pericarditis	8	1.02	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 20/07/2021 YTD:

Astra Zeneca	**YTD**		**Week 18**		
Total Number of reports	**1,664**	**% of Total AZ vacc admin***	**55**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	72	0.016	3	4.17	0.001
Chest Pain	51	0.011	4	7.84	0.001
Clot	31	0.007	0	0.00	0.000
Vertigo	41	0.009	1	2.44	0.000
Visual disturbance	25	0.006	0	0.00	0.000
Hypertension	27	0.006	2	7.41	0.000
Epistaxis	20	0.005	0	0.00	0.000
Deep vein thrombosis	30	0.007	0	0.00	0.000
Death	16	0.004	1	6.25	0.000
Herpes zoster	17	0.004	1	5.88	0.000
Pulmonary embolism	26	0.006	1	3.85	0.000
Atrial fibrillation	10	0.002	0	0.00	0.000
Hyperglycaemia	8	0.002	0	0.00	0.000
Cerebral vascular accident see Stroke	4	0.001	0	0.00	0.000
Stroke	8	0.002	1	12.50	0.000
Thrombocytopenia	5	0.001	0	0.000	0.000
Bells Palsy	3	0.001	0	0.000	0.000
Anaphylaxis	3	0.001	0	0.000	0.000
Angina pectoris	2	0.000	0	0.000	0.000
Pericarditis	1	0.000	0	0.000	0.000
Arthritis	1	0.000	0	0.000	0.000

Menstrual Irregularity	2	0.000	0	0.000	0.000
Guillain Barré syndrome	2	0.000	0	0.000	0.000
Myocarditis	0	0.000	0	0.000	0.000
Exacerbation of existing medical condition	12	0.003	1	8.33	0.000
Thrombosis with thrombocytopenia syndrome TTS	3	0.001	0	0.00	0.000
Cerebral Venous Sinus Thrombosis	2	0.000	0	0.00	0.000
Dyskinesia	2	0.000	0	0.00	0.000
Idiopathic thrombocytopenic purpura	1	0.0002	0	0.000	0.0000
Multiple sclerosis	1	0.0002	0	0.000	0.0000
Pancreatitis	1	0.0002	0	0.000	0.0000
Purpura	8	0.002	1	12.50	0.000
Ecchymosis	6	0.001	0	0.00	0.000
Dysgeusia	14	0.003	0	0.000	0.000
Thrombophlebitis	7	0.002	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 18**		
Total Number of reports	**1009**	**% of Total Pfizer vacc admin.***	**63**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	33	0.009	6	18.182	0.002
Chest Pain	61	0.017	7	11.475	0.002
Clot	8	0.002	1	12.500	0.000
Vertigo	25	0.007	2	8.000	0.001
Visual disturbance	14	0.004	0	0.000	0.000
Hypertension	29	0.008	2	6.897	0.001
Epistaxis	3	0.001	0	0.000	0.000
Deep vein thrombosis	1	0.000	0	0.000	0.000
Death	14	0.004	0	0.000	0.000
Herpes zoster	6	0.002	1	16.667	0.000
Pulmonary embolism	3	0.001	0	0.000	0.000
Atrial fibrillation	3	0.001	0	0.000	0.000

Hyperglycaemia	2	0.001	0	0.000	0.000
Cerebral vascular accident see Stroke	0	0.000	0	0.000	0.000
Stroke	4	0.001	0	0.000	0.000
Thrombocytopenia	1	0.000	0	0.000	0.000
Bells Palsy	2	0.001	1	50.000	0.000
Anaphylaxis	5	0.001	1	20.000	0.000
Angina pectoris	0	0.000	0	0.000	0.000
Pericarditis	8	0.002	1	12.500	0.000
Arthritis	4	0.001	0	0.000	0.000
Menstrual Irregularity	20	0.005	4	20.000	0.001
Exacerbation of existing medical condition	13	0.004	3	0.000	0.001
Miscarriage	1	0.000	0	0.000	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 27 July 2021 YTD:

Confirmed	Probable	Unlikely	Unclassified	Removed from TTS listing 13/7/21	Total
3	3	1	1	7 (*1 removed from list 30/6/21 & added back to list 6/7/21 & removed 13/7/21)	15

Summary of cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]

[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	59 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	-
[redacted]	91 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 27/07/2021 YTD:

Number unmatched reports: 6 *Reporter contacted to submit SAVSS report	56 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	43 [redacted]	**Date and time vaccinated:** 20/7/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	47 [redacted]	**Date and time vaccinated:** 15/7/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	30 [redacted]	**Date and time vaccinated:** 15/07/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	31 [redacted]	**Date and time vaccinated:** 13/07/2021 **Dose number:** 2 [redacted]	[redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	76 [redacted]	**Date and time vaccinated:** 18/06/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	76 [redacted]	**Date and time vaccinated:** 23/06/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	60 [redacted]	**Date and time vaccinated:** 09/07/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	78 [redacted]	**Date and time vaccinated:** 06/06/21 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	81 [redacted]	**Date and time vaccinated:** 28/04/21 **Dose number:** 1 [redacted]	[redacted]	[redacted]

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 22 July 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-22-07-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with many vaccines.
- Over the last week, four additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the UK case definition, one was confirmed and three were deemed probable TTS. This brings the total number of cases of TTS to 87 from 6.1 million doses of the AstraZeneca vaccine administered to date.
- Sadly two people with confirmed TTS following the first dose of the AstraZeneca vaccine died in the last week. One was a 44-year-old man from Tasmania and the other was a 48-year-old woman from Victoria. We extend our sincere condolences to their families and loved ones.
- In particular, we continue to closely monitor reports of immune thrombocytopenia (ITP) and Guillain-Barre Syndrome (GBS) following vaccination with the AstraZeneca vaccine, and myocarditis and pericarditis with the Pfizer (Comirnaty) vaccine.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 12-18 July 2021 we received 1,177 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination. We also monitor signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 18 July 2021, over 10.1 million doses of COVID-19 vaccines have been given. The TGA has received and reviewed 399 reports of deaths in people who have recently been vaccinated and found six that were linked to immunisation. These deaths were all related to the first dose of the AstraZeneca vaccine – five were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 18 July 2021

4.1	41,406	10,125,533
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

27,451	13,672	291
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.4	New South Wales	2.9
Northern Territory	3.6	Queensland	3.8
South Australia	3.7	Tasmania	6.2
Victoria	5.5	Western Australia	3.7

Most commonly reported vaccine side effects

The most common adverse effects following immunisation reported to the TGA are predictable and have been observed with many other vaccines. They include headache, muscle pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 12-18 July 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Pfizer (Comirnaty) COVID-19 vaccine in the week of 12-18 July 2021 were headache, muscle pain, fatigue, dizziness and nausea.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

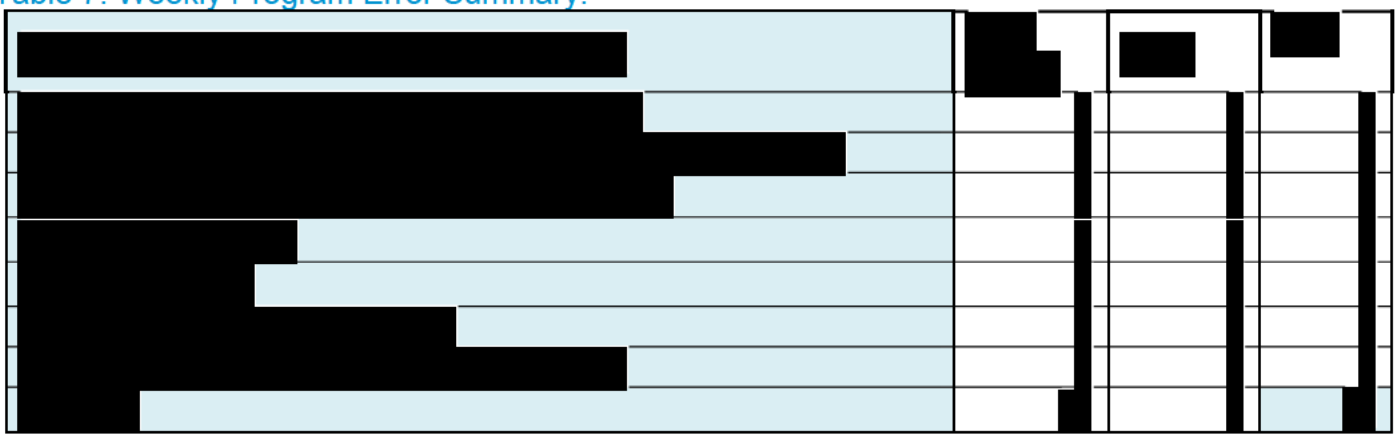
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 22

Meeting date: 6 August 2021

Report period: 28 July 2021 to 3 August 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 03/08/2021*

Total doses/episodes: 890,606
Individuals received dose 1 = 603,886
Individuals received dose 2 = 286,720
AstraZeneca doses = 475,113 (Dose 1: 351,362 – Dose 2: 123,751)
Pfizer doses = 415,826 (Dose 1: 252,847 – Dose 2: 162,979)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 03/08/2021 YTD

Number of Reports		**2,392**
Gender	Male	619
	Female	1,766
Indigenous	Yes	31
	No	2,231
	Unknown	91
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**594**
General reactions Total number of COVID-19 Vaccines Reports		**2,224**

Astra Zeneca **Total General Reactions:**	**1364**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	486	35.63	0.10
Myalgia	319	23.39	0.07
Chills	242	17.74	0.05
Nausea	215	15.76	0.05
Fever not recorded	201	14.74	0.04
Fatigue	155	11.36	0.03
Lethargy	135	9.90	0.03
Arthralgia	127	9.31	0.03
Vomiting	81	5.94	0.02
Abdominal Pain	73	5.35	0.02
Diarrhoea	68	4.99	0.01
Rash	61	4.47	0.01
Fever mild	58	4.25	0.01
Dizziness - see vertigo	57	4.18	0.01
Chest Pain	53	3.89	0.01
Pain	51	3.74	0.01
Dyspnoea	50	3.67	0.01
Malaise	50	3.67	0.01
Vertigo	42	3.08	0.01
Rigors	39	2.86	0.01
Tachycardia	39	2.86	0.01
Injection-site pain	35	2.57	0.01
Light headedness	35	2.57	0.01
Coughing	34	2.49	0.01
Deep vein thrombosis	33	2.42	0.01
Sweating	32	2.35	0.01
Urticaria	32	2.35	0.01
Clot	31	2.27	0.01
Fever high	31	2.27	0.01

Paresthesia	31	2.27	0.01
Hypertension	29	2.13	0.01
Influenza-like illness	28	2.05	0.01
Shivering	28	2.05	0.01
Pulmonary embolism	26	1.91	0.01
Visual disturbance	26	1.91	0.01
Confusion	23	1.69	0.005
Migraine	23	1.69	0.005
Rash unspecified	23	1.69	0.005
Palpitations	22	1.61	0.005
Flushing	21	1.54	0.004
Epistaxis	20	1.47	0.004
Pain in extremity	20	1.47	0.004
Thrombosis with thrombocytopenia syndrome TTS	3	0.22	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**860**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	254	32.48	0.06
Myalgia	168	21.48	0.04
Nausea	134	17.14	0.03
Fatigue	125	15.98	0.03
Lymphadenopathy	94	12.02	0.02
Chest Pain	77	9.85	0.02
Chills	76	9.72	0.02
Fever not recorded	74	9.46	0.02
Lethargy	74	9.46	0.02
Arthralgia	69	8.82	0.02
Rash	54	6.91	0.01
Paresthesia	52	6.65	0.01
Dizziness - see vertigo	50	6.39	0.01
Pain	46	5.88	0.01
Vomiting	42	5.37	0.01
Light headedness	41	5.24	0.01
Coughing	39	4.99	0.01
Diarrhoea	37	4.73	0.01
Abdominal Pain	35	4.48	0.01
Dyspnoea	32	4.09	0.01
Urticaria	32	4.09	0.01
Hypertension	30	3.84	0.01
Fever mild	29	3.71	0.01
Tachycardia	27	3.45	0.01
Palpitations	26	3.32	0.01
Vertigo	26	3.32	0.01

Sweating	25	3.20	0.01
Rash unspecified	24	3.07	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	23	2.94	0.006
Menstrual Irregularity	22	2.81	0.005
Injection-site pain	21	2.69	0.005
Throat soreness	21	2.69	0.005
Flushing	20	2.56	0.005
Pericarditis	11	1.41	0.003

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 03/08/2021 YTD:

Astra Zeneca	**YTD**		**Week 18**		
Total Number of reports	**1,447**	**% of Total AZ vacc admin***	**38**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	73	0.015	1	1.37	0.0002
Chest Pain	53	0.011	2	3.77	0.0004
Clot	31	0.007	0	0.00	0.0000
Vertigo	42	0.009	2	4.76	0.0004
Visual disturbance	26	0.005	1	3.85	0.0002
Hypertension	29	0.006	2	6.90	0.0004
Epistaxis	20	0.004	0	0.00	0.0000
Deep vein thrombosis	33	0.007	3	9.09	0.0006
Death	19	0.004	3	15.79	0.0006
Herpes zoster	17	0.004	1	5.88	0.0002
Pulmonary embolism	26	0.005	0	0.00	0.0000
Atrial fibrillation	11	0.002	1	9.09	0.0002
Hyperglycaemia	8	0.002	0	0.00	0.0000
Cerebral vascular accident see Stroke	4	0.001	0	0.00	0.0000
Stroke	8	0.002	0	0.00	0.0000
Thrombocytopenia	5	0.001	0	0.000	0.0000
Bells Palsy	4	0.001	1	25.00	0.0002
Anaphylaxis	3	0.001	0	0.000	0.0000
Angina pectoris	2	0.0004	0	0.000	0.0000
Pericarditis	1	0.000	0	0.000	0.0000

Arthritis	1	0.000	0	0.000	0.0000
Menstrual Irregularity	4	0.001	2	50.000	0.0004
Guillain Barré syndrome	2	0.000	0	0.000	0.0000
Myocarditis	0	0.000	0	0.000	0.0000
Exacerbation of existing medical condition	14	0.003	1	0.000	0.0002
Thrombosis with thrombocytopenia syndrome TTS	3	0.001	0	0.00	0.0000
Cerebral Venous Sinus Thrombosis	2	0.0004	0	0.00	0.0000
Dyskinesia	2	0.0004	1	50.00	0.0002
Idiopathic thrombocytopenic purpura	1	0.0002	0	0.000	0.0000
Multiple sclerosis	1	0.0002	0	0.000	0.0000
Pancreatitis	1	0.0002	0	0.000	0.0000
Purpura	8	0.002	0	0.00	0.0000
Ecchymosis	7	0.001	0	0.00	0.0000
Dysgeusia	15	0.003	1	6.66	0.0002
Thrombophlebitis	9	0.002	2	22.22	0.0004

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 18**		
Total Number of reports	**945**	**% of Total Pfizer vacc admin.***	**78**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	35	0.008	4	11.42	0.001
Chest Pain	77	0.019	15	19.48	0.004
Clot	8	0.002	0	0.000	0.000
Vertigo	26	0.006	4	15.38	0.001
Visual disturbance	19	0.005	4	21.05	0.001
Hypertension	30	0.007	1	3.33	0.000
Epistaxis	4	0.001	0	0.000	0.000
Deep vein thrombosis	1	0.000	0	0.000	0.000
Death	14	0.003	0	0.000	0.000
Herpes zoster	8	0.002	2	25.00	0.000
Pulmonary embolism	3	0.001	0	0.000	0.000

Atrial fibrillation	3	0.001	0	0.000	0.000
Hyperglycaemia	3	0.001	1	33.33	0.000
Cerebral vascular accident see Stroke	0	0.000	0	0.000	0.000
Stroke	4	0.001	0	0.000	0.000
Thrombocytopenia	1	0.000	0	0.000	0.000
Bells Palsy	2	0.000	0	0.000	0.000
Anaphylaxis	11	0.003	6	54.54	0.001
Angina pectoris	0	0.000	0	0.000	0.000
Pericarditis	11	0.003	3	27.27	0.001
Arthritis	4	0.001	0	0.000	0.000
Menstrual Irregularity	22	0.005	2	9.09	0.000
Exacerbation of existing medical condition	18	0.004	5	0.000	0.001
Miscarriage	1	0.000	0	0.000	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 3 August 2021 YTD:

Confirmed	Probable	Unlikely	Unclassified	Removed from TTS listing 13/7/21	Total
3	2	0	1	9	15

Summary of cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]

[redacted]					
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	59 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 03/08/2021 YTD:

Number unmatched reports: 9 *Reporter contacted to submit SAVSS report	56 [redacted] 76 [redacted] 49 [redacted] 65 [redacted] 71 [redacted] 85 [redacted] *76 [redacted] *72 [redacted] *70 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	55 [redacted]	**Date and time vaccinated:** 15/7/21 **Dose number:** 2 [redacted]	[redacted]	[redacted] :
[redacted]	[redacted]	55 [redacted]	**Date and time vaccinated:** 22/7/2021 **Dose number:** 2 [redacted] : Yes	[redacted]	[redacted]
[redacted]	[redacted]	54 [redacted]	**Date and time vaccinated:** 29/7/2021 **Dose number:** 2	[redacted]	[redacted]

			[redacted]		
[redacted]	[redacted]	46[redacted]	**Date and time vaccinated:** 13/07/2021 **Dose number:** 2	[redacted]	[redacted]
			[redacted]		
[redacted]	[redacted]	46[redacted]	**Date and time vaccinated:** 31/07/2021 **Dose number:** 1	[redacted]	[redacted]

			[redacted] **Laboratory Results: -** **Imaging & Findings: -** **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted]		
[redacted]	[redacted]	19 [redacted]	**Date and time vaccinated:** [redacted] **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings: -** **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted]	[redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	74 [redacted]	**Date and time vaccinated:** 04/05/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	49 [redacted]	**Date and time vaccinated:** 08/04/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	61 [redacted]	**Date and time vaccinated:** 17/6/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	52 [redacted]	**Date and time vaccinated:** 5/6/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

			[redacted]		
[redacted]	[redacted]	91 [redacted]	**Date and time vaccinated:** 17/4/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	92 [redacted]	**Date and time vaccinated:** 14/07/2021 **Dose number:** 2 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	67 [redacted]	**Date and Time Vaccinated:** 24/05/2012 **Dose:** 1 [redacted]	[redacted]	[redacted]

			[redacted]		
[redacted]		78 [redacted]	**Date and time vaccinated:** 22/6/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 29 July 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-29-07-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with many vaccines.
- Over the last week, 6 additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, one was confirmed and 5 were deemed probable TTS.
- An external Vaccine Safety Investigation Group (VSIG), convened by the TGA on 28 July 2021, concluded that three previously reported cases of probable TTS that occurred after a second AstraZeneca dose were unlikely to be related to the vaccine. They also considered a fatal case and concluded it was not related to vaccination.
- This brings the total number of cases of TTS to 90 from approximately 6.3 million doses of the AstraZeneca vaccine administered to date.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 19-25 July 2021 we processed an additional 2,405 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination. We also monitor the database of reports for signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 25 July 2021, over 11.2 million doses of COVID-19 vaccines have been given. The TGA has received and reviewed 407 reports of deaths in people who have recently been vaccinated and found that 6 were linked to immunisation. These deaths were all related to the first dose of the AstraZeneca vaccine – 5 were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 25 July 2021

3.9	43,811	11,211,447
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

28,638	14,883	301
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.3	New South Wales	2.7
Northern Territory	3.5	Queensland	3.6
South Australia	3.5	Tasmania	6.0
Victoria	5.4	Western Australia	3.5

Most commonly reported vaccine side effects

The most common adverse effects following immunisation reported to the TGA are predictable and have been observed with vaccines generally. They include headache, muscle pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 19-25 July 2021 were headache, fever, muscle pain, fatigue and nausea.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 19-25 July 2021 were headache, muscle pain, fatigue, dizziness and nausea.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

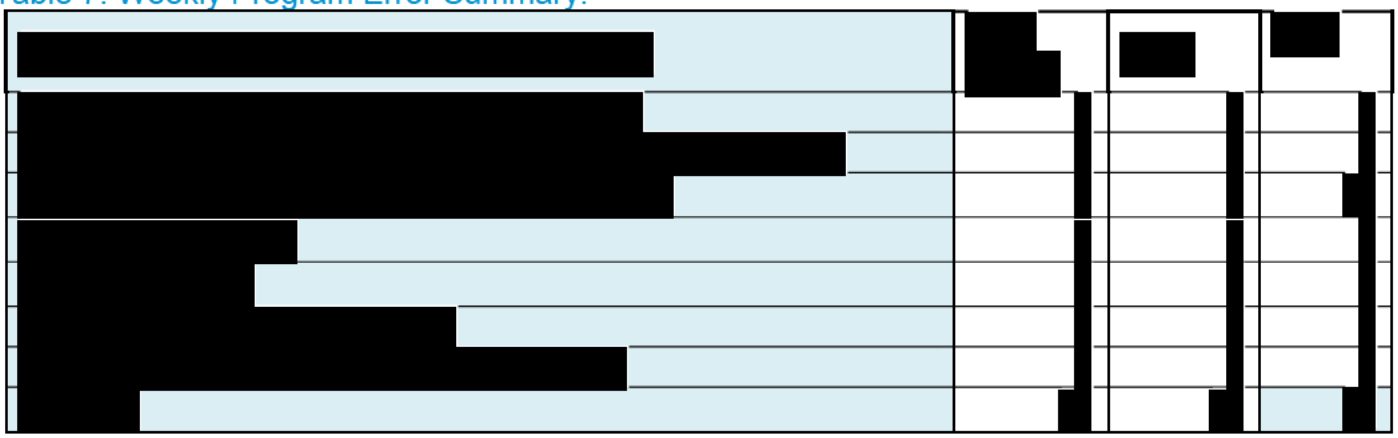
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia

- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis[†]	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

Document 12

OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 23

Meeting date: 12 August 2021

Report period: 4 August 2021 to 10 August 2021

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 10/08/2021*

Total doses/episodes: 972,694
Individuals received dose 1 = 641,059
Individuals received dose 2 = 330,725
AstraZeneca doses = 508,476 (Dose 1: 362,094 – Dose 2: 146,382)
Pfizer doses = 463,727 (Dose 1: 279,372 – Dose 2: 184,355)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 10/08/2021 YTD

Number of Reports		**2,542**
Gender	Male	659
	Female	1,873
Indigenous	Yes	36
	No	2,373
	Unknown	92
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**631**
General reactions Total number of COVID-19 Vaccines Reports		**2,339**

Astra Zeneca **Total General Reactions:**	**1,407**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	505	28.68	0.10
Myalgia	330	18.74	0.06
Chills	242	13.74	0.05
Nausea	219	12.44	0.04
Fever not recorded	202	11.47	0.04
Fatigue	162	9.20	0.03
Lethargy	138	7.84	0.03
Arthralgia	130	7.38	0.03
Vomiting	81	4.60	0.02
Abdominal Pain	80	4.54	0.02
Diarrhoea	69	3.92	0.01
Dizziness - see vertigo	63	3.58	0.01
Rash	62	3.52	0.01
Chest Pain	60	3.41	0.01
Fever mild	59	3.35	0.01
Dyspnoea	55	3.12	0.01
Pain	54	3.07	0.01
Malaise	51	2.90	0.01
Vertigo	43	2.44	0.01
Tachycardia	40	2.27	0.01
Rigors	39	2.21	0.01
Light headedness	36	2.04	0.01
Coughing	35	1.99	0.01
Injection-site pain	35	1.99	0.01
Deep vein thrombosis	33	1.87	0.01
Clot	32	1.82	0.01
Fever high	32	1.82	0.01
Paresthesia	32	1.82	0.01
Sweating	32	1.82	0.01

Urticaria	32	1.82	0.01
Pulmonary embolism	31	1.76	0.01
Hypertension	29	1.65	0.01
Influenza-like illness	28	1.59	0.01
Shivering	28	1.59	0.01
Visual disturbance	27	1.53	0.01
Confusion	23	1.31	0.005
Migraine	23	1.31	0.005
Rash unspecified	23	1.31	0.005
Palpitations	22	1.25	0.004
Flushing	21	1.19	0.004
Epistaxis	20	1.14	0.004
Injection site pain restricting limb mobility	20	1.14	0.004
Lymphadenopathy	20	1.14	0.004
Pain in extremity	20	1.14	0.004
Thrombosis with thrombocytopenia syndrome TTS	3	0.17	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**1,209**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	275	22.75	0.06
Myalgia	184	15.22	0.04
Nausea	148	12.24	0.03
Fatigue	140	11.58	0.03
Lymphadenopathy	100	8.27	0.02
Chest Pain	89	7.36	0.02
Lethargy	87	7.20	0.02
Fever not recorded	81	6.70	0.02
Chills	80	6.62	0.02
Arthralgia	73	6.04	0.02
Dizziness - see vertigo	57	4.71	0.01
Paresthesia	56	4.63	0.01
Rash	54	4.47	0.01
Pain	53	4.38	0.01
Vomiting	47	3.89	0.01
Coughing	43	3.56	0.01
Light headedness	43	3.56	0.01
Diarrhoea	41	3.39	0.01
Abdominal Pain	37	3.06	0.01
Urticaria	37	3.06	0.01
Dyspnoea	36	2.98	0.01
Palpitations	36	2.98	0.01
Hypertension	31	2.56	0.01
Fever mild	30	2.48	0.01

Sweating	27	2.23	0.01
Tachycardia	27	2.23	0.01
Vertigo	26	2.15	0.01
Rash unspecified	25	2.07	0.01
Menstrual Irregularity	24	1.99	0.005
Vasovagal episode (syncope, faint) +/-tonic clonic movements	23	1.90	0.005
Numbness	22	1.82	0.005
Throat soreness	22	1.82	0.005
Flushing	21	1.74	0.005
Injection-site pain	21	1.74	0.005
Visual disturbance	21	1.74	0.005
Lymphadenopathy localized to the region of the injection site	20	1.65	0.004
Pericarditis	15	1.24	0.003

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 10/08/2021 YTD:

Astra Zeneca	**YTD**		**Week 18**		
Total Number of reports	**1,501**	**% of Total AZ vacc admin***	**52**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	80	0.0157	7	8.75	0.0014
Chest Pain	60	0.0118	7	11.67	0.0014
Clot	32	0.0063	0	0.000	0.0000
Vertigo	43	0.0085	1	2.33	0.0002
Visual disturbance	27	0.0053	1	3.70	0.0002
Hypertension	29	0.0057	0	0.000	0.0000
Epistaxis	20	0.0039	0	0.000	0.0000
Deep vein thrombosis	33	0.0065	0	0.000	0.0000
Death	19	0.0037	0	0.000	0.0000
Herpes zoster	18	0.0035	1	5.56	0.0002
Pulmonary embolism	31	0.0061	4	12.90	0.0008
Atrial fibrillation	11	0.0022	0	0.000	0.0000
Hyperglycaemia	8	0.0016	0	0.000	0.0000
Cerebral vascular accident see Stroke	5	0.0010	1	20.00	0.0002
Stroke	8	0.0016	0	0.000	0.0000
Thrombocytopenia	7	0.0014	2	28.571	0.0004

Bells Palsy	4	0.0008	0	0.000	0.0000
Anaphylaxis	3	0.0006	0	0.000	0.0000
Angina pectoris	2	0.0004	0	0.000	0.0000
Pericarditis	2	0.0004	1	50.000	0.0002
Arthritis	1	0.0002	0	0.000	0.0000
Menstrual Irregularity	4	0.0008	0	0.000	0.0000
Guillain Barré syndrome	2	0.0004	0	0.000	0.0000
Myocarditis	1	0.0002	1	0.000	0.0002
Exacerbation of existing medical condition	15	0.0029	1	0.000	0.0002
Thrombosis with thrombocytopenia syndrome TTS	3	0.0006	0	0.000	0.0000
Cerebral Venous Sinus Thrombosis	2	0.0004	0	0.000	0.0000
Dyskinesia	2	0.0004	0	0.000	0.0000
Idiopathic thrombocytopenic purpura	2	0.0004	1	50.000	0.0002
Multiple sclerosis	1	0.0002	0	0.000	0.0000
Pancreatitis	1	0.0002	0	0.000	0.0000
Purpura	10	0.0020	2	20.00	0.0004
Ecchymosis	7	0.0014	0	0.000	0.0000
Dysgeusia	15	0.0029	0	0.000	0.0000
Thrombophlebitis	9	0.0018	0	0.000	0.0000

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 18**		
Total Number of reports	**1,041**	**% of Total Pfizer vacc admin.***	**92**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	37	0.008	2	5.405	0.000
Chest Pain	89	0.019	11	12.360	0.002
Clot	8	0.002	0	0.000	0.000
Vertigo	26	0.006	0	0.000	0.000
Visual disturbance	21	0.005	2	9.524	0.000
Hypertension	31	0.007	1	3.226	0.000
Epistaxis	5	0.001	1	20.000	0.000

Deep vein thrombosis	1	0.000	0	0.000	0.000
Death	14	0.003	0	0.000	0.000
Herpes zoster	13	0.002	5	38.462	0.001
Pulmonary embolism	5	0.001	2	40.000	0.000
Atrial fibrillation	3	0.001	0	0.000	0.000
Hyperglycaemia	3	0.001	0	0.000	0.000
Cerebral vascular accident see Stroke	0	0.000	0	0.000	0.000
Stroke	4	0.001	0	0.000	0.000
Thrombocytopenia	1	0.000	0	0.000	0.000
Bells Palsy	2	0.000	0	0.000	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	27	0.003	2	7.407	0.000
Angina pectoris	0	0.000	0	0.000	0.000
Pericarditis	15	0.003	0	0.000	0.000
Myocarditis	2	0.000	1	50.000	0.000
Arthritis	4	0.001	0	0.000	0.000
Menstrual Irregularity	24	0.005	2	8.333	0.000
Exacerbation of existing medical condition	19	0.004	1	5.263	0.000
Miscarriage	1	0.000	0	0.000	0.000
Tinnutis	7	0.002	1	14.286	0.000
Dysgeusia	8	0.002	0	0.000	0.000
Parethesia	56	0.012	4	7.143	0.001

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 10 August 2021 YTD:

Confirmed	Probable	Unlikely	Unclassified	Removed from TTS listing 13/7/21	Total
3	2	1	1	9	16

Summary of cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	83 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 10/08/2021 YTD:

Number unmatched reports:8 *Reporter contacted to submit SAVSS report	56 [redacted] 76 [redacted] 49 [redacted] 65 [redacted] 71 [redacted] 85 [redacted] 76 [redacted] 86 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	36 [redacted]	**Date and time vaccinated**: 3/8/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	57 [redacted]	**Date and time vaccinated**: 14/7/21 + 4/8/21 **Dose number:** 1 + 2 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	46 [redacted]	**Date and time vaccinated**: 14/07/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

[redacted]	[redacted]	33 [redacted]	**Date and time vaccinated**: 24/06/2021 **Dose number: 2** [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	22 [redacted]	**Date and time vaccinated**: 27/07/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

			[redacted]		
[redacted]	[redacted]	49 [redacted]	**Date and time vaccinated:** 30/07/2021 **Dose:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	52 [redacted]	**Date and time vaccinated:** 6/8/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

			[redacted]		
[redacted]	[redacted]	57 [redacted]	**Date and time vaccinated:** 24/7/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Not discussed due to time constraints, held over until next Committee meeting.

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 05 August 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-05-08-2021

Summary

- To 1 August 2021, approximately 12.4 million vaccine doses have been given in Australia – 8.4 million first doses and 4 million second doses.
- The TGA is continually monitoring the safety of the COVID-10 vaccines. The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials and include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia or TTS) following the AstraZeneca vaccine.
- Three additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, 2 were confirmed and one was deemed probable TTS. Sadly, a 34-year-old woman from NSW died yesterday from confirmed TTS following a first dose of the AstraZeneca vaccine. The TGA extends its sincerest condolences to her family and loved ones. We are in close communication with NSW health who are undertaking further investigation of this case.
- The TGA is also closely monitoring reports of suspected immune thrombocytopenia (ITP) and Guillain-Barre Syndrome (GBS) following the AstraZeneca vaccine and reports of myocarditis and pericarditis following the Comirnaty (Pfizer) vaccine.
- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 26 July-1 August 2021 staff at the TGA have accepted an additional 2,257 AEFI reports into our database for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have received the vaccination. We also monitor the database of reports for signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 1 August 2021, over 12.4 million doses of COVID-19 vaccines have been given. The TGA has found that 7 reports of deaths were likely to be linked to immunisation from 425 reports received and reviewed. These deaths occurred after the first dose of the AstraZeneca vaccine – 6 were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 1 August 2021

3.7	46,068	12,393,893
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
29,763	**15,998**	**318**
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.1	New South Wales	2.5
Northern Territory	3.4	Queensland	3.5
South Australia	3.4	Tasmania	5.7
Victoria	5.2	Western Australia	3.4

Most commonly reported vaccine side effects

The most common adverse effects reported to the TGA following immunisation are predictable and have been observed with vaccines generally. They include headache, muscle pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 26 July-1 August 2021 were headache, fever, muscle pain, joint pain and fatigue.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 26 July-1 August 2021 were headache, fatigue, muscle pain, nausea and dizziness.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

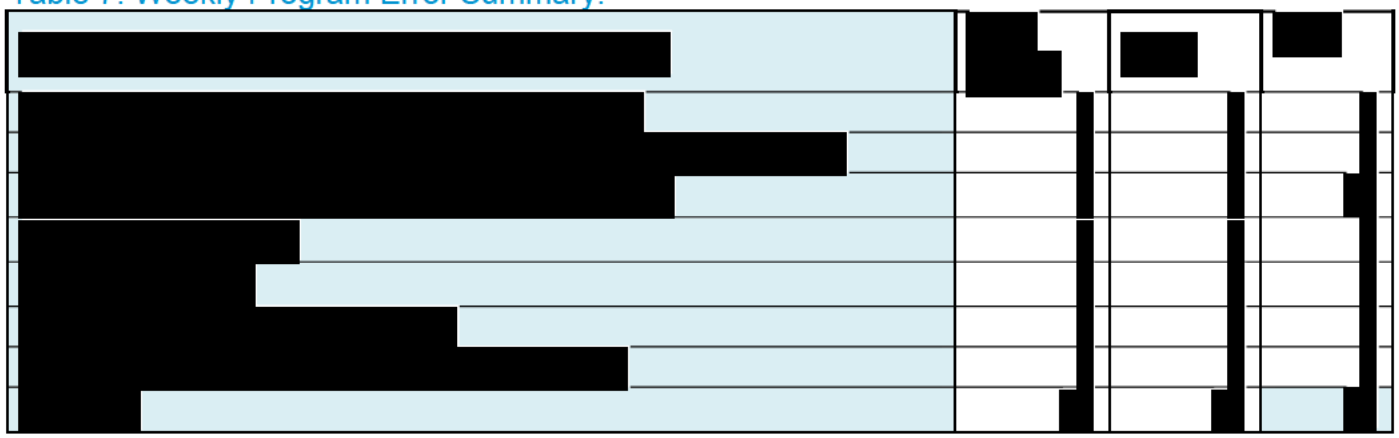
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

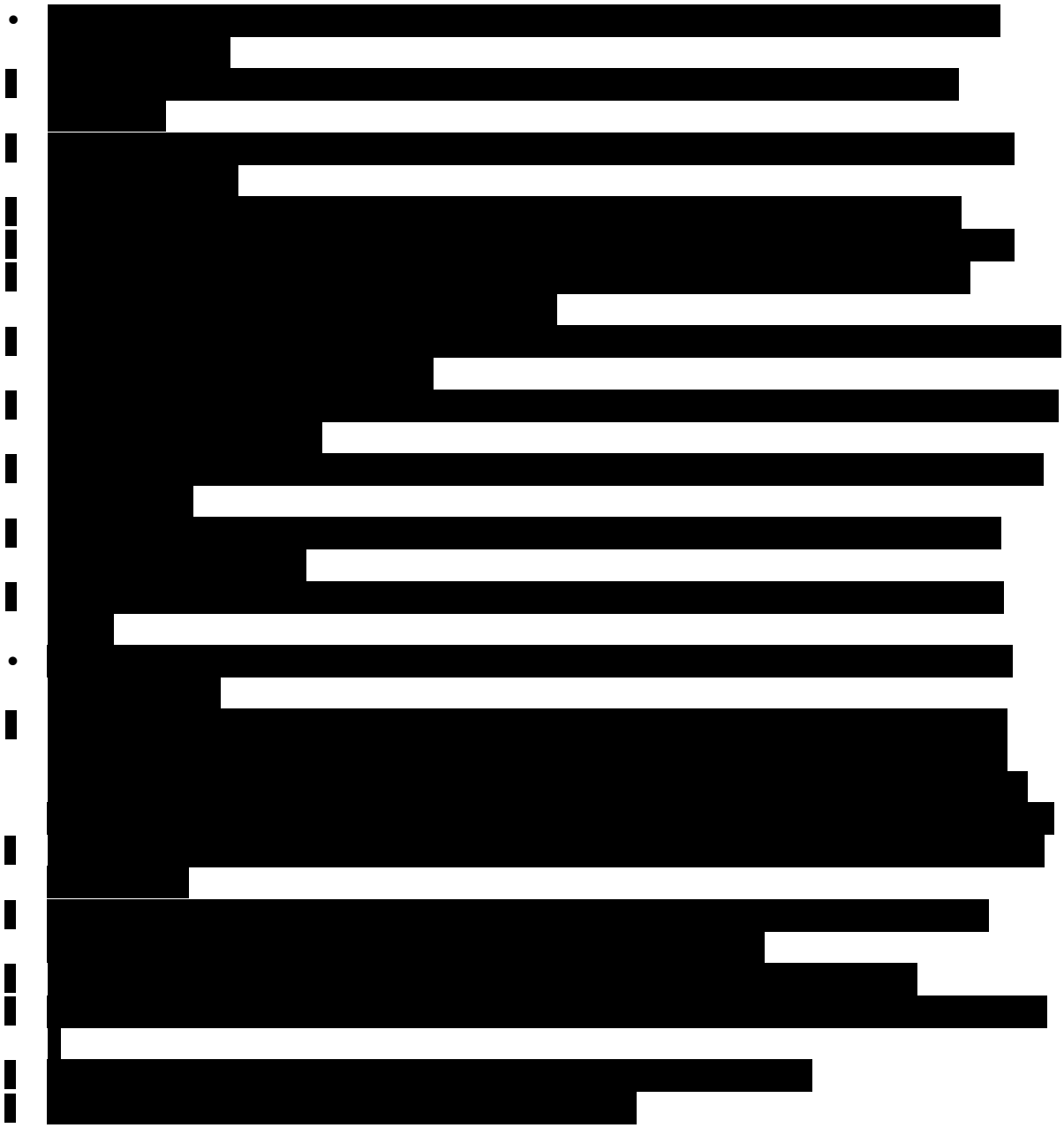


As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- [redacted]

Non-Critical Errors



Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 24

Meeting date: 19 August 2021

Report period: 11 August 2021 to 17 August 2021

Government of South Australia
SA Health

Contents

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 17/08/2021*

Total doses/episodes: 1,061,698
Individuals received dose 1 = 678,417
Individuals received dose 2 = 382,242
AstraZeneca doses = 544,045 (Dose 1: 371,882 – Dose 2: 172,163)
Pfizer doses = 517,097 (Dose 1: 307,004 – Dose 2: 210,093)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 17/08/2021 YTD

Number of Reports		**2,645**
Gender	Male	675
	Female	1,964
Indigenous	Yes	39
	No	2,461
	Unknown	100
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**667**
General reactions Total number of COVID-19 Vaccines Reports		**2,434**

Astra Zeneca **Total General Reactions:**	**1437**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	518	33.64	0.10
Myalgia	336	21.82	0.06
Chills	246	15.97	0.05
Nausea	229	14.87	0.04
Fever not recorded	211	13.70	0.04
Fatigue	166	10.78	0.03
Lethargy	142	9.22	0.03
Arthralgia	132	8.57	0.02
Vomiting	88	5.71	0.02
Abdominal Pain	86	5.58	0.02
Diarrhoea	77	5.00	0.01
Dizziness - see vertigo	65	4.22	0.01
Chest Pain	64	4.16	0.01
Rash	61	3.96	0.01
Dyspnoea	59	3.83	0.01
Fever mild	59	3.83	0.01
Pain	55	3.57	0.01
Malaise	53	3.44	0.01
Rigors	42	2.73	0.01
Vertigo	42	2.73	0.01
Tachycardia	40	2.60	0.01
Light headedness	39	2.53	0.01
Coughing	35	2.27	0.01
Injection-site pain	35	2.27	0.01
Clot	33	2.14	0.01
Fever high	33	2.14	0.01
Pulmonary embolism	33	2.14	0.01
Sweating	33	2.14	0.01
Urticaria	33	2.14	0.01

Deep vein thrombosis	32	2.08	0.01
Paresthesia	32	2.08	0.01
Shivering	32	2.08	0.01
Hypertension	29	1.88	0.01
Visual disturbance	29	1.88	0.01
Influenza-like illness	28	1.82	0.01
Rash unspecified	28	1.82	0.005
Palpitations	24	1.56	0.004
Confusion	23	1.49	0.004
Migraine	23	1.49	0.004
Epistaxis	21	1.36	0.004
Flushing	21	1.36	0.004
Pain in extremity	21	1.36	0.004
Injection site pain restricting limb mobility	20	1.30	0.004
Lymphadenopathy	20	1.30	0.004
Thrombosis with thrombocytopenia syndrome TTS	3	0.19	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**997**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	296	26.79	0.06
Myalgia	190	17.19	0.04
Nausea	161	14.57	0.03
Fatigue	145	13.12	0.03
Lymphadenopathy	112	10.14	0.02
Chest Pain	101	9.14	0.02
Chills	95	8.60	0.02
Lethargy	94	8.51	0.02
Fever not recorded	90	8.14	0.02
Arthralgia	76	6.88	0.01
Dizziness - see vertigo	61	5.52	0.01
Paresthesia	58	5.25	0.01
Rash	57	5.16	0.01
Vomiting	52	4.71	0.01
Pain	50	4.52	0.01
Abdominal Pain	44	3.98	0.01
Diarrhoea	43	3.89	0.01
Light headedness	43	3.89	0.01
Dyspnoea	41	3.71	0.01
Coughing	39	3.53	0.01
Urticaria	39	3.53	0.01
Palpitations	38	3.44	0.01
Hypertension	32	2.90	0.01
Fever mild	31	2.81	0.01

Vertigo	31	2.81	0.01
Sweating	30	2.71	0.01
Tachycardia	29	2.62	0.01
Lymphadenopathy localized to the region of the injection site	28	2.53	0.01
Menstrual Irregularity	28	2.53	0.005
Rash unspecified	27	2.44	0.005
Vasovagal episode (syncope, faint) +/-tonic clonic movements	25	2.26	0.005
Flushing	22	1.99	0.004
Throat soreness	22	1.99	0.004
Visual disturbance	22	1.99	0.004
Exacerbation of existing medical condition	21	1.90	0.004
Injection-site pain	21	1.90	0.004
Numbness	20	1.81	0.004

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 17/08/2021 YTD:

Astra Zeneca	**YTD**		**Week 24**		
Total Number of reports	**1,540**	**% of Total AZ vacc admin***	**45**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	86	0.016	4	4.65	0.0007
Chest Pain	64	0.012	3	4.69	0.0006
Clot	33	0.006	1	3.03	0.0002
Vertigo	42	0.008	0	0.00	0.0000
Visual disturbance	27	0.005	2	7.41	0.0004
Hypertension	29	0.005	0	0.000	0.0000
Epistaxis	21	0.004	1	4.76	0.0002
Deep vein thrombosis	32	0.006	0	0.000	0.0000
Death	19	0.004	0	0.000	0.0000
Herpes zoster	17	0.003	1	5.88	0.0002
Pulmonary embolism	33	0.006	1	3.03	0.0002
Atrial fibrillation	11	0.002	0	0.000	0.0000
Hyperglycaemia	8	0.002	0	0.000	0.0000
Cerebral vascular accident see Stroke	6	0.001	1	16.67	0.0002
Stroke	8	0.002	0	0.000	0.0000
Thrombocytopenia	7	0.001	0	0.000	0.0000

Bells Palsy	3	0.0006	0	0.000	0.0000
Anaphylaxis	3	0.0006	0	0.000	0.0000
Angina pectoris	2	0.0004	0	0.000	0.0000
Pericarditis	2	0.0004	1	50.00	0.0002
Arthritis	1	0.0002	0	0.000	0.0000
Menstrual Irregularity	6	0.001	2	33.33	0.0004
Guillain Barré syndrome	2	0.0004	0	0.000	0.0000
Myocarditis	1	0.0002	0	0.000	0.0000
Exacerbation of existing medical condition	16	0.003	1	0.000	0.0002
Thrombosis with thrombocytopenia syndrome TTS	3	0.0006	0	0.000	0.0000
Cerebral Venous Sinus Thrombosis	2	0.0004	0	0.000	0.0000
Dyskinesia	2	0.0004	0	0.000	0.0000
Idiopathic thrombocytopenic purpura	1	0.0002	0	0.000	0.0000
Multiple sclerosis	1	0.0002	0	0.000	0.0000
Pancreatitis	1	0.0002	0	0.000	0.0000
Purpura	10	0.002	0	0.00	0.0000
Ecchymosis	6	0.001	0	0.000	0.0000
Dysgeusia	15	0.003	0	0.000	0.0000
Thrombophlebitis	8	0.002	0	0.000	0.0000
Lymphadenopathy	20	0.004	0	0.000	0.0000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 24**		
Total Number of reports	**1,105**	**% of Total Pfizer vacc admin.***	**96**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	44	0.009	6	13.64	0.001
Chest Pain	101	0.02	15	14.85	0.003
Clot	8	0.002	0	0.000	0.000
Vertigo	31	0.006	0	0.000	0.000
Visual disturbance	22	0.004	1	4.54	0.000
Hypertension	32	0.006	1	3.12	0.000

Epistaxis	5	0.001	0	0.000	0.000
Deep vein thrombosis	1	0.000	0	0.000	0.000
Death	14	0.003	0	0.000	0.000
Herpes zoster	13	0.003	4	30.77	0.001
Pulmonary embolism	6	0.001	1	16.67	0.000
Atrial fibrillation	3	0.001	0	0.000	0.000
Hyperglycaemia	3	0.001	0	0.000	0.000
Cerebral vascular accident see Stroke	1	0.000	1	0.000	0.000
Stroke	4	0.001	0	0.000	0.000
Thrombocytopenia	1	0.000	0	0.000	0.000
Bells Palsy	3	0.001	0	0.000	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	25	0.005	2	8.00	0.000
Angina pectoris	0	0.000	0	0.000	0.000
Pericarditis	17	0.003	2	11.77	0.000
Myocarditis	2	0.000	0	0.000	0.000
Menstrual Irregularity	28	0.005	5	17.86	0.001
Exacerbation of existing medical condition	21	0.004	2	9.52	0.000
Miscarriage	1	0.000	0	0.000	0.000
Tinnitus	9	0.002	2	22.22	0.000
Dysgeusia	9	0.002	1	11.11	0.000
Parethesia	58	0.01	2	3.45	0.000
Facial Paralysis	3	0.001	1	33.33	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 17 August 2021 YTD:

Confirmed	Probable	Possible	Unlikely	Unclassified	Removed from TTS listing 13/7/21	Total
3	2	1	1	0	9	16

Summary of cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	83 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 17/08/2021 YTD:

Number unmatched reports:8 *Reporter contacted to submit SAVSS report	56 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	76 [redacted]
	86 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	45[redacted]	**Date and time vaccinated:** 12/7/2021 **Dose number:** 2 [redacted]	[redacted]	[redacted]
[redacted]		46[redacted]	**Date and time vaccinated:** 11/08/21 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	53[redacted]	**Date and time vaccinated:** 10/08/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	83[redacted]	**Date and time vaccinated:** 13/07/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]e
[redacted]	[redacted]	68[redacted]	**Date and time vaccinated:** 14/4/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	62[redacted]	**Date and time vaccinated:** 21/05/2021 **Dose number:** 1 [redacted]	[redacted]	[redacted]

			Laboratory Results: [redacted] **Imaging & Findings:** O[redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted].		
[redacted]	[redacted]	67[redacted]	**Date and time vaccinated:** [redacted] **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted].	[redacted]	[redacted]
[redacted]	[redacted]	54[redacted]	**Date and Time vaccinated:** Dose 1 - 26/3/21 Dose 2 – 18/6/21 **Dose Number:** 1 and/or 2 [redacted]	[redacted]	[redacted]

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 12 August 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-12-08-2021

Summary

- To 8 August 2021, approximately 13.7 million vaccine doses have been given in Australia – 9.1 million first doses and 4.6 million second doses.
- The TGA is continually monitoring the safety of the COVID-19 vaccines. The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials and include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) which have been found to be linked to the AstraZeneca vaccine. Early detection of this syndrome may help to prevent more serious complications developing and guidance for health professionals is now available.
- In the last week, an additional 11 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS. Ten of these were in individuals aged 60 years or over. None of these cases were fatal.
- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 2-8 August 2021, staff at the TGA have accepted an additional 2,075 AEFI reports into our database for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have received the vaccination. We also monitor the database of reports for signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 8 August 2021, over 13.7 million doses of COVID-19 vaccines have been given. The TGA has found that 7 reports of deaths were linked to immunisation from 447 reports received and reviewed. These deaths occurred after the first dose of the AstraZeneca vaccine – 6 were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 8 August 2021

3.5	48,143	13,723,146
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
30,795	17,034	326
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	2.9	New South Wales	2.4
Northern Territory	3.2	Queensland	3.2
South Australia	3.2	Tasmania	5.5
Victoria	5.0	Western Australia	3.2

Most commonly reported vaccine side effects

The most common adverse effects reported to the TGA following immunisation are predictable and have been observed with many vaccines. They include headache, muscle pain, fever, chills and injection site reactions for both vaccines.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

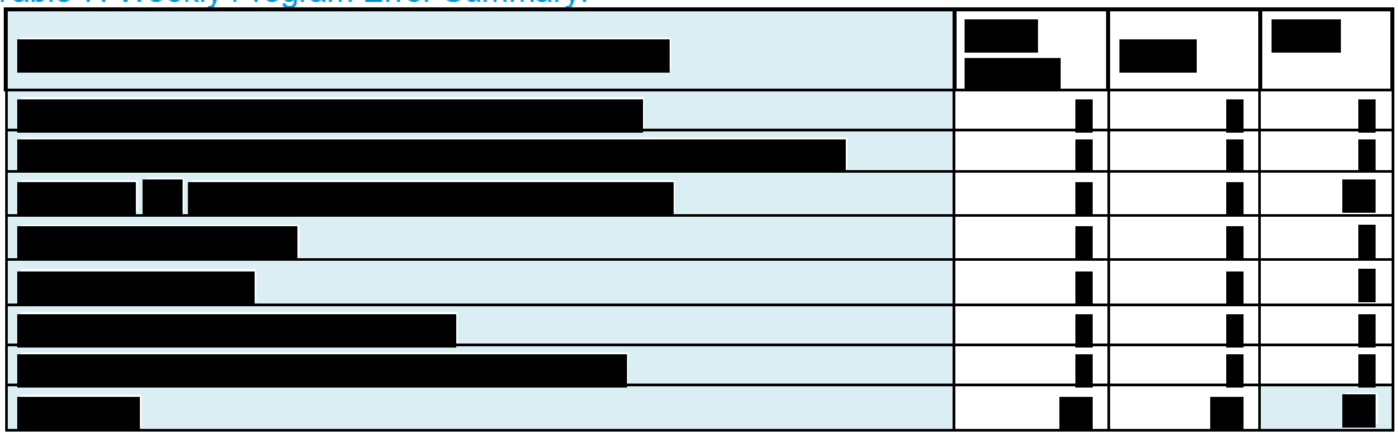
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

-

Non-Critical Errors

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine#

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COV D-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 25

Meeting date: 31 August 2021

Report period: 18 August 2021 to 24 August 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 24/08/2021*

Total doses/episodes: 1,244,651
Individuals received dose 1 = 757,394
Individuals received dose 2 = 487,257
AstraZeneca doses = 620,179 (Dose 1: 391,474 – Dose 2: 228,705)
Pfizer doses = 625,101 (Dose 1: 366,529 – Dose 2: 258,572)

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 24/08/2021 YTD

Number of Reports		**2,820**
Gender	Male	734
	Female	2,073
Indigenous	Yes	41
	No	2,622
	Unknown	104
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**712**
General reactions Total number of COVID-19 Vaccines Reports		**2,585**

Astra Zeneca **Total General Reactions:**	**1,587**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	526	33.14	0.08
Myalgia	345	21.74	0.06
Chills	252	15.88	0.04
Nausea	233	14.68	0.04
Fever not recorded	215	13.55	0.03
Fatigue	169	10.65	0.03
Lethargy	145	9.14	0.02
Arthralgia	134	8.44	0.02
Vomiting	90	5.67	0.01
Abdominal Pain	87	5.48	0.01
Diarrhoea	78	4.91	0.01
Chest Pain	68	4.28	0.01
Dizziness - see vertigo	67	4.22	0.01
Rash	62	3.91	0.01
Dyspnoea	61	3.84	0.01
Fever mild	59	3.72	0.01
Pain	56	3.53	0.01
Malaise	53	3.34	0.01
Vertigo	43	2.71	0.01
Rigors	42	2.65	0.01
Tachycardia	40	2.52	0.01
Light headedness	39	2.46	0.01
Pulmonary embolism	38	2.39	0.01
Coughing	35	2.21	0.01
Injection-site pain	35	2.21	0.01
Paresthesia	35	2.21	0.01
Shivering	35	2.21	0.01
Sweating	35	2.21	0.01
Deep vein thrombosis	34	2.14	0.01

Fever high	34	2.14	0.01
Clot	33	2.08	0.01
Urticaria	33	2.08	0.01
Visual disturbance	32	2.02	0.01
Hypertension	29	1.83	0.00
Rash unspecified	29	1.83	0.00
Influenza-like illness	28	1.76	0.005
Confusion	24	1.51	0.004
Migraine	24	1.51	0.004
Palpitations	24	1.51	0.004
Pain in extremity	22	1.39	0.004
Anorexia	21	1.32	0.003
Epistaxis	21	1.32	0.003
Flushing	21	1.32	0.003
Injection site pain restricting limb mobility	20	1.26	0.003
Lymphadenopathy	20	1.26	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.25	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total General Reactions**	**1,233**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	321	26.03	0.05
Myalgia	208	16.87	0.03
Nausea	173	14.03	0.03
Fatigue	157	12.73	0.03
Lymphadenopathy	125	10.14	0.02
Chest Pain	117	9.49	0.02
Fever not recorded	105	8.52	0.02
Lethargy	104	8.43	0.02
Chills	103	8.35	0.02
Arthralgia	79	6.41	0.01
Dizziness - see vertigo	68	5.52	0.01
Rash	62	5.03	0.01
Paresthesia	61	4.95	0.01
Vomiting	61	4.95	0.01
Pain	56	4.54	0.01
Dyspnoea	47	3.81	0.01
Light headedness	47	3.81	0.01
Abdominal Pain	46	3.73	0.01
Diarrhoea	45	3.65	0.01
Coughing	43	3.49	0.01
Palpitations	42	3.41	0.01
Urticaria	40	3.24	0.01
Hypertension	33	2.68	0.01

Menstrual Irregularity	32	2.60	0.01
Vertigo	32	2.60	0.01
Fever mild	31	2.51	0.00
Sweating	31	2.51	0.00
Tachycardia	31	2.51	0.00
Lymphadenopathy localized to the region of the injection site	29	2.35	0.005
Vasovagal episode (syncope, faint) +/-tonic clonic movements	29	2.35	0.005
Rash unspecified	27	2.19	0.004
Visual disturbance	27	2.19	0.004
Throat soreness	23	1.87	0.004
Flushing	22	1.78	0.004
Injection-site pain	22	1.78	0.004
Exacerbation of existing medical condition	21	1.70	0.003
Pericaditis	21	1.70	0.003
Itching	20	1.62	0.003
Numbness	20	1.62	0.003

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 24/08/2021 YTD:

Astra Zeneca	**YTD**		**Week 24**		
Total Number of reports	**1,587**	**% of Total AZ vacc admin***	**40**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	87	0.014	1	1.15	0.0002
Chest Pain	68	0.011	4	5.88	0.0006
Clot	33	0.0053	0	0.00	0.000
Vertigo	43	0.0069	0	0.00	0.000
Visual disturbance	32	0.0052	3	9.38	0.0005
Hypertension	29	0.0047	0	0.00	0.000
Epistaxis	21	0.0034	0	0.00	0.000
Deep vein thrombosis	34	0.0055	1	2.94	0.0002
Death	19	0.0031	0	0.00	0.000
Herpes zoster	18	0.0029	0	0.00	0.000
Pulmonary embolism	38	0.0061	5	13.16	0.0008
Atrial fibrillation	11	0.0018	0	0.00	0.000
Cerebral vascular accident see Stroke	6	0.001	0	0.00	0.000
Stroke	8	0.0013	0	0.00	0.000

Thrombocytopenia	8	0.0013	1	12.50	0.0002
Bells Palsy	4	0.0006	0	0.00	0.000
Anaphylaxis	3	0.0005	0	0.00	0.000
Pericarditis	2	0.0003	0	0.00	0.000
Menstrual Irregularity	6	0.0010	0	0.00	0.000
Guillain Barré syndrome	2	0.0003	0	0.00	0.000
Myocarditis	1	0.0002	0	0.00	0.000
Exacerbation of existing medical condition	18	0.0029	1	5.56	0.0002
Thrombosis with thrombocytopenia syndrome TTS	4	0.0006	1	25.00	0.0002
Cerebral Venous Sinus Thrombosis	3	0.0005	1	0.000	0.0002
Dyskinesia	2	0.0003	0	0.00	0.000
Idiopathic thrombocytopenic purpura	1	0.0002	0	0.00	0.000
Multiple sclerosis	1	0.0002	0	0.00	0.000
Purpura	10	0.0016	0	0.00	0.000
Ecchymosis	7	0.0011	0	0.00	0.000
Dysgeusia	16	0.0026	1	6.25	0.0002
Thrombophlebitis	9	0.0015	0	0.00	0.000
Lymphadenopathy	20	0.0032	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 24**		
Total Number of reports	**1,233**	**% of Total Pfizer vacc admin.***	**89**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	46	0.007	2	4.35	0.0003
Chest Pain	117	0.019	10	8.55	0.0016
Clot	8	0.001	0	0.00	0.000
Vertigo	32	0.005	1	3.13	0.0002
Visual disturbance	27	0.004	1	3.70	0.0002
Hypertension	33	0.005	1	3.03	0.0002
Death	15	0.002	1	6.67	0.0002
Herpes zoster	18	0.003	1	5.56	0.0002

Pulmonary embolism	6	0.001	0	0.00	0.000
Bells Palsy	3	0.000	0	0.00	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	33	0.005	4	12.12	0.0006
Pericarditis	21	0.003	4	19.05	0.0006
Myocarditis	5	0.001	3	60.00	0.0005
Menstrual Irregularity	32	0.005	3	0.00	0.0005
Exacerbation of existing medical condition	21	0.003	0	0.00	0.000
Miscarriage	2	0.000	1	50.00	0.0002
Tinnitus	13	0.002	4	30.77	0.0006
Dysgeusia	11	0.002	1	9.09	0.0002
Parethesia	61	0.010	2	0.00	0.0003
Facial Paralysis	3	0.000	0	66.67	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 24 August 2021 YTD:

Confirmed	Probable	Possible	Unlikely	Unclassified	Removed from TTS listing 13/7/21	Total
4	2	2	1	0	9	18

Summary of cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]

[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	68yo [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	72yo [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	83 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 24/08/2021 YTD:

Number unmatched reports: 9 *Reporter contacted to submit SAVSS report	56 [redacted]
	38 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	76 [redacted]
	86 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
4398 [redacted]	[redacted]	52 [redacted]	**Date and time vaccinated:**19/8/2021 19:20 **Dose number:** 1 **Details:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Laboratory Results: -** **Imaging & Findings: -** **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	56yo [redacted]	**Date and time vaccinated**: 19/08/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings: -** **Medical History:** [redacted] **GP contacted/notified:** **Classification:**	[redacted]	No Change Change/Review rationale:

Table 6: Events received following AstraZeneca's COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications

[redacted]	[redacted]	68 [redacted]	**Date and time vaccinated**: 26/07/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	62 [redacted]	**Date and time vaccinated**: 17/06/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**:	[redacted]	No Change Change/Review rationale:

			GP contacted/notified: **Classification:**		
		87	**Date and time vaccinated**: 02/08/2021 **Dose number:** 1 **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**		No Change Change/Review rationale:
		72yo	**Date and time vaccinated**: 9/4/2021 **Dose number:** 1 **Details:** **Laboratory Results:** **Imaging & Findings:** **Medical History:** **GP contacted/notified:** **Classification:**		No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 19 August 2021:

Summary

- To 15 August 2021, approximately 15.3 million vaccine doses have been given in Australia – 9.9 million first doses and 5.4 million second doses.
- The TGA is continually monitoring the safety of the COVID-19 vaccines. The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials and include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) which have been found to be linked to the AstraZeneca vaccine. Early detection of this syndrome may help to prevent more serious complications developing and guidance for health professionals is now available.
- In the last week, an additional 8 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS. Only one of these was in an individual aged under 50 years. None of these cases were fatal.
- This takes the total Australian reports assessed as TTS following the AstraZeneca vaccine to 112 cases (62 confirmed, 50 probable) from approximately 8.1 million vaccine doses.
- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.
- Due to strong public interest in side effects relating to COVID-19 vaccinations, the TGA is now making reports of suspected side effects to vaccines and medicines publicly available in the Database of Adverse Event Notifications (DAEN) 14 days after they are completed.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 9-15 August 2021, staff at the TGA have accepted an additional 2,454 AEFI reports into our database for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have received the vaccination. We also monitor reports for signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. As the number of vaccinated people has increased, so has reporting of fatal events with a coincidental association with vaccination. This does not indicate a link between vaccination and the fatalities reported. Review of individual reports and patterns of reporting does not suggest the vaccines played a role in these deaths.

Since the beginning of the vaccine rollout to 15 August 2021, over 15.3 million doses of COVID-19 vaccines have been given. So far, the TGA has found that 7 reports of deaths were linked to immunisation from 460 reports received and reviewed. These deaths occurred after the first dose of the AstraZeneca vaccine – 6 were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 15 August 2021

3.3	50,597	15,341,039
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

31,890	18,388	331
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	2.4	New South Wales	2.2
Northern Territory	2.9	Queensland	3.1
South Australia	3.1	Tasmania	5.4
Victoria	4.8	Western Australia	3.0

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

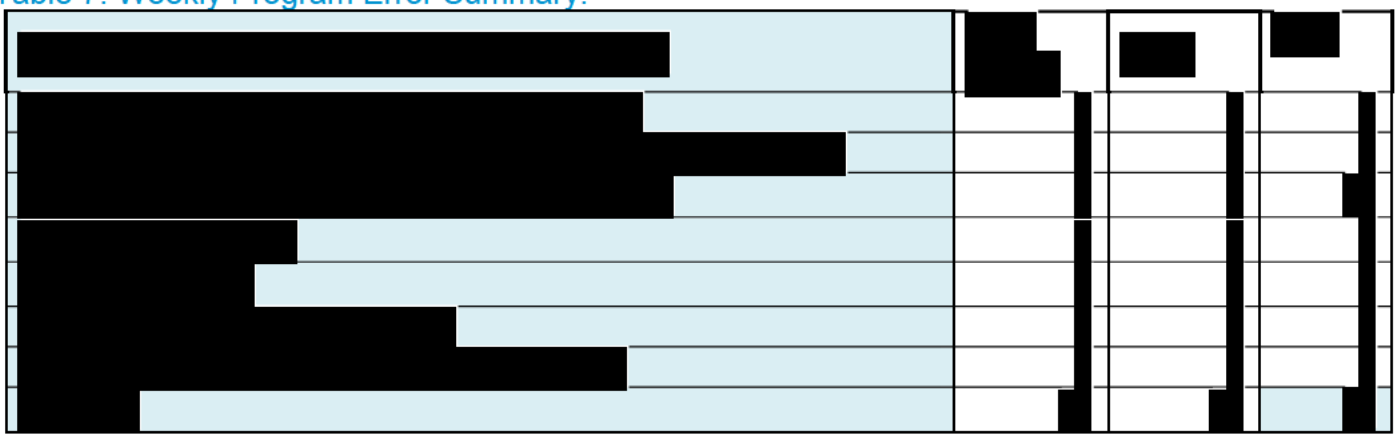
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

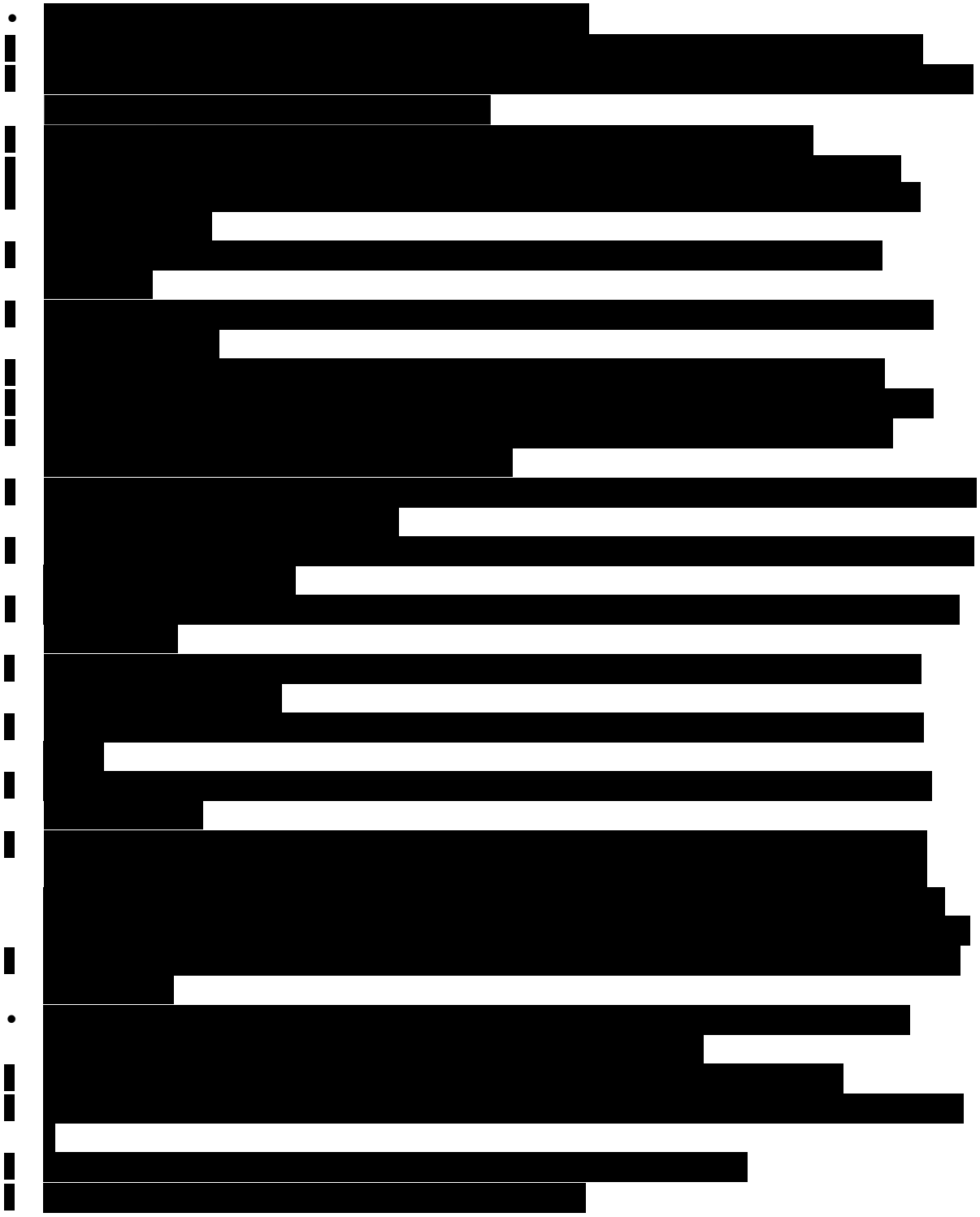


As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- 

Non-Critical Errors



Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 26

Meeting date: 7 September 2021

Report period: 25 August 2021 to 31 August 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 31/08/2021*

Total doses/episodes: 1,244,651
Individuals received dose 1 = 757,394
Individuals received dose 2 = 487,257
Vaxzevria (Astra Zeneca) doses = 620,179 (Dose 1: 391,474 – Dose 2: 228,705)
Pfizer doses = 625,101 (Dose 1: 366,529 – Dose 2: 258,572)

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 31/08/2021 YTD

Number of Reports		**2,979**
Gender	Male	783
	Female	2,189
Indigenous	Yes	43
	No	2,772
	Unknown	115
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**748**
General reactions Total number of COVID-19 Vaccines Reports		**2,719**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,637**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	540	32.99	0.09
Myalgia	352	21.50	0.06
Chills	256	15.64	0.04
Nausea	234	14.29	0.04
Fever not recorded	220	13.44	0.04
Fatigue	172	10.51	0.03
Lethargy	149	9.10	0.02
Arthralgia	138	8.43	0.02
Abdominal Pain	91	5.56	0.01
Vomiting	91	5.56	0.01
Diarrhoea	78	4.76	0.01
Dizziness - see vertigo	69	4.22	0.01
Chest Pain	68	4.15	0.01
Rash	66	4.03	0.01
Dyspnoea	62	3.79	0.01
Fever mild	59	3.60	0.01
Pain	56	3.42	0.01
Malaise	54	3.30	0.01
Vertigo	43	2.63	0.01
Rigors	42	2.57	0.01
Pulmonary embolism	40	2.44	0.01
Tachycardia	40	2.44	0.01
Deep vein thrombosis	39	2.38	0.01
Light headedness	39	2.38	0.01
Coughing	36	2.20	0.01
Paresthesia	36	2.20	0.01
Sweating	36	2.20	0.01
Injection-site pain	35	2.14	0.01
Shivering	35	2.14	0.01

Urticaria	35	2.14	0.01
Visual disturbance	35	2.14	0.01
Fever high	34	2.08	0.01
Clot	33	2.02	0.01
Hypertension	30	1.83	0.00
Rash unspecified	30	1.83	0.00
Influenza-like illness	28	1.71	0.005
Confusion	24	1.47	0.004
Migraine	24	1.47	0.004
Pain in extremity	24	1.47	0.004
Palpitations	24	1.47	0.004
Lymphadenopathy	22	1.34	0.004
Anorexia	21	1.28	0.003
Epistaxis	21	1.28	0.003
Flushing	21	1.28	0.003
Herpes zoster	21	1.28	0.003
Exacerbation of existing medical condition	20	1.22	0.003
Injection site pain restricting limb mobility	20	1.22	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.24	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**1,342**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	346	25.78	0.06
Myalgia	221	16.47	0.04
Nausea	187	13.93	0.03
Fatigue	182	13.56	0.03
Lymphadenopathy	134	9.99	0.02
Chest Pain	131	9.76	0.02
Fever not recorded	123	9.17	0.02
Chills	119	8.87	0.02
Lethargy	107	7.97	0.02
Arthralgia	94	7.00	0.02
Dizziness - see vertigo	76	5.66	0.01
Vomiting	68	5.07	0.01
Paresthesia	67	4.99	0.01
Rash	65	4.84	0.01
Pain	60	4.47	0.01
Dyspnoea	55	4.10	0.01
Diarrhoea	51	3.80	0.01
Light headedness	50	3.73	0.01
Palpitations	50	3.73	0.01
Abdominal Pain	49	3.65	0.01
Coughing	45	3.35	0.01

Urticaria	40	2.98	0.01
Menstrual Irregularity	38	2.83	0.01
Hypertension	37	2.76	0.01
Vertigo	36	2.68	0.01
Fever mild	35	2.61	0.01
Tachycardia	35	2.61	0.01
Sweating	34	2.53	0.01
Rash unspecified	31	2.31	0.005
Vasovagal episode (syncope, faint) +/-tonic clonic movements	31	2.31	0.005
Lymphadenopathy localized to the region of the injection site	29	2.16	0.005
Visual disturbance	29	2.16	0.005
Flushing	28	2.09	0.004
Exacerbation of existing medical condition	27	2.01	0.004
Itching	25	1.86	0.004
Throat soreness	25	1.86	0.004
Injection-site pain	23	1.71	0.004
Pericarditis	22	1.64	0.004
Numbness	21	1.56	0.003
Oedema	21	1.56	0.003
Shivering	20	1.49	0.003

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 31/08/2021 YTD:

Vaxzevria (Astra Zeneca)	**YTD**		**Week 24**		
Total Number of reports	**1,637**	**% of Total AZ vacc admin***	**49**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	91	0.015	3	3.30	0.0005
Chest Pain	68	0.011	0	0.00	0.000
Clot	33	0.0053	0	0.000	0.000
Vertigo	43	0.0069	0	0.00	0.000
Visual disturbance	35	0.0056	2	5.71	0.0003
Hypertension	30	0.0048	1	3.33	0.0002
Epistaxis	21	0.0034	0	0.000	0.000
Deep vein thrombosis	39	0.0063	0	0.000	0.000
Death	19	0.0031	0	0.000	0.000
Herpes zoster	21	0.0034	3	14.29	0.0005
Pulmonary embolism	40	0.0064	2	5.00	0.0003

Atrial fibrillation	12	0.0019	1	8.33	0.0002
Cerebral vascular accident see Stroke	6	0.0010	0	0.000	0.000
Stroke	8	0.0013	0	0.00	0.000
Thrombocytopenia	8	0.0013	1	12.50	0.0002
Bells Palsy	4	0.0006	0	0.000	0.000
Anaphylaxis	3	0.0005	0	0.000	0.000
Pericarditis	4	0.0006	0	0.000	0.000
Menstrual Irregularity	6	0.0010	0	0.000	0.000
Guillain Barré syndrome	2	0.0003	0	0.000	0.000
Myocarditis	3	0.0005	1	33.33	0.0002
Exacerbation of existing medical condition	20	0.0032	5	25.00	0.0008
Thrombosis with thrombocytopenia syndrome TTS	4	0.0006	0	0.000	0.000
Cerebral Venous Sinus Thrombosis	3	0.0005	1	0.000	0.0002
Dyskinesia	2	0.0003	0	0.000	0.000
Idiopathic thrombocytopenic purpura	5	0.0008	0	0.000	0.000
Multiple sclerosis	1	0.0002	0	0.000	0.000
Purpura	10	0.0016	0	0.000	0.000
Ecchymosis	7	0.0011	0	0.000	0.000
Dysgeusia	16	0.0026	1	6.25	0.0002
Thrombophlebitis	10	0.0016	1	10.00	0.0002
Lymphadenopathy	22	0.0035	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 24**		
Total Number of reports	**1,342**	**% of Total Pfizer vacc admin.***	**105**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	49	0.008	3	6.12	0.000
Chest Pain	131	0.021	13	9.93	0.002
Clot	8	0.001	0	0.000	0.000
Vertigo	36	0.006	4	11.11	0.001
Dizziness – see Vertigo	76	0.012	8	10.53	0.001

Visual disturbance	29	0.005	2	6.90	0.000
Hypertension	37	0.006	3	8.11	0.000
Death	15	0.002	0	0.000	0.000
Herpes zoster	18	0.003	0	0.000	0.000
Pulmonary embolism	6	0.001	0	0.000	0.000
Bells Palsy	3	0.000	0	0.000	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	32	0.005	1	3.13	0.000
Pericarditis	22	0.004	1	4.55	0.000
Myocarditis	5	0.001	0	0.000	0.000
Menstrual Irregularity	38	0.006	5	13.16	0.001
Exacerbation of existing medical condition	27	0.004	6	22.22	0.001
Miscarriage	2	0.000	0	0.000	0.000
Tinnitus	15	0.002	2	13.33	0.000
Dysgeusia	11	0.002	0	0.000	0.000
Parethesia	67	0.011	5	7.46	0.001
Facial Paralysis	3	0.000	0	0.000	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 31 August 2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	5	1	4	2	19

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	73 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	48 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	27 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]					
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 31/08/2021 YTD:

Number unmatched reports: 10 *Reporter contacted to submit SAVSS report	23 [redacted]
	38 [redacted]
	86 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]
	76 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	33 [redacted]	**Date and time vaccinated**: 29/08/2021 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted]	[redacted]	No Change Change/Review rationale:

			Medical History: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	42[redacted]	**Date and time vaccinated:**29/08/21 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings: -** **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	[redacted]	**Date and time vaccinated:** [redacted]r vaccinated 23/8/21 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** **Imaging & Findings:** **Treatment:** [redacted] **Medical History:** **GP contacted/notified:** [redacted] **Classification:**	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	17[redacted]	**Date and time vaccinated:** 18/08/2021 **Dose number:** 1 **Details:** [redacted]. **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]		**Date and time vaccinated:** 10/08/21 **Dose number:** 1 **Details:** [redacted].	[redacted]	No Change Change/Review rationale:

			[redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	68 [redacted]	**Date and time vaccinated**: 29/07/21 1315 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	64 [redacted]	**Date and time vaccinated**: 28/08/2021 **Dose number:** 2 **Details**: [redacted].	[redacted]	No Change

			Laboratory Results: . **Imaging & Findings:** **Treatment:** . **Medical History**: **GP contacted/notified:** **Classification:**		Change/Review rationale:
		70	**Date and time vaccinated**: 28/07/2021 **Dose number:** 2 **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: . **GP contacted notified:** **Classification:**		No Change Change/Review rationale:
		85	**Date and time vaccinated**:1/5/21 **Dose number:** 1 **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment**: **Medical History**:		No Change Change/Review rationale:

			GP contacted/notified: [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	69[redacted]	**Date and time vaccinated:** 19/8/21 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	56[redacted]	**Date and time vaccinated:**05/08/21 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	77[redacted]	**Date and time vaccinated:**11/08/21 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	77 [redacted]	**Date and time vaccinated**:29/04/21 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 26 August 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-26-08-2021

Summary

- To 22 August 2021, approximately 17.1 million vaccine doses have been given in Australia – 10.9 million first doses and 6.2 million second doses.
- The TGA is continually monitoring the safety of the COVID-19 vaccines. The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials and include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) which have been found to be linked to the Vaxzevria (AstraZeneca) vaccine. Early detection of this syndrome may help to prevent more serious complications developing and guidance for health professionals is now available.
- In the last week, an additional 8 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS. None of these cases were fatal.
- An external Vaccine Safety Investigation Group (VSIG), convened by the TGA on 24 August 2021, assessed the available evidence for 5 suspected cases of TTS in people who had received their second dose of the Vaxzevria (AstraZeneca) vaccine. The panel concluded that 2 cases were unlikely to be related to vaccination. For the other 3 patients, medical evidence was insufficient to confirm a link with vaccination.
- The Product Information for the Vaxzevria (AstraZeneca) vaccine has been updated to include a warning about Guillain-Barre Syndrome (GBS), and a caution about anxiety-related reactions in response to vaccination.
- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.
- AusVaxSafety's active COVID-19 vaccine surveillance program has reached a new milestone – over 2 million SMS and email surveys have now been completed by Australians who have received a vaccine.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 16-22 August 2021, staff at the TGA have accepted an additional 2,327 AEFI reports into our database for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have received the vaccination. We also monitor reports for signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. As the number of vaccinated people has increased, so has reporting of fatal events with a coincidental association with vaccination. This does not indicate a link between vaccination and the fatalities reported. Review of individual reports and patterns of reporting does not suggest the vaccines played a role in these deaths.

Since the beginning of the vaccine rollout to 22 August 2021, over 17.1 million doses of COVID-19 vaccines have been given. So far, the TGA has found that 7 reports of deaths were linked to immunisation from 476 reports received and reviewed. These deaths occurred after the first dose of the Vaxzevria (AstraZeneca) vaccine – 6 were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 22 August 2021

3.1	52,849	17,150,654
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

32,818	19,706	338
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	2.2	New South Wales	2.0
Northern Territory	2.7	Queensland	2.9
South Australia	3.0	Tasmania	5.1
Victoria	4.5	Western Australia	2.8

Most commonly reported vaccine side effects

The most common adverse effects reported to the TGA following immunisation are predictable and have been observed with many vaccines. They include headache, muscle pain, fever, chills and injection site reactions for both vaccines.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team,

with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

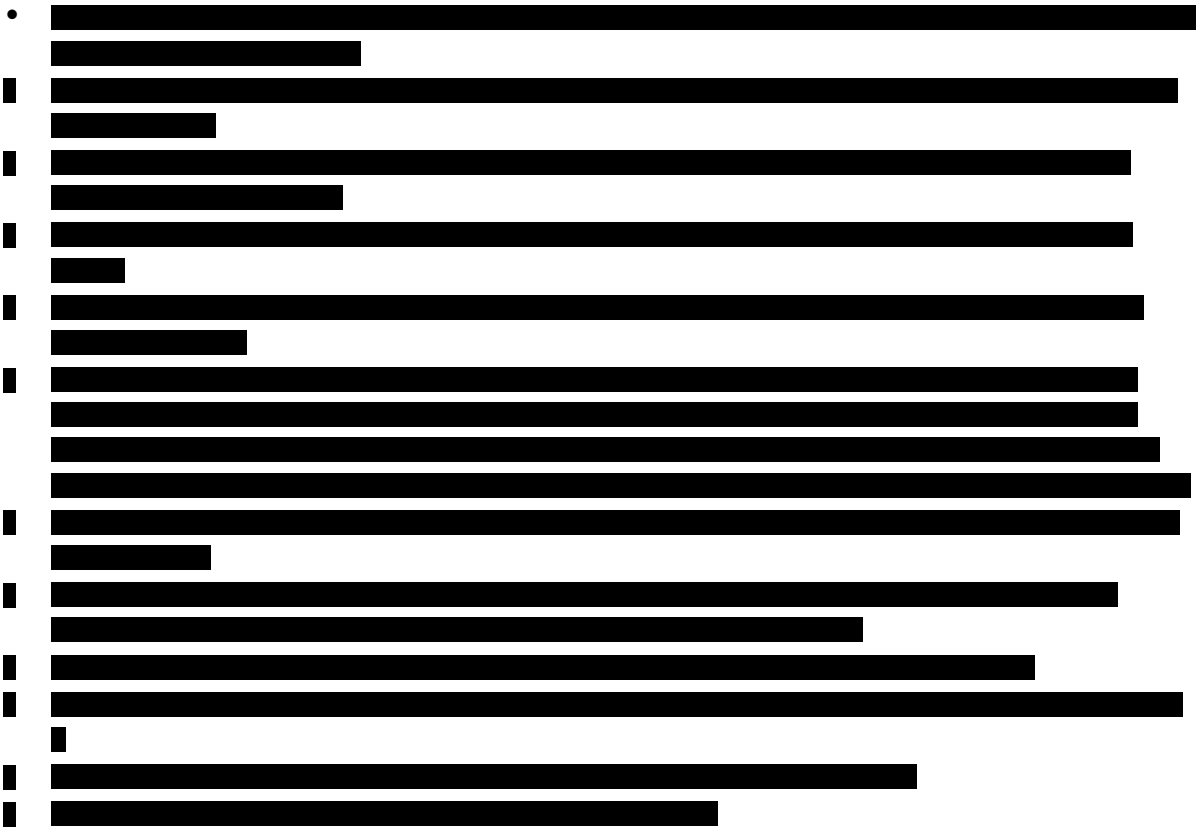
As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- [redacted]

Non-Critical Errors

- [redacted]



Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 27

Meeting date: 14 September 2021

Report period:

1 September 2021 to 7 September 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 7/09/2021*

Total doses/episodes: 1,362,295
Individuals received dose 1 = 813,986
Individuals received dose 2 = 546,765
Vaxzevria (Astra Zeneca) doses = 662,887 (Dose 1: 402,619 – Dose 2: 259,803)
Pfizer doses = 699,408 (Dose 1: 412,050 – Dose 2: 286,883)

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 7/09/2021 YTD

Number of Reports		**3,127**
Gender	Male	826
	Female	2,295
Indigenous	Yes	44
	No	2,913
	Unknown	118
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**775**
General reactions Total number of COVID-19 Vaccines Reports		**2,833**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,671**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	552	33.03	0.08
Myalgia	356	21.30	0.05
Chills	258	15.44	0.04
Nausea	236	14.12	0.04
Fever not recorded	221	13.23	0.03
Fatigue	175	10.47	0.03
Lethargy	154	9.22	0.02
Arthralgia	140	8.38	0.02
Abdominal Pain	94	5.63	0.01
Vomiting	93	5.57	0.01
Diarrhoea	78	4.67	0.01
Dizziness - see vertigo	73	4.37	0.01
Chest Pain	71	4.25	0.01
Rash	67	4.01	0.01
Dyspnoea	64	3.83	0.01
Fever mild	59	3.53	0.01
Pain	57	3.41	0.01
Malaise	54	3.23	0.01
Vertigo	44	2.63	0.01
Rigors	43	2.57	0.01
Pulmonary embolism	41	2.45	0.01
Tachycardia	41	2.45	0.01
Deep vein thrombosis	40	2.39	0.01
Light headedness	39	2.33	0.01
Paresthesia	38	2.27	0.01
Visual disturbance	38	2.27	0.01
Coughing	36	2.15	0.01
Sweating	36	2.15	0.01
Urticaria	36	2.15	0.01

Injection-site pain	35	2.09	0.01
Shivering	35	2.09	0.01
Clot	34	2.03	0.01
Fever high	34	2.03	0.01
Hypertension	32	1.92	0.00
Rash unspecified	32	1.92	0.00
Influenza-like illness	28	1.68	0.004
Confusion	26	1.56	0.004
Palpitations	25	1.50	0.004
Exacerbation of existing medical condition	24	1.44	0.004
Migraine	24	1.44	0.004
Pain in extremity	24	1.44	0.004
Epistaxis	22	1.32	0.003
Herpes zoster	22	1.32	0.003
Lymphadenopathy	22	1.32	0.003
Anorexia	21	1.26	0.003
Flushing	21	1.26	0.003
Death	20	1.20	0.003
Injection site pain restricting limb mobility	20	1.20	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.24	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**1,456**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	365	25.07	0.05
Myalgia	245	16.83	0.04
Nausea	210	14.42	0.03
Fatigue	200	13.74	0.03
Chest Pain	154	10.58	0.02
Lymphadenopathy	145	9.96	0.02
Chills	133	9.13	0.02
Fever not recorded	131	9.00	0.02
Lethargy	113	7.76	0.02
Arthralgia	102	7.01	0.01
Dizziness - see vertigo	89	6.11	0.01
Vomiting	77	5.29	0.01
Paresthesia	73	5.01	0.01
Rash	69	4.74	0.01
Pain	68	4.67	0.01
Dyspnoea	60	4.12	0.01
Palpitations	58	3.98	0.01
Abdominal Pain	55	3.78	0.01
Diarrhoea	55	3.78	0.01
Light headedness	55	3.78	0.01

Coughing	47	3.23	0.01
Tachycardia	43	2.95	0.01
Hypertension	42	2.88	0.01
Urticaria	42	2.88	0.01
Menstrual Irregularity	39	2.68	0.01
Vertigo	37	2.54	0.01
Fever mild	35	2.40	0.01
Sweating	35	2.40	0.01
Rash unspecified	33	2.27	0.005
Vasovagal episode (syncope, faint) +/-tonic clonic movements	32	2.20	0.005
Lymphadenopathy localized to the region of the injection site	30	2.06	0.004
Visual disturbance	30	2.06	0.004
Exacerbation of existing medical condition	29	1.99	0.004
Flushing	29	1.99	0.004
Itching	26	1.79	0.004
Pericaditis	25	1.72	0.004
Throat soreness	25	1.72	0.004
Numbness	24	1.65	0.003
Oedema	24	1.65	0.003
Injection-site pain	23	1.58	0.003
Malaise	22	1.51	0.003
Shivering	21	1.44	0.003
Herpes zoster	20	1.37	0.003
Migraine	20	1.37	0.003
Pain in extremity	20	1.37	0.003

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 7/09/2021 YTD:

Vaxzevria (Astra Zeneca)	**YTD**		**Week 24**		
Total Number of reports	**1,671**	**% of Total AZ vacc admin***	**31**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	94	0.014	3	3.19	0.0005
Chest Pain	71	0.011	3	4.23	0.0005
Clot	34	0.005	1	2.94	0.0002
Vertigo	44	0.007	1	2.27	0.0002
Visual disturbance	38	0.006	2	5.26	0.0003
Hypertension	32	0.005	2	6.25	0.0003
Epistaxis	22	0.003	0	0.00	0.00
Deep vein thrombosis	40	0.006	1	2.50	0.0002

Death	20	0.003	0	0.00	0.0000
Herpes zoster	22	0.003	1	4.55	0.0002
Pulmonary embolism	41	0.006	1	2.44	0.0002
Atrial fibrillation	12	0.002	0	0.000	0.00
Cerebral vascular accident see Stroke	6	0.001	0	0.00	0.00
Stroke	8	0.001	0	0.00	0.00
Thrombocytopenia	8	0.001	0	0.00	0.00
Bells Palsy	5	0.0008	1	20.00	0.0002
Anaphylaxis	3	0.0005	0	0.00	0.00
Pericarditis	4	0.0006	0	0.00	0.00
Menstrual Irregularity	6	0.001	0	0.00	0.00
Guillain Barré syndrome	2	0.0003	0	0.00	0.00
Myocarditis	3	0.0005	0	0.00	0.00
Exacerbation of existing medical condition	24	0.004	2	8.33	0.0003
Thrombosis with thrombocytopenia syndrome TTS	4	0.0006	0	0.00	0.00
Cerebral Venous Sinus Thrombosis	4	0.0006	1	0.00	0.0002
Dyskinesia	2	0.0003	0	0.00	0.00
Idiopathic thrombocytopenic purpura	5	0.0008	0	0.00	0.00
Multiple sclerosis	1	0.0002	0	0.00	0.00
Purpura	10	0.002	0	0.00	0.00
Ecchymosis	9	0.001	2	22.22	0.0003
Dysgeusia	16	0.002	1	6.25	0.0002
Thrombophlebitis	10	0.002	0	0.00	0.00
Lymphadenopathy	22	0.003	0	0.00	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 24**		
Total Number of reports	**1,456**	**% of Total Pfizer vacc admin.***	**112**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	55	0.008	5	9.09	0.001
Chest Pain	154	0.022	21	13.64	0.003

Clot	9	0.001	0	0.00	0.000
Vertigo	42	0.006	1	2.38	0.00
Dizziness – see Vertigo	89	0.013	11	12.36	0.002
Visual disturbance	30	0.004	1	3.33	0.00
Hypertension	37	0.005	5	13.51	0.001
Death	16	0.002	1	6.25	0.00
Herpes zoster	20	0.003	2	10.00	0.00
Pulmonary embolism	6	0.001	0	0.00	0.00
Bells Palsy	4	0.001	1	25.00	0.00
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	36	0.005	2	5.56	0.00
Pericarditis	25	0.004	3	12.00	0.00
Myocarditis	6	0.001	1	0.00	0.00
Menstrual Irregularity	39	0.006	1	2.56	0.00
Exacerbation of existing medical condition	29	0.004	1	3.45	0.00
Miscarriage	2	0.00	0	0.00	0.00
Tinnitus	19	0.003	4	21.05	0.001
Dysgeusia	12	0.002	1	0.00	0.00
Paresthesia	73	0.01	6	8.22	0.001
Facial Paralysis	3	0.00	0	0.00	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 7/09/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	5	1	4	3	20

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	73 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	48 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	27 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]					
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 7/09/2021 YTD:

Number unmatched reports: 9 *Reporter contacted to submit SAVSS report	38 [redacted]
	86 [redacted]
	76 [redacted]
	49 Male – [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]
	76 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	45[redacted]	**Date vaccinated**: 14/8/2021 **Dose number:** 2 **Details**: [redacted]	[redacted]	No Change Change/Review rationale:

			Laboratory Results: [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted]. **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	17[redacted]	**Date vaccinated**: 20/8/2021 **Dose number:** 1 **Details**: 2[redacted]. **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	51[redacted]	**Date and time vaccinated**: 05/08/21 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** **Imaging & Findings:** [redacted]	[redacted]	No Change Change/Review rationale:

			Treatment: [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	34[redacted]	**Date vaccinated**: 13/8/2021 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	23[redacted]	**Date and time vaccinated**: 19/08/2021 **Dose number:** 1 **Details**: [redacted] **Laboratory Results: 24/08/2021** [redacted] **27/08/2021** [redacted] **4/09/2021** [redacted] **5/09/2021** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	83 [redacted]	**Date vaccinated**: 9/07/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	56 [redacted]	**Date vaccinated**: 6/6/2021 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** [redacted]	[redacted]	No Change Change/Review rationale:

			Imaging & Findings: [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	56[redacted]	**Date and time vaccinated**: 7/7//21 **Dose number:** 2 **Details**: [redacted] **Laboratory Results** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 02 September 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-02-09-2021

Summary

- To 29 August 2021, over 19 million vaccine doses have been given in Australia – approximately 12 million first doses and 7 million second doses.
- The TGA is continually monitoring the safety of the COVID-19 vaccines. The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials and include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) which have been found to be linked to the Vaxzevria (AstraZeneca) vaccine. Early detection of this syndrome may help to prevent more serious complications developing and guidance for health professionals is now available.
- In the last week, an additional 9 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS. Sadly, two people died this week – a 59-year-old woman from Queensland with confirmed TTS and a 54-year-old man from NSW with probable TTS. Both were following their first dose of the AstraZeneca vaccine. The TGA extends its sincerest condolences to her family and loved ones. We are in close communication with the Queensland and NSW authorities who are undertaking further investigation of these cases.
- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.

> The Database of Adverse Event Notifications (DAEN) is currently unavailable due to performance issues resulting from high rates of access. This is being investigated as a priority. We will provide further information on our website when it is available again.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 23-29 August 2021, staff at the TGA have accepted an additional 2,167 AEFI reports into our internal database for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have received the vaccination. We also monitor reports for signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. As the number of vaccinated people has increased, so has reporting of fatal events with a coincidental association with vaccination. This does not indicate a link between vaccination and the fatalities reported. Review of individual reports and patterns of reporting does not suggest the vaccines played a role in these deaths.

Since the beginning of the vaccine rollout to 29 August 2021, over 19 million doses of COVID-19 vaccines have been given. So far, the TGA has found that 9 reports of deaths were linked to immunisation from 495 reports received and reviewed. These deaths occurred after the first dose of the Vaxzevria (AstraZeneca) vaccine – 8 were TTS cases and 1 was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 29 August 2021

2.9	55,016	19,085,741
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

33,746	20,940	346
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	2.1	New South Wales	1.9
Northern Territory	2.6	Queensland	2.8
South Australia	2.8	Tasmania	4.9
Victoria	4.2	Western Australia	2.7

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- [redacted]

[redacted]

Non-Critical Errors

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 28

Meeting date: 21 September 2021

Report period:

8 September 2021 to 14 September 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 14/09/2021*

Total doses/episodes: 1,485,269
Individuals received dose 1 = 877,887
Individuals received dose 2 = 605,641
Vaxzevria (Astra Zeneca) doses = 696,648 (Dose 1: 411,870 – Dose 2: 284,264)
Pfizer doses = 788,621 (Dose 1: 466,791– Dose 2: 321,402)

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 14/09/2021 YTD

Number of Reports		**3,295**
Gender	Male	880
	Female	2,408
Indigenous	Yes	46
	No	3,074
	Unknown	119
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**809**
General reactions Total number of COVID-19 Vaccines Reports		**2,966**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,725**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	563	32.64	0.08
Myalgia	367	21.28	0.05
Chills	266	15.42	0.04
Nausea	239	13.86	0.03
Fever not recorded	228	13.22	0.03
Fatigue	181	10.49	0.03
Lethargy	161	9.33	0.02
Arthralgia	145	8.41	0.02
Abdominal Pain	97	5.62	0.01
Vomiting	96	5.57	0.01
Diarrhoea	80	4.64	0.01
Dizziness - see vertigo	75	4.35	0.01
Chest Pain	71	4.12	0.01
Rash	71	4.12	0.01
Dyspnoea	65	3.77	0.01
Fever mild	61	3.54	0.01
Pain	57	3.30	0.01
Malaise	56	3.25	0.01
Vertigo	44	2.55	0.01
Rigors	43	2.49	0.01
Tachycardia	42	2.43	0.01
Deep vein thrombosis	41	2.38	0.01
Pulmonary embolism	41	2.38	0.01
Paresthesia	40	2.32	0.01
Light headedness	39	2.26	0.01
Visual disturbance	39	2.26	0.01
Coughing	37	2.14	0.01
Sweating	36	2.09	0.01
Urticaria	36	2.09	0.01

Injection-site pain	35	2.03	0.01
Shivering	35	2.03	0.01
Clot	34	1.97	0.00
Fever high	34	1.97	0.00
Hypertension	32	1.86	0.00
Rash unspecified	32	1.86	0.00
Influenza-like illness	28	1.62	0.004
Confusion	26	1.51	0.004
Exacerbation of existing medical condition	26	1.51	0.004
Pain in extremity	26	1.51	0.004
Palpitations	25	1.45	0.004
Migraine	24	1.39	0.003
Herpes zoster	23	1.33	0.003
Anorexia	22	1.28	0.003
Epistaxis	22	1.28	0.003
Flushing	22	1.28	0.003
Lymphadenopathy	22	1.28	0.003
Death	21	1.22	0.003
Injection site pain restricting limb mobility	20	1.16	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.23	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**1,570**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	393	25.03	0.05
Myalgia	258	16.43	0.03
Nausea	227	14.46	0.03
Fatigue	217	13.82	0.03
Chest Pain	168	10.70	0.02
Lymphadenopathy	151	9.62	0.02
Chills	141	8.98	0.02
Fever not recorded	137	8.73	0.02
Lethargy	119	7.58	0.02
Arthralgia	111	7.07	0.01
Dizziness - see vertigo	97	6.18	0.01
Vomiting	86	5.48	0.01
Paresthesia	79	5.03	0.01
Pain	77	4.90	0.01
Rash	73	4.65	0.01
Dyspnoea	68	4.33	0.01
Abdominal Pain	64	4.08	0.01
Palpitations	63	4.01	0.01
Diarrhoea	59	3.76	0.01
Light headedness	58	3.69	0.01

Coughing	48	3.06	0.01
Tachycardia	47	2.99	0.01
Hypertension	44	2.80	0.01
Urticaria	44	2.80	0.01
Rash unspecified	43	2.74	0.01
Vertigo	42	2.68	0.01
Menstrual Irregularity	40	2.55	0.01
Fever mild	38	2.42	0.00
Sweating	35	2.23	0.004
Lymphadenopathy localized to the region of the injection site	34	2.17	0.004
Vasovagal episode (syncope, faint) +/-tonic clonic movements	33	2.10	0.004
Exacerbation of existing medical condition	32	2.04	0.004
Visual disturbance	32	2.04	0.004
Itching	30	1.91	0.004
Pericarditis	30	1.91	0.004
Flushing	29	1.85	0.004
Numbness	28	1.78	0.004
Oedema	28	1.78	0.004
Throat soreness	27	1.72	0.003
Injection-site pain	24	1.53	0.003
Malaise	24	1.53	0.003
Shivering	24	1.53	0.003
Tinnitus	22	1.40	0.003
Anxious	21	1.34	0.003
Herpes zoster	21	1.34	0.003

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 14/09/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 28		
Total Number of reports	**1,725**	**% of Total AZ vacc admin***	**49**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	97	0.014	2	2.06	0.0003
Chest Pain	71	0.010	0	0.00	0.00
Clot	34	0.005	0	0.00	0.00
Vertigo	44	0.006	0	0.00	0.00
Visual disturbance	39	0.006	0	0.00	0.00
Hypertension	32	0.005	0	0.00	0.00
Epistaxis	22	0.003	0	0.00	0.00
Deep vein thrombosis	41	0.006	1	2.44	0.0001
Death	21	0.003	1	4.76	0.0001
Herpes zoster	23	0.003	0	0.00	0.00
Pulmonary embolism	41	0.006	0	0.00	0.00
Atrial fibrillation	13	0.002	1	7.69	0.0001
Cerebral vascular accident see Stroke	7	0.001	1	14.29	0.0001
Stroke	12	0.008	4	33.33	0.0006
Thrombocytopenia	8	0.001	0	0.00	0.00
Bells Palsy	5	0.0007	0	0.00	0.00
Anaphylaxis	3	0.0004	0	0.00	0.00
Pericarditis	4	0.0006	0	0.00	0.00
Menstrual Irregularity	6	0.0009	0	0.00	0.00
Guillain Barré syndrome	3	0.0004	0	0.00	0.00
Myocarditis	4	0.0006	1	25.00	0.0001
Exacerbation of existing medical condition	26	0.004	2	7.69	0.0003
Thrombosis with thrombocytopenia syndrome TTS	4	0.0006	0	0.00	0.00
Cerebral Venous Sinus Thrombosis	4	0.0006	0	0.00	0.00
Dyskinesia	2	0.0003	0	0.00	0.00
Idiopathic thrombocytopenic purpura	5	0.0007	0	0.00	0.00
Multiple sclerosis	1	0.0001	0	0.00	0.00

Purpura	11	0.007	0	0.00	0.00
Ecchymosis	9	0.001	0	0.00	0.00
Dysgeusia	17	0.002	1	5.88	0.0001
Thrombophlebitis	11	0.007	0	0.00	0.00
Lymphadenopathy	22	0.003	0	0.00	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 28**		
Total Number of reports	**1,570**	**% of Total Pfizer vacc admin.***	**102**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	64	0.008	8	12.50	0.001
Chest Pain	168	0.021	12	7.14	0.002
Clot	9	0.001	0	0.00	0.00
Vertigo	42	0.005	0	0.00	0.00
Dizziness – see Vertigo	97	0.012	6	6.19	0.001
Visual disturbance	32	0.004	0	0.00	0.00
Hypertension	44	0.006	2	4.55	0.00
Death	16	0.002	0	0.00	0.00
Herpes zoster	21	0.003	1	4.76	0.00
Pulmonary embolism	6	0.001	0	0.00	0.00
Bells Palsy	4	0.001	0	0.00	0.00
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	36	0.005	0	0.00	0.00
Pericarditis	30	0.004	5	16.68	0.001
Myocarditis	6	0.001	0	0.00	0.00
Menstrual Irregularity	40	0.005	0	0.00	0.00
Exacerbation of existing medical condition	32	0.004	2	6.25	0.00
Miscarriage	3	0.00	1	33.33	0.00
Tinnitus	22	0.003	3	13.64	0.00
Dysgeusia	13	0.002	0	0.00	0.00
Paresthesia	79	0.010	4	5.06	0.001

Facial Paralysis	3	0.00	0	0.00	0.00

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 14/09/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	**6**	**0**	4	3	20

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]	73 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	48 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	27 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 14/09/2021 YTD:

Number unmatched reports: 8 *Reporter contacted to submit SAVSS report	86 [redacted]
	76 [redacted]
	49 Male – [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]
	76 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	35 F	**Date vaccinated**: 15/8/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Multiple other tests completed** **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

[redacted]	[redacted]	43[redacted]	**Date vaccinated**: 2/8 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	76[redacted]	**Date vaccinated**: 29/4 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	89[redacted]	**Date vaccinated**: 7/9/21 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** [redacted] **GP contacted/notified:** yes. [redacted] **Classification:**	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	79[redacted]	**Date vaccinated**: 8/7/2021 **Dose number:** 1 **Details:** [redacted]	[redacted]	No Change Change/Review rationale:

			Laboratory Results: [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	63 [redacted]	**Date vaccinated**: 16/07/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 09 September 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-09-09-2021

Summary

- To 5 September 2021, approximately 21 million vaccine doses have been given in Australia – 13.1 million first doses and 7.9 million second doses.
- The TGA is continually monitoring the safety of the COVID-19 vaccines. The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials and include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) which have been found to be linked to the Vaxzevria (AstraZeneca) vaccine. Early detection of this syndrome may help to prevent more serious complications developing and guidance for health professionals is now available.
- In the last week, an additional 7 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS. None of these cases was fatal.
- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 30 August – 5 September 2021, staff at the TGA have accepted an additional 2,145 AEFI reports into our database for COVID-19 vaccines.

The most common adverse effects reported to the TGA following immunisation are predictable and have been observed with many vaccines. They include headache, muscle pain, fever, chills and injection site reactions for both vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have received the vaccination. We also monitor reports for signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. As the number of vaccinated people has increased, so has reporting of fatal events with a coincidental association with vaccination. This does not indicate a link between vaccination and the fatalities reported. Review of individual reports and patterns of reporting does not suggest the vaccines played a role in these deaths.

Since the beginning of the vaccine rollout to 5 September 2021, approximately 21 million doses of COVID-19 vaccines have been given. So far, the TGA has found that 9 reports of deaths were linked to immunisation from 516 reports received and reviewed. These deaths occurred after the first dose of the Vaxzevria (AstraZeneca) vaccine – 8 were TTS cases and 1 was a case of immune thrombocytopenia (ITP). The overwhelming majority of deaths reported to the TGA following vaccination occurred in people aged 65 years and older.

Total adverse event reports to 5 September 2021

2.7	57,161	20,985,989
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

34,659	22,180	347
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	1.9	New South Wales	1.8
Northern Territory	2.5	Queensland	2.6
South Australia	2.7	Tasmania	4.7
Victoria	4.0	Western Australia	2.6

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

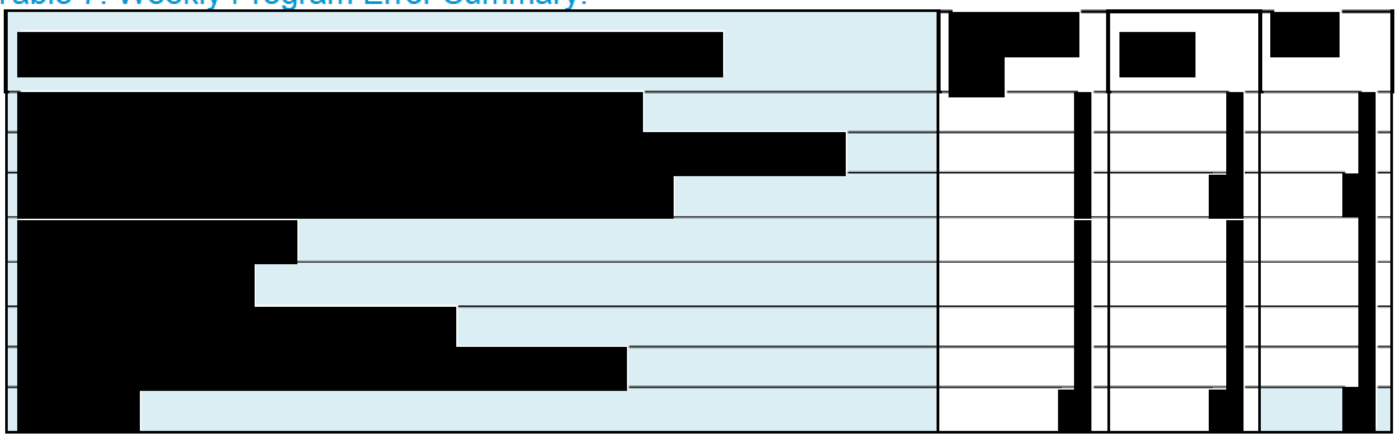
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

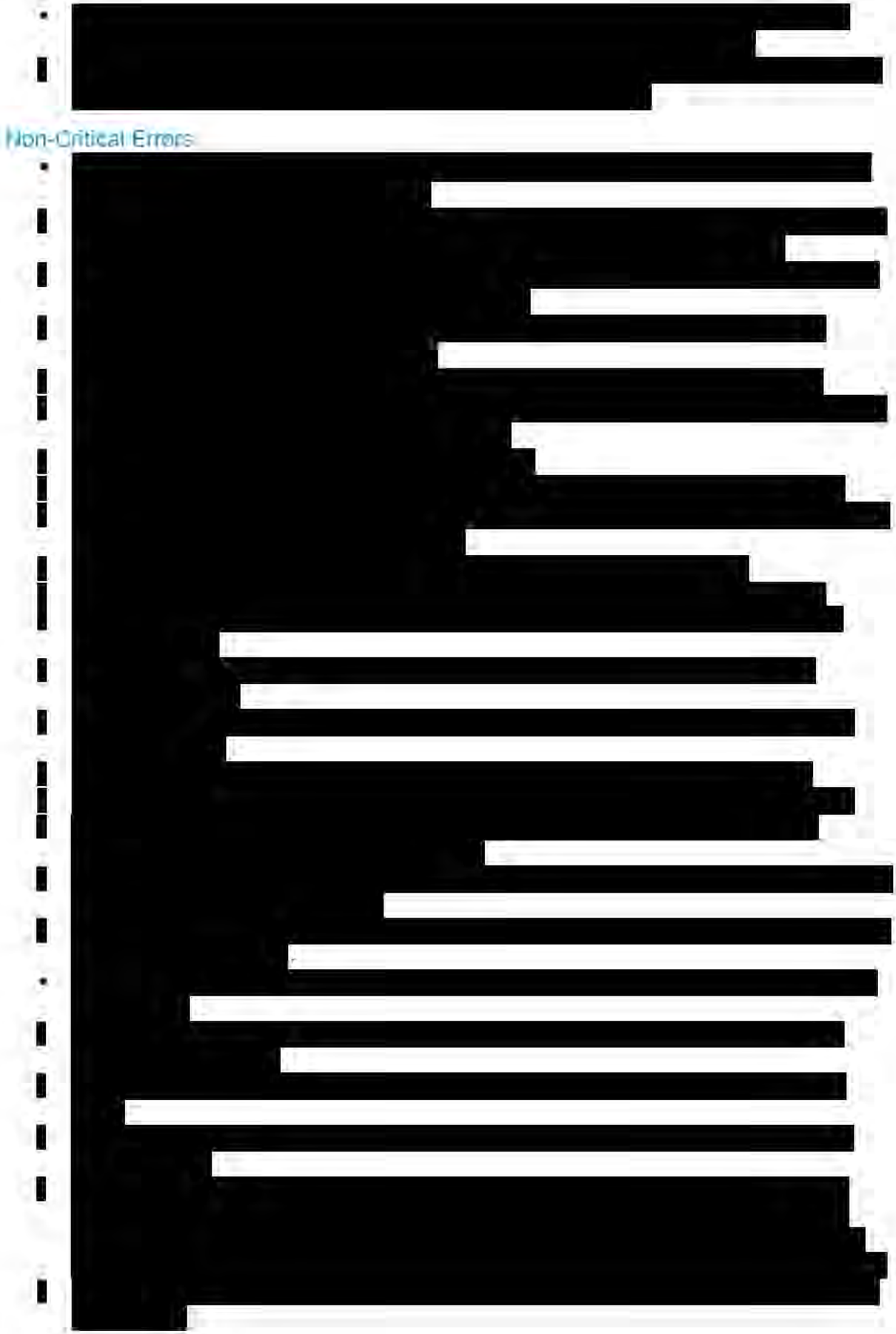
Table 7: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- 



Non-Critical Errors

- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 29

Meeting date: 28 September 2021

Report period:

15 September 2021 to 21 September 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 21/09/2021*

Total doses/episodes: 1,570,718
Individuals received dose 1 = 922,939
Individuals received dose 2 = 647,779
Vaxzevria (Astra Zeneca) doses = 712,429 (Dose 1: 414,987 – Dose 2: 297,442)
Pfizer doses = 859,139 (Dose 1: 508,775 – Dose 2: 350,364)

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 21/09/2021 YTD

Number of Reports		**3,404**
Gender	Male	920
	Female	2,476
Indigenous	Yes	46
	No	3,181
	Unknown	166
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**830**
General reactions Total number of COVID-19 Vaccines Reports		**3,081**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,753**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	573	32.69	0.08
Myalgia	372	21.22	0.05
Chills	271	15.46	0.04
Nausea	242	13.80	0.03
Fever not recorded	229	13.06	0.03
Fatigue	184	10.50	0.03
Lethargy	165	9.41	0.02
Arthralgia	146	8.33	0.02
Vomiting	100	5.70	0.01
Abdominal Pain	98	5.59	0.01
Diarrhoea	84	4.79	0.01
Dizziness - see vertigo	81	4.62	0.01
Chest Pain	74	4.22	0.01
Rash	73	4.16	0.01
Dyspnoea	66	3.76	0.01
Fever mild	62	3.54	0.01
Malaise	61	3.48	0.01
Pain	60	3.42	0.01
Visual disturbance	45	2.57	0.01
Paresthesia	44	2.51	0.01
Vertigo	44	2.51	0.01
Rigors	43	2.45	0.01
Deep vein thrombosis	42	2.40	0.01
Tachycardia	42	2.40	0.01
Pulmonary embolism	41	2.34	0.01
Light headedness	39	2.22	0.01
Coughing	38	2.17	0.01
Sweating	38	2.17	0.01
Urticaria	36	2.05	0.01

Injection-site pain	35	2.00	0.00
Shivering	35	2.00	0.00
Clot	34	1.94	0.00
Fever high	34	1.94	0.00
Hypertension	32	1.83	0.00
Rash unspecified	32	1.83	0.00
Influenza-like illness	28	1.60	0.004
Exacerbation of existing medical condition	27	1.54	0.004
Confusion	26	1.48	0.004
Pain in extremity	26	1.48	0.004
Palpitations	25	1.43	0.004
Herpes zoster	24	1.37	0.003
Migraine	24	1.37	0.003
Anorexia	23	1.31	0.003
Lymphadenopathy	23	1.31	0.003
Epistaxis	22	1.25	0.003
Flushing	22	1.25	0.003
Death	21	1.20	0.003
Injection site pain restricting limb mobility	21	1.20	0.003
Pruritus	20	1.14	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.23	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**1,570**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	412	24.95	0.05
Myalgia	269	16.29	0.03
Nausea	238	14.42	0.03
Fatigue	224	13.57	0.03
Chest Pain	188	11.39	0.02
Lymphadenopathy	153	9.27	0.02
Chills	149	9.02	0.02
Fever not recorded	146	8.84	0.02
Lethargy	122	7.39	0.01
Arthralgia	118	7.15	0.01
Dizziness - see vertigo	108	6.54	0.01
Vomiting	90	5.45	0.01
Paresthesia	83	5.03	0.01
Pain	81	4.91	0.01
Dyspnoea	75	4.54	0.01
Rash	73	4.42	0.01
Palpitations	72	4.36	0.01
Abdominal Pain	68	4.12	0.01
Diarrhoea	60	3.63	0.01

Light headedness	59	3.57	0.01
Tachycardia	55	3.33	0.01
Coughing	47	2.85	0.01
Rash unspecified	45	2.73	0.01
Urticaria	45	2.73	0.01
Hypertension	44	2.67	0.01
Vertigo	43	2.60	0.01
Fever mild	38	2.30	0.00
Menstrual Irregularity	38	2.30	0.00
Sweating	36	2.18	0.004
Lymphadenopathy localized to the region of the injection site	35	2.12	0.004
Vasovagal episode (syncope, faint) +/-tonic clonic movements	34	2.06	0.004
Visual disturbance	34	2.06	0.004
Exacerbation of existing medical condition	33	2.00	0.004
Pericaditis	33	2.00	0.004
Itching	32	1.94	0.004
Flushing	30	1.82	0.003
Malaise	30	1.82	0.003
Oedema	30	1.82	0.003
Numbness	29	1.76	0.003
Throat soreness	29	1.76	0.003
Tinnitus	27	1.64	0.003
Shivering	26	1.57	0.003
Injection-site pain	24	1.45	0.003
Migraine	23	1.39	0.003
Herpes zoster	22	1.33	0.003
Anxious	21	1.27	0.002
Pain in extremity	21	1.27	0.002
Insomnia	20	1.21	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 21/09/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 29		
Total Number of reports	**1753**	**% of Total AZ vacc admin***	**26**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	98	0.014	1	1.02	0.0001
Chest Pain	74	0.010	2	2.70	0.0002
Clot	34	0.005	0	0.000	0.0000
Vertigo	44	0.006	0	0.00	0.0000
Visual disturbance	45	0.006	6	13.33	0.0007
Hypertension	32	0.005	0	0.000	0.0000
Epistaxis	22	0.003	0	0.000	0.0000
Deep vein thrombosis	42	0.006	1	2.381	0.0001
Death	21	0.003	0	0.000	0.0000
Herpes zoster	24	0.003	1	4.17	0.0001
Pulmonary embolism	41	0.006	0	0.00	0.0000
Atrial fibrillation	13	0.002	0	0.000	0.0000
Cerebral vascular accident see Stroke	7	0.001	1	14.286	0.0001
Stroke	12	0.002	0	0.00	0.0000
Thrombocytopenia	8	0.001	0	0.000	0.0000
Bells Palsy	6	0.001	1	16.667	0.0001
Anaphylaxis	3	0.0004	0	0.000	0.0000
Pericarditis	5	0.001	1	20.000	0.0001
Menstrual Irregularity	7	0.001	1	14.29	0.0000
Guillain Barré syndrome	3	0.0004	0	0.000	0.0000
Myocarditis	4	0.001	0	0.000	0.0000
Exacerbation of existing medical condition	27	0.004	0	0.000	0.0000
Thrombosis with thrombocytopenia syndrome TTS	4	0.001	0	0.000	0.0000
Cerebral Venous Sinus Thrombosis	4	0.001	0	0.000	0.0000
Dyskinesia	2	0.0003	0	0.000	0.0000
Idiopathic thrombocytopenic purpura	5	0.001	0	0.000	0.0000
Multiple sclerosis	1	0.0001	0	0.000	0.0000

Purpura	11	0.002	0	0.000	0.0000
Ecchymosis	9	0.001	0	0.000	0.0000
Dysgeusia	18	0.003	0	0.000	0.0000
Thrombophlebitis	11	0.002	0	0.000	0.0000
Lymphadenopathy	23	0.003	1	4.35	0.0001

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 29**		
Total Number of reports	**1,651**	**% of Total Pfizer vacc admin.***	**79**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	68	0.008	3	4.412	0.000
Chest Pain	188	0.022	14	7.447	0.002
Vertigo	43	0.005	1	2.326	0.000
Dizziness – see Vertigo	108	0.013	8	7.407	0.001
Visual disturbance	34	0.004	1	2.941	0.000
Hypertension	44	0.005	0	0.000	0.000
Death	16	0.002	0	0.000	0.000
Herpes zoster	22	0.003	1	4.545	0.000
Pulmonary embolism	7	0.001	1	14.286	0.000
Bells Palsy	6	0.001	2	33.333	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	36	0.004	0	0.000	0.000
Pericarditis	33	0.004	3	9.091	0.000
Myocarditis	6	0.001	0	0.000	0.000
Menstrual Irregularity	38	0.004	5	13.16	0.001
Exacerbation of existing medical condition	33	0.004	1	3.030	0.000
Miscarriage	3	0.000	0	0.000	0.000
Tinnitus	27	0.003	0	0.000	0.000
Dysgeusia	14	0.002	1	7.143	0.000
Paresthesia	83	0.010	6	0.000	0.001
Facial Paralysis	3	0.000	0	0.000	0.000

Oedema Eyelid	10	0.001		10.000	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 21/09/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	**6**	**0**	4	3	20

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	73 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]	48 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	27 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 21/09/2021 YTD:

Number unmatched reports: 10 *Reporter contacted to submit SAVSS report	76 [redacted]
	35 [redacted]
	86 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]

	76 Female – Bilateral PE – Vaxzevria *

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	74 [redacted]	**Date and time vaccinated**:24/6 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	49 [redacted]	**Date and time vaccinated**: 12/9/21 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	45 [redacted]	**Date and time vaccinated**:9/7/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:**	[redacted]	No Change Change/Review rationale:

			Imaging & Findings: [redacted] **Treatment:** [redacted] **Medical History**: [redacted]. **GP contacted/notified:** [redacted] **Classification:** [redacted]		

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	65 [redacted]	**Date and time vaccinated**:12/08/21 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** **Imaging & Findings:** **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 16 September 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-16-09-2021

Summary

- The protective benefits of vaccination against COVID-19 continue to far outweigh the potential risks of vaccination.
- To 12 September 2021, approximately 22.8 million vaccine doses have been given in Australia – 14 million first doses and 8.8 million second doses.
- The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials. They include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) linked to the Vaxzevria (AstraZeneca) vaccine.
- In the last week, an additional 5 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS. None of these cases were fatal.

Reported side effects for COVID-19 vaccines

The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials. They include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have been vaccinated. As the number of vaccinated people has increased, so has reporting of fatal events with a coincidental association with vaccination. This does not indicate a link between vaccination and the fatalities reported. Review of individual reports and patterns of reporting does not suggest the vaccines played a role in these deaths.

Since the beginning of the vaccine rollout to 12 September 2021, over 22.8 million doses of COVID-19 vaccines have been given. So far, the TGA has found that 9 reports of deaths were linked to immunisation from 535 reports received and reviewed. These deaths occurred after the first dose of the Vaxzevria (AstraZeneca) vaccine – 8 were TTS cases and one was a case of immune thrombocytopenia (ITP). The overwhelming majority of deaths reported to the TGA following vaccination occurred in people aged 65 years and older.

Total adverse event reports to 12 September 2021

2.6	59,199	22,802,573
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

35,441	23,434	352
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	1.8	New South Wales	1.7
Northern Territory	2.4	Queensland	2.5
South Australia	2.6	Tasmania	4.5
Victoria	3.7	Western Australia	2.5

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- [redacted]

- [redacted]

Non-Critical Errors

- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 30

Meeting date: 5 October 2021

Report period:

22 September 2021 to 28 September 2021

Government of South Australia

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 28/09/2021*

Total doses/episodes: 1,698,583
Individuals received dose 1 = 986,655
Individuals received dose 2 = 709,796
Vaxzevria (Astra Zeneca) doses = 733,186 (Dose 1: 417,658 – Dose 2: 314,944)
Pfizer doses = 961,405 (Dose 1: 565,953 – Dose 2: 394,855)
Moderna doses = 3,992 (Dose 1: 3,962 – Dose 2: 30)

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 28/09/2021 YTD

Number of Reports		**3,537**
Gender	Male	955
	Female	2,573
Indigenous	Yes	47
	No	3,312
	Unknown	122
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**858**
General reactions Total number of COVID-19 Vaccines Reports		**3,188**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,778**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	581	32.68	0.08
Myalgia	374	21.03	0.05
Chills	274	15.41	0.04
Nausea	245	13.78	0.03
Fever not recorded	233	13.10	0.03
Fatigue	187	10.52	0.03
Lethargy	166	9.34	0.02
Arthralgia	151	8.49	0.02
Vomiting	101	5.68	0.01
Abdominal Pain	100	5.62	0.01
Diarrhoea	84	4.72	0.01
Dizziness - see vertigo	81	4.56	0.01
Chest Pain	76	4.27	0.01
Rash	73	4.11	0.01
Dyspnoea	67	3.77	0.01
Fever mild	62	3.49	0.01
Malaise	61	3.43	0.01
Pain	61	3.43	0.01
Paresthesia	46	2.59	0.01
Visual disturbance	46	2.59	0.01
Vertigo	45	2.53	0.01
Rigors	44	2.47	0.01
Pulmonary embolism	43	2.42	0.01
Deep vein thrombosis	42	2.36	0.01
Tachycardia	42	2.36	0.01
Light headedness	39	2.19	0.01
Coughing	38	2.14	0.01
Sweating	38	2.14	0.01
Exacerbation of existing medical condition	37	2.08	0.01

Urticaria	36	2.02	0.00
Injection-site pain	35	1.97	0.00
Shivering	35	1.97	0.00
Clot	34	1.91	0.00
Fever high	34	1.91	0.00
Hypertension	32	1.80	0.00
Rash unspecified	32	1.80	0.004
Influenza-like illness	28	1.57	0.004
Confusion	26	1.46	0.004
Pain in extremity	26	1.46	0.004
Palpitations	26	1.46	0.004
Migraine	25	1.41	0.003
Epistaxis	24	1.35	0.003
Herpes zoster	24	1.35	0.003
Anorexia	23	1.29	0.003
Lymphadenopathy	23	1.29	0.003
Flushing	22	1.24	0.003
Death	21	1.18	0.003
Injection site pain restricting limb mobility	21	1.18	0.003
Pruritus	20	1.12	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.22	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**1,759**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	432	24.56	0.04
Myalgia	286	16.26	0.03
Nausea	247	14.04	0.03
Fatigue	237	13.47	0.02
Chest Pain	199	11.31	0.02
Lymphadenopathy	166	9.44	0.02
Chills	160	9.10	0.02
Fever not recorded	157	8.93	0.02
Lethargy	129	7.33	0.01
Arthralgia	125	7.11	0.01
Dizziness - see vertigo	120	6.82	0.01
Paresthesia	95	5.40	0.01
Vomiting	94	5.34	0.01
Pain	85	4.83	0.01
Dyspnoea	79	4.49	0.01
Palpitations	79	4.49	0.01
Rash	79	4.49	0.01
Abdominal Pain	73	4.15	0.01
Diarrhoea	66	3.75	0.01

Light headedness	63	3.58	0.01
Tachycardia	58	3.30	0.01
Rash unspecified	48	2.73	0.00
Coughing	47	2.67	0.00
Urticaria	46	2.62	0.00
Hypertension	45	2.56	0.00
Menstrual Irregularity	45	2.56	0.00
Vertigo	44	2.50	0.00
Vasovagal episode (syncope, faint) +/-tonic clonic movements	39	2.22	0.00
Fever mild	38	2.16	0.004
Oedema	38	2.16	0.004
Lymphadenopathy localized to the region of the injection site	36	2.05	0.004
Sweating	36	2.05	0.004
Exacerbation of existing medical condition	35	1.99	0.004
Malaise	35	1.99	0.004
Visual disturbance	35	1.99	0.004
Itching	33	1.88	0.003
Pericaditis	33	1.88	0.003
Throat soreness	33	1.88	0.003
Tinnitus	33	1.88	0.003
Flushing	31	1.76	0.003
Numbness	30	1.71	0.003
Shivering	26	1.48	0.003
Migraine	25	1.42	0.003
Injection-site pain	24	1.36	0.002
Pain in extremity	23	1.31	0.002
Herpes zoster	22	1.25	0.002
Altered breathing	21	1.19	0.002
Anxious	21	1.19	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 28/09/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 30		
Total Number of reports	**1,778**	**% of Total AZ vacc admin***	**23**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	100	0.014	2	2.00	0.0003
Chest Pain	76	0.010	1	2.63	0.0003
Clot	34	0.005	0	0.000	0.0000
Vertigo	45	0.006	0	0.00	0.0000
Visual disturbance	46	0.006	1	2.17	0.0001
Hypertension	32	0.004	0	0.000	0.0000
Epistaxis	24	0.003	2	8.333	0.0003
Deep vein thrombosis	42	0.006	0	0.000	0.0000
Death	21	0.003	0	0.000	0.0000
Herpes zoster	24	0.0033	0	0.00	0.0000
Pulmonary embolism	43	0.006	2	4.65	0.0003
Atrial fibrillation	13	0.0018	0	0.000	0.0000
Cerebral vascular accident see Stroke	8	0.0011	0	0.000	0.0000
Stroke	12	0.0016	0	0.00	0.0000
Thrombocytopenia	8	0.0011	0	0.000	0.0000
Bells Palsy	6	0.0008	0	0.000	0.0000
Anaphylaxis	3	0.0004	0	0.000	0.0000
Pericarditis	5	0.0007	0	0.000	0.0000
Menstrual Irregularity	7	0.001	0	0.000	0.0000
Guillain Barré syndrome	4	0.0005	1	25.000	0.0001
Myocarditis	4	0.0005	0	0.000	0.0000
Exacerbation of existing medical condition	37	0.005	10	0.000	0.0000
Thrombosis with thrombocytopenia syndrome TTS	4	0.0005	0	0.000	0.0000
Cerebral Venous Sinus Thrombosis	4	0.0005	0	0.000	0.0000
Dyskinesia	2	0.0003	0	0.000	0.0000
Idiopathic thrombocytopenic purpura	5	0.0007	0	0.000	0.0000
Multiple sclerosis	1	0.0001	0	0.000	0.0000

Purpura	11	0.006	0	0.000	0.0000
Ecchymosis	9	0.001	0	0.000	0.0000
Dysgeusia	18	0.003	0	0.000	0.0000
Thrombophlebitis	11	0.006	0	0.000	0.0000
Lymphadenopathy	23	0.003	0	0.00	0.0000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 30**		
Total Number of reports	**1,759**	**% of Total Pfizer vacc admin.***	**101**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	73	0.008	4	5.479	0.000
Chest Pain	199	0.02	9	4.523	0.001
Vertigo	44	0.005	1	2.273	0.000
Dizziness – see Vertigo	120	0.01	11	9.167	0.001
Visual disturbance	35	0.004	1	2.857	0.000
Hypertension	45	0.005	1	2.222	0.000
Death	16	0.002	0	0.000	0.000
Herpes zoster	22	0.002	0	0.000	0.000
Pulmonary embolism	11	0.001	4	36.364	0.000
Bells Palsy	6	0.001	0	0.000	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	37	0.004	1	2.703	0.000
Pericarditis	33	0.003	0	0.000	0.000
Myocarditis	6	0.001	0	0.000	0.000
Menstrual Irregularity	45	0.005	3	6.667	0.000
Exacerbation of existing medical condition	35	0.004	2	5.714	0.000
Miscarriage	3	0.00	0	0.000	0.000
Tinnitus	33	0.003	6	18.182	0.001
Dysgeusia	18	0.002	4	22.222	0.000
Paresthesia	95	0.01	8	0.000	0.001
Facial Paralysis	3	0.00	0	0.000	0.000

Oedema Eyelid	11	0.001	1	9.09	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 28/09/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	**5**	3	21

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	73 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]	48 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	27 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 28/09/2021 YTD:

Number unmatched reports:11 *Reporter contacted to submit SAVSS report	**83** [redacted]
	76 [redacted]
	35 [redacted]
	86 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]
	76 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Date and time vaccinated: **Dose number:** **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	61[redacted]	**Date and time vaccinated**: 04/08/2021 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted]	[redacted]	No Change Change/Review rationale:

			Medical History: [redacted] **GP contacted/notified:** [redacted]. **Classification:** [redacted]		
			Date and time vaccinated: **Dose number:** **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 23 September 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-23-09-2021

Summary

- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.
- To 19 September 2021, approximately 24.8 million vaccine doses have been given in Australia – 15.1 million first doses and 9.7 million second doses.
- The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials. They include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) linked to Vaxzevria (AstraZeneca).
- In the last week, an additional 7 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS. None of these cases were fatal.
- We also continue to carefully monitor reports of suspected myocarditis following the Comirnaty (Pfizer) vaccine, particularly in the younger age groups.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

The most frequently reported side effects suspected to be associated with the vaccines include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.

Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination.

The TGA reviews all deaths reported in people who have been vaccinated. As the number of vaccinated people has increased, so has reporting of fatal events with a coincidental association with vaccination. This does not indicate a link between vaccination and the fatalities reported. Review of individual reports and patterns of reporting does not suggest the vaccines played a role in these deaths.

Since the beginning of the vaccine rollout to 19 September 2021, approximately 24.8 million doses of COVID-19 vaccines have been given. So far, the TGA has found that 9 reports of deaths were linked to immunisation from 556 reports received and reviewed. The overwhelming majority of deaths reported to the TGA following vaccination occurred in people aged 65 years and older. The deaths linked to immunisation occurred after the first dose of Vaxzevria (AstraZeneca) – 8 were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 19 September 2021

2.5	61,738	24,792,054
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

36,255	25,158	355
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	1.7	New South Wales	1.6
Northern Territory	2.3	Queensland	2.4
South Australia	2.5	Tasmania	4.4
Victoria	3.5	Western Australia	2.4

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- [redacted]

- [redacted]

Non-Critical Errors

- [redacted]

[redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

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

- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 31

Meeting date: 12 October 2021

Report period:

29 September 2021 to 05 October 2021

Government of South Australia

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 05/10/2021*

Total doses/episodes: 1,799,795
Individuals received dose 1 = 1,038,158
Individuals received dose 2 = 759,289
Vaxzevria (Astra Zeneca) doses = 744,565 (Dose 1: 418,772 – Dose 2: 325,179)
Pfizer doses = 1,044,870 (Dose 1: 610,070 – Dose 2: 434,106)
Moderna doses = 10,360 (Dose 1: 10,317– Dose 2: 41)

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 05/10/2021 YTD

Number of Reports		**3,638**
Gender	Male	977
	Female	2,652
Indigenous	Yes	49
	No	3,405
	Unknown	128
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**873**
General reactions Total number of COVID-19 Vaccines Reports		**3,305**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,792**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	588	32.81	0.08
Myalgia	376	20.98	0.05
Chills	274	15.29	0.04
Nausea	246	13.73	0.03
Fever not recorded	234	13.06	0.03
Fatigue	189	10.55	0.03
Lethargy	168	9.38	0.02
Arthralgia	153	8.54	0.02
Abdominal Pain	101	5.64	0.01
Vomiting	101	5.64	0.01
Diarrhoea	84	4.69	0.01
Dizziness - see vertigo	82	4.58	0.01
Chest Pain	76	4.24	0.01
Rash	74	4.13	0.01
Dyspnoea	68	3.79	0.01
Malaise	63	3.52	0.01
Fever mild	62	3.46	0.01
Pain	61	3.40	0.01
Paresthesia	47	2.62	0.01
Vertigo	45	2.51	0.01
Pulmonary embolism	44	2.46	0.01
Rigors	44	2.46	0.01
Visual disturbance	43	2.40	0.01
Deep vein thrombosis	42	2.34	0.01
Tachycardia	42	2.34	0.01
Light headedness	40	2.23	0.01
Coughing	39	2.18	0.01
Sweating	38	2.12	0.01
Exacerbation of existing medical condition	37	2.06	0.00

Shivering	36	2.01	0.00
Urticaria	36	2.01	0.00
Injection-site pain	35	1.95	0.00
Clot	34	1.90	0.00
Fever high	34	1.90	0.00
Hypertension	32	1.79	0.00
Rash unspecified	32	1.79	0.004
Migraine	29	1.62	0.004
Influenza-like illness	28	1.56	0.004
Confusion	26	1.45	0.003
Pain in extremity	26	1.45	0.003
Palpitations	26	1.45	0.003
Epistaxis	24	1.34	0.003
Herpes zoster	24	1.34	0.003
Anorexia	23	1.28	0.003
Lymphadenopathy	23	1.28	0.003
Flushing	22	1.23	0.003
Death	21	1.17	0.003
Injection site pain restricting limb mobility	21	1.17	0.003
Pruritus	21	1.17	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.22	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**1,846**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	448	24.27	0.04
Myalgia	310	16.79	0.03
Nausea	263	14.25	0.03
Fatigue	251	13.60	0.02
Chest Pain	226	12.24	0.02
Lymphadenopathy	173	9.37	0.02
Fever not recorded	167	9.05	0.02
Chills	166	8.99	0.02
Lethargy	140	7.58	0.01
Dizziness - see vertigo	135	7.31	0.01
Arthralgia	134	7.26	0.01
Paresthesia	101	5.47	0.01
Vomiting	98	5.31	0.01
Palpitations	90	4.88	0.01
Dyspnoea	85	4.60	0.01
Pain	83	4.50	0.01
Rash	82	4.44	0.01
Abdominal Pain	78	4.23	0.01
Diarrhoea	73	3.95	0.01

Light headedness	66	3.58	0.01
Tachycardia	59	3.20	0.01
Rash unspecified	54	2.93	0.01
Hypertension	47	2.55	0.00
Coughing	46	2.49	0.00
Menstrual Irregularity	46	2.49	0.00
Urticaria	46	2.49	0.00
Vertigo	46	2.49	0.00
Oedema	43	2.33	0.00
Pericaditis	40	2.17	0.004
Sweating	39	2.11	0.004
Vasovagal episode (syncope, faint) +/-tonic clonic movements	39	2.11	0.004
Exacerbation of existing medical condition	38	2.06	0.004
Fever mild	38	2.06	0.004
Malaise	37	2.00	0.004
Itching	36	1.95	0.003
Lymphadenopathy localized to the region of the injection site	36	1.95	0.003
Visual disturbance	36	1.95	0.003
Tinnitus	35	1.90	0.003
Throat soreness	34	1.84	0.003
Flushing	32	1.73	0.003
Shivering	31	1.68	0.003
Numbness	30	1.63	0.003
Migraine	26	1.41	0.002
Altered breathing	24	1.30	0.002
Injection-site pain	24	1.30	0.002
Pain in extremity	23	1.25	0.002
Fever high	22	1.19	0.002
Anxious	21	1.14	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 05/10/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 30		
Total Number of reports	**1,792**	**% of Total AZ vacc admin***	**17**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	101	0.014	1	0.99	0.0001
Chest Pain	76	0.010	0	1.32	0.0001
Clot	34	0.005	0	0.000	0.0000
Vertigo	45	0.006	0	0.00	0.0000
Visual disturbance	43	0.006	0	0.00	0.0000
Hypertension	32	0.004	0	0.000	0.0000
Epistaxis	24	0.003	0	0.000	0.0000
Deep vein thrombosis	42	0.006	0	0.000	0.0000
Death	21	0.003	0	0.000	0.0000
Herpes zoster	24	0.003	0	0.00	0.0000
Pulmonary embolism	44	0.006	1	2.27	0.0001
Atrial fibrillation	13	0.008	0	0.000	0.0000
Cerebral vascular accident see Stroke	8	0.0011	0	0.000	0.0000
Stroke	12	0.0016	0	0.00	0.0000
Thrombocytopenia	8	0.0011	0	0.000	0.0000
Bells Palsy	6	0.0008	0	0.000	0.0000
Anaphylaxis	3	0.0004	0	0.000	0.0000
Pericarditis	5	0.0007	0	0.000	0.0000
Menstrual Irregularity	7	0.0009	0	0.000	0.0000
Guillain Barré syndrome	4	0.0005	0	0.000	0.0000
Myocarditis	4	0.0005	0	0.000	0.0000
Exacerbation of existing medical condition	37	0.0050	0	0.000	0.0000
Thrombosis with thrombocytopenia syndrome TTS	4	0.0005	0	0.000	0.0000
Cerebral Venous Sinus Thrombosis	4	0.0005	0	0.000	0.0000
Dyskinesia	2	0.0003	0	0.000	0.0000
Idiopathic thrombocytopenic purpura	5	0.0007	0	0.000	0.0000
Multiple sclerosis	1	0.0001	0	0.000	0.0000

Purpura	11	0.0015	0	0.000	0.0000
Ecchymosis	9	0.0012	0	0.000	0.0000
Dysgeusia	18	0.0024	0	0.000	0.0000
Thrombophlebitis	11	0.0015	0	0.000	0.0000
Lymphadenopathy	23	0.0031	0	0.00	0.0000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 30**		
Total Number of reports	**1,846**	**% of Total Pfizer vacc admin.***	**93**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	78	0.007	5	6.410	0.000
Chest Pain	226	0.022	27	11.947	0.003
Vertigo	46	0.004	2	4.348	0.000
Dizziness – see Vertigo	135	0.013	15	11.111	0.001
Visual disturbance	36	0.003	1	2.778	0.000
Hypertension	47	0.004	2	4.255	0.000
Death	16	0.002	0	0.000	0.000
Herpes zoster	20	0.002	1	5.000	0.000
Pulmonary embolism	11	0.001	0	0.000	0.000
Bells Palsy	6	0.001	0	0.000	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	34	0.003	0	0.000	0.000
Pericarditis	40	0.004	7	17.500	0.001
Myocarditis	7	0.001	1	14.286	0.000
Menstrual Irregularity	46	0.004	1	2.174	0.000
Exacerbation of existing medical condition	38	0.004	2	5.263	0.000
Miscarriage	3	0.000	0	0.000	0.000
Tinnitus	35	0.003	2	5.714	0.000
Dysgeusia	19	0.002	1	5.263	0.000
Paresthesia	101	0.010	6	0.000	0.001
Facial Paralysis	4	0.000	1	25.000	0.000

Oedema Eyelid	11	0.001	0	0.000	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 05/10/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	**6**	3	22

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	73 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]	48 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	27 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	65 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 05/10/2021 YTD:

Number unmatched reports:11 *Reporter contacted to submit SAVSS report	83 [redacted]
	76 Male – [redacted]
	35 [redacted]
	86 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]
	76 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Date and time vaccinated: **Dose number:** **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	66[redacted]	**Date and time vaccinated**:28/9/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 30 September 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-30-09-2021

Summary

- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.
- To 26 September 2021, approximately 26.8 million vaccine doses have been given in Australia – 16.1 million first doses and 10.7 million second doses.
- The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials. They include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) linked to Vaxzevria (AstraZeneca).
- In the last week, an additional 7 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS, bringing the total number of cases to 148.
- We also continue to carefully monitor reports of suspected myocarditis following the Comirnaty (Pfizer) vaccine, particularly in the younger age groups. To 26 September 2021, we have received 115 reports which were classified as likely to be myocarditis.
- The Spikevax (Moderna) vaccine is now being rolled out in Australia. To 26 September 2021, we have received 5 reports of suspected adverse events.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the general population (16 years of age and over), the most frequently reported side effects suspected to be associated with the vaccines include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle and joint pain, and fever and chills.

Now the vaccines are being rolled out more widely, we are receiving more reports in younger individuals. The TGA is monitoring these reports closely. We know from the Comirnaty (Pfizer) and Spikevax (Moderna) clinical trials that the most common adverse reactions in adolescents are similar to those in older people and include injection-site pain, fatigue and headache. Most of these side effects were mild and resolved within a day or two. For both vaccines, they were more common after the second vaccine dose than the first.

To help us monitor the safety of the COVID-19 vaccines, we encourage people to report suspected side effects even if there is only a small chance that the vaccine caused them. You can also participate in the AusVaxSafety COVID-19 vaccine surveillance program by completing a short survey after receiving your COVID-19 vaccination. The survey is available through state immunisation clinics and other participating vaccine providers. Information collected from the survey is published each week on the AusVaxSafety website and complements our ongoing safety surveillance activities at the TGA.

Total adverse event reports to 26 September 2021

2.4	64,293	26,806,343
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
37,049	26,921	5
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax

To 26 September 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 361.

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	1.7	New South Wales	1.6
Northern Territory	2.3	Queensland	2.4
South Australia	2.4	Tasmania	4.2
Victoria	3.3	Western Australia	2.3

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

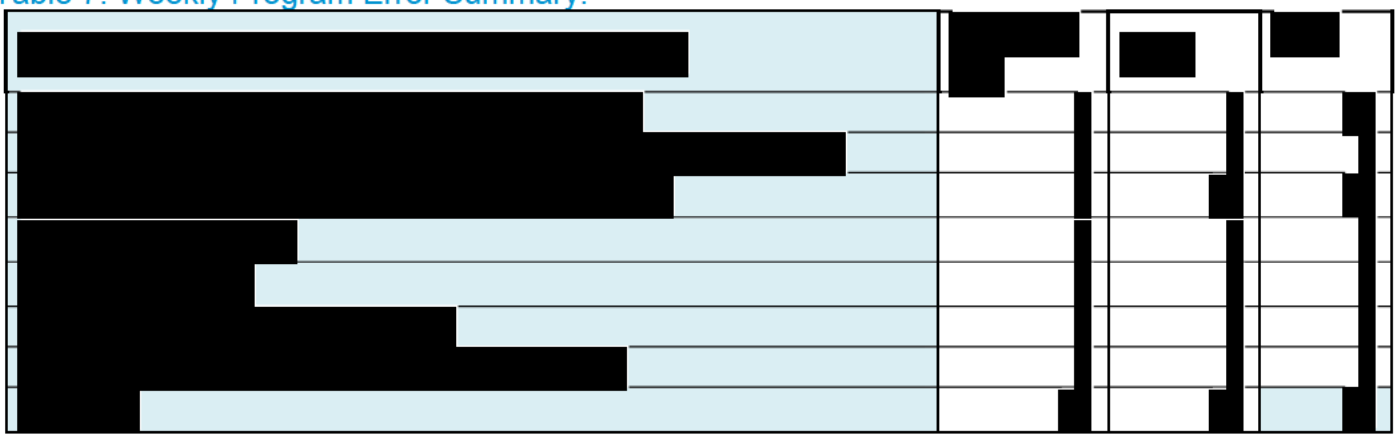
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

[redacted]

ccine) 30/09/2021 – not administered

[redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis

- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Document 21

OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 11

Meeting date: 19 May 2021

Report period: 13 May 2021 to 19 May 2021

Government of South Australia

SA Health

List of Tables

Appendices

Summary

Vaccination recorded to the Australian Immunisation Register as at 18 May 2021*

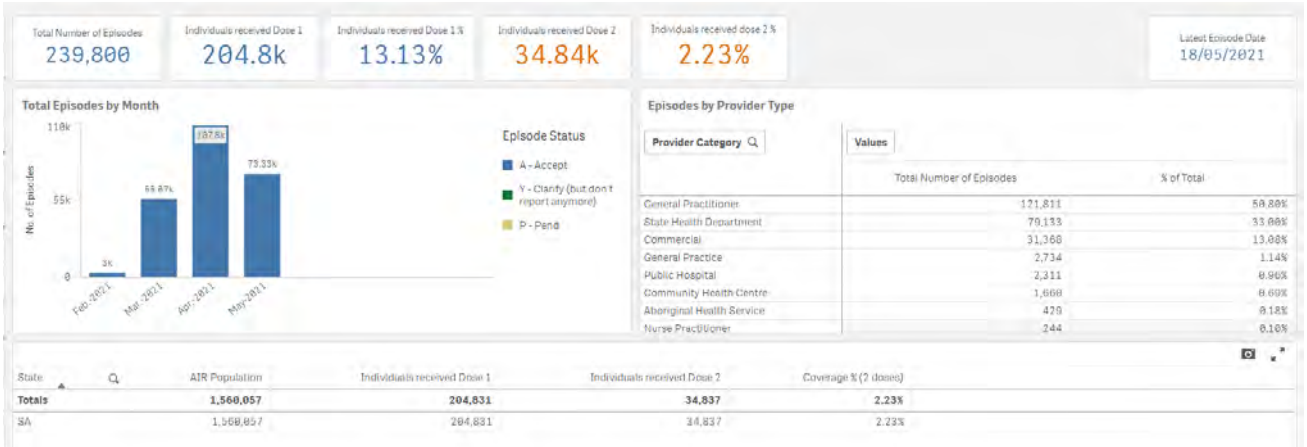
Total doses/episodes: 239,800

Individuals received dose 1 = 204831

Individuals received dose 2 = 34,837

Pfizer doses = 90,310

AstraZeneca = 149,490



*Latest available data from Australian Immunisation Regsiter report

Background

South Australia's COVID-19 vaccination program commenced on 22 February 2021 with Pfizer's Comirnaty vaccine and on 5 March 2021 with AstraZeneca's COVID-19 vaccine.

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.

Adverse reactions definitions and the TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines are listed in Appendix 1.

As part of the vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program, reports are received and analysed by the South Australian Vaccine Safety Surveillance System (SAVSSS). Each report is automatically uploaded to the TGA. Any report requiring follow up is analysed by the COVID-19 Vaccination Program - Immunisation Coordination Unit and reported to the COVID-19 Vaccine Safety Committee for review.

This report provides a record of all reports received into SAVSSS on Table 1.

Details of AEFIs and AESIs received following Pfizer's COVID-19 Comirnaty vaccine and AstraZeneca vaccines administered are recorded on Table 2 and Table 3 respectively. These will be reviewed by the Committee on weekly basis.

The report will be tabled up to 24 hours prior to the Committee meeting.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Table 5 will outlines the Therapeutic Goods Administration COVID-19 vaccine weekly safety report.

Table 1: Summary of all COVID-19 vaccine AEFI report received into SAVSSS as at 19/05/2021 YTD

Number of Reports		1,031
Gender	Male	259
	Female	767
Indigenous	Yes	15
	No	941
	Unknown	48

Injection Site Reactions Total Number of Reports	259

General reactions	
Total number of reports	961
Headache	323
Myalgia	244
Nausea	165
Fever not recorded	138
Chills	135
Fatigue	106
Lethargy	106
Arthralgia	82
Fever mild	54
Vomiting	53
Dizziness - see vertigo	51
Abdominal Pain	40
Dyspnoea	40
Injection-site pain	36
Rash	36
Chest Pain	33
Diarrhoea	33
Hypertension	31
Lymphadenopathy	31
Pain	31
Clot	29
Rash unspecified	29
Tachycardia	29
Light headedness	26
Paresthesia	25

Vertigo	25
Malaise	24
Rigors	24
Confusion	23
Fever high	21
Flushing	21

Individual Brands	AstraZeneca COVID 19 vaccine	685
	Pfizer Comirnaty	360

Table 2: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	88[redacted]	**Date and time vaccinated**: 13/5/21 @ 12:47pm **Dose number:** 1 [redacted]	[redacted]

Table 3: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	77[redacted]	**Date and time vaccinated**: 7/5/2021 @ 10:10 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	54[redacted]	**Date and time vaccinated**: 4/5/2021 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	72[redacted]	**Date and time vaccinated**: 28/4/21 @ 10:28am **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]	80[redacted]	**Date and time vaccinated**: 05/05/21 @ 10:00 **Dose number: 1** [redacted]	[redacted]

[redacted]	[redacted]	70[redacted]	**Date and time vaccinated**: 29/4/21 @ 14:00 **Dose number:** 1 **Details:** [redacted] - [redacted]	[redacted]
[redacted]	[redacted]	71[redacted]	**Date and time vaccinated**: 27/4/2021 @ 09:46am **Dose number:** 1 [redacted])- [redacted]	[redacted]

Table 4: Special Interest AEFI Topics:

	YTD	Week 11
Total Number of reports	564	69
Myalgia	354	42
Arthralgia	160	25
Abdominal Pain (pancreatitis)	69 (2 pancreatitis)	9 (1 pancreatitis)
Chest Pain (chest tightness, angina)	52	5
Pain	45	6
Clot	38	4
Visual disturbance	24	6
Epistaxis	16	0
Death	21	4
Deep vein thrombosis	4	4
Stroke	12	3
Atrial fibrillation	8	0
Cellulitis at the injection site	5	0
Thrombocytopenia	3	0
Hyperglycaemia	8	6
Miscarriage	1	0
Pericaditis	4	0
Vertigo	33	2
Arthritis	2	1
Herpes Zoster	5	0

TGA unmatched reports

Four as at 19/05/2021.

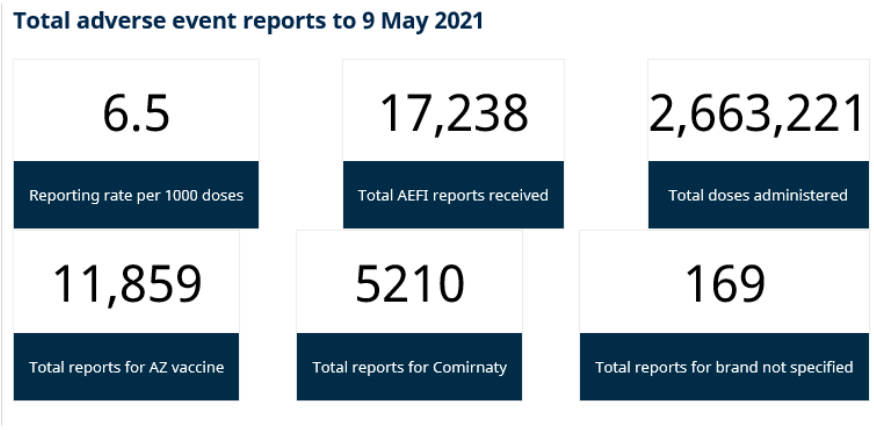
Table 5: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website as – [COVID-19 vaccine weekly safety report-13/05/2021](https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report)

https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

Summary

- The most frequently reported suspected side effects associated with COVID-19 vaccines continue to be events that are commonly experienced with vaccines generally, including headache, muscle and joint pain, fever and injection site reactions. Most people in clinical trials of the AstraZeneca and Pfizer Comirnaty COVID-19 vaccines experienced one or more of these side effects.
- Seven additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca COVID-19 vaccine. The United Kingdom (UK) is the country with the widest utilisation of the AstraZeneca vaccine. When assessed using the case definition developed by the UK's Medicines and Health products Regulatory Agency, three cases are confirmed and four are deemed probable TTS.



Reporting rates per 1000 doses by jurisdiction

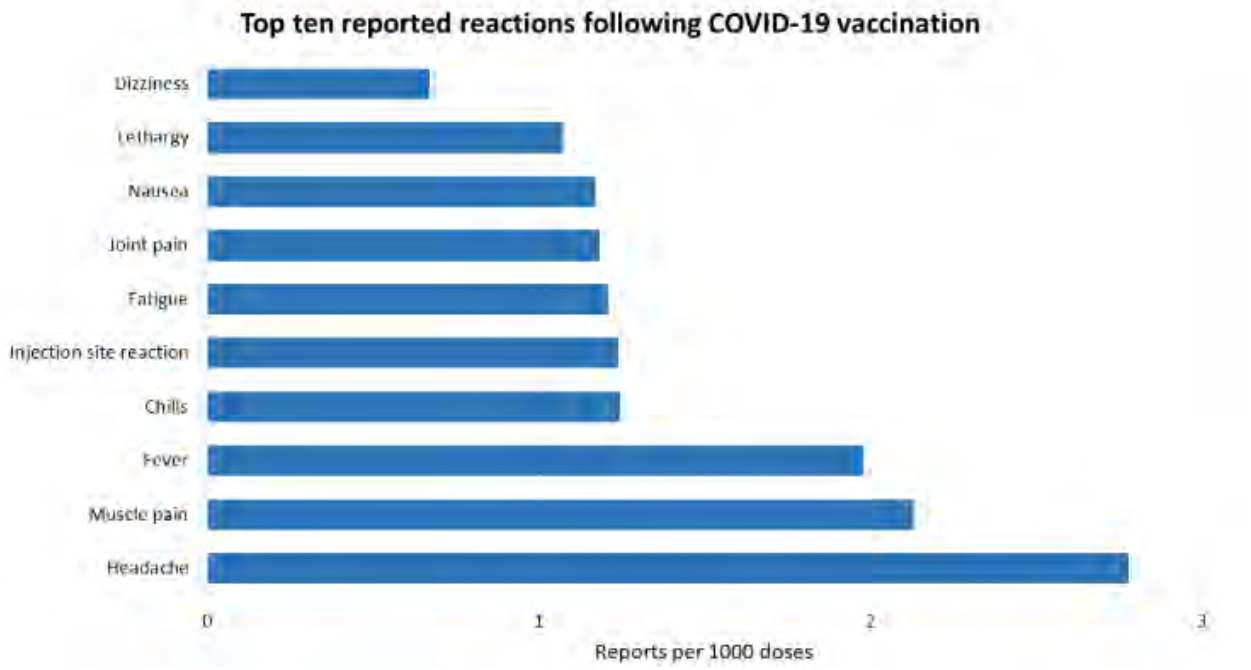
Australian Capital Territory	5.4	New South Wales	4.5
Northern Territory	6.9	Queensland	5.8
South Australia	5.4	Tasmania	8.4
Victoria	10.0	Western Australia	4.4

Most commonly reported COVID-19 vaccine side effects

The adverse events most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally, including headache, muscle and joint pain, fever and injection site reactions.

Adverse events following immunisation (AEFI) most frequently reported to the TGA are shown in the below graph.

Headache is the most common reaction reported to the TGA for both vaccines. Almost half of the headaches reported to the TGA lasted for less than a day, and most headaches had resolved by three days. People who have a severe or persistent headache should seek medical advice.



Thrombosis with thrombocytopenia syndrome

Thrombosis with thrombocytopenia syndrome (TTS) is a very rare event involving serious blood clots with a low blood platelet count. Emerging evidence suggests it is caused by the AstraZeneca vaccine. The TGA and other medicines regulators around the world continue to monitor and investigate this issue.

In response to this safety concern, ATAGI has recommended that Comirnaty (Pfizer) be preferred over the AstraZeneca vaccine in people aged under 50. This week the TGA has approved further changes to the Product Information to inform health professionals about recognising and managing possible TTS. ATAGI also addresses TTS in its weekly statements about COVID-19 vaccines(link is external).

Medical officers at the TGA continue to investigate suspected cases and share information with other medicines regulators. The TGA determines whether a report is likely to represent TTS by assessing cases against a consistent set of criteria,

based on the case definitions established by the UK Medicines and Health products Regulatory Agency. This allows for rapid assessment and facilitates comparison with the assessments of other medicines regulators. These criteria include:

- evidence of a thrombosis (blood clot)
- thrombocytopenia (blood platelet count below a certain threshold)
- results of blood tests for a specific protein produced by the body to break down clots (D-dimer) and antibodies that activate platelets (anti-PF4 antibodies).

Cases that meet all of the criteria are considered to be confirmed. Cases meeting most of the criteria are classified as probable. Internationally and in Australia, research continues on the utility of other blood tests (including platelet functional assays) on suspected cases to contribute to understanding of TTS. At present, the results of these other tests are not routinely included in our assessment of criteria.

Since last week's report, a further seven reports of blood clots and low blood platelets have been assessed as TTS and considered likely to be linked to the AstraZeneca vaccine. Three of these cases are considered confirmed, and include a 75-year-old man from Victoria, a 75-year-old man from Western Australia, and a 59-year-old Queensland man who was diagnosed in Victoria. Of these, only the Victorian man remains in hospital, but is responding to treatment and is in a stable condition. The other two patients are not currently in hospital and are thought to be well. Four other newly reported cases are considered to be probable TTS. This includes three men from Victoria aged 65, 70 and 81 years, and a 70-year-old man from NSW. All but one of the newly reported cases was vaccinated after the 8 April 2021 recommendation by ATAGI that Comirnaty is preferred over the AstraZeneca vaccine in adults aged under 50 years.

This takes the total Australian reports of cases assessed as TTS following the AstraZeneca vaccine to 18. So far about 1.8 million doses of the AstraZeneca vaccine have been administered.

With regard to all confirmed cases of TTS mentioned in previous weekly reports, all patients (with the exception of the fatality of a 48-year-old woman from NSW) are recovering and stable.

The reporting rates of TTS in Australia are consistent with what is being seen internationally. However, we believe that a higher proportion of less severe cases may be being reported in Australia. This may be due to high levels of awareness in the community and among the medical profession around TTS along with less strain on the healthcare system around COVID infections with much lower infection rates than internationally.

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

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OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 12

Meeting date: 27 May 2021

Report period: 19 May 2021 to 26 May 2021

Government of South Australia

SA Health

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Appendices

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 25/05/2021*

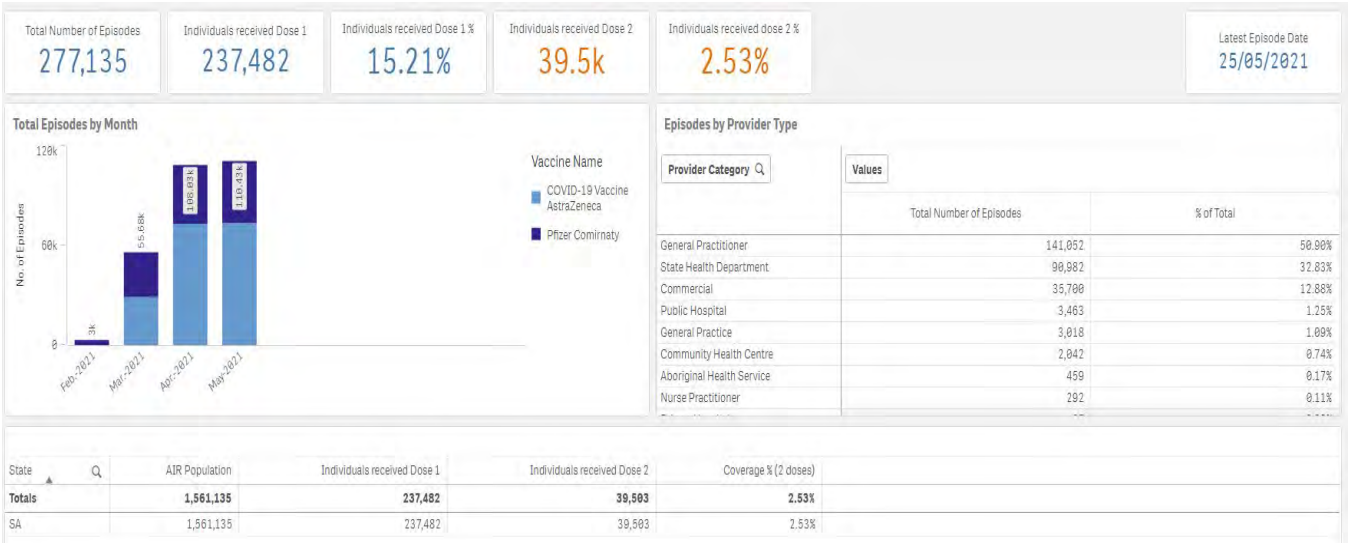
Total doses/episodes: 277,135

Individuals received dose 1 = 237,482

Individuals received dose 2 = 39,500

Pfizer doses = 102,365 (Dose 1 63,379 – Dose 2 38,900)

AstraZeneca doses = 174, 774 (Dose 1 174,160 – Dose 2 609)



*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 26/05/2021 YTD

Number of Reports		**1,177**
Gender	Male	299
	Female	872
Indigenous	Yes	15
	No	1,078
	Unknown	56

Injection Site Reactions Total Number of Reports	**283**

General reactions	**1,105**
Headache	375
Myalgia	276
Nausea	185
Chills	166
Fever not recorded	159
Fatigue	119
Lethargy	119
Arthralgia	103
Vomiting	61
Dizziness - see vertigo	60
Fever mild	59
Abdominal Pain	54
Dyspnoea	47
Diarrhoea	44
Rash	43
Chest Pain	41
Lymphadenopathy	38
Injection-site pain	37
Pain	36
Hypertension	33
Clot	32
Rash unspecified	32
Tachycardia	32
Light headedness	28
Paresthesia	28
Vertigo	28
Rigors	27
Flushing	25
Malaise	25
Confusion	24

Coughing	23
Fever high	23
Urticaria	22
Visual disturbance	21
Death	20

Individual Brands	AstraZeneca COVID 19 vaccine	794
	Pfizer Comirnaty	397

Table 2: Special Interest AEFI Topics:

Total Number of reports	YTD	Week 12
	671	89
Myalgia	407	45
Arthralgia	200	34
Abdominal Pain (pancreatitis)	92 (2 pancreatitis)	21 (1 pancreatitis)
Chest Pain (chest tightness, angina)	66	12
Pain	51	4
Clot	44	6
Visual disturbance	30	5
Epistaxis	19	3
Death	26	5
Deep vein thrombosis	6	2
Stroke (CVA)	12	4
Atrial fibrillation	10	2
Cellulitis at the injection site	5	0
Thrombocytopenia	3	0
Hyperglycaemia	10	2
Miscarriage	1	0
Pericaditis	4	0
Vertigo	38	5
Arthritis	3	1
Herpes Zoster (including varicella like rash)	5	0 (2 varicella like rash)
Angina Pectoris	2	2
Pulmonary Embolus	3	2
Ananphylaxis	3	0

Table 3: TGA Possible/Confirmed TTS Summary as at 26/5/2021

Confirmed	Probable (deemed to meet criteria*, awaiting TGA determination)	Possible	Total
1	1	3	5

[redacted]	Age [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	53	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	48	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	74	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	68	[redacted]	[redacted]	Astra Zeneca - ?	[redacted]

Table 4: TGA unmatched AEFI reports as at 26/05/2021

Number unmatched reports: 6	81 [redacted]
	26 [redacted]
	82 [redacted]
	78 [redacted]
	52 [redacted]
*Reporter contacted to submit SAVSS report	73 [redacted]

Table 5: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	[redacted] 88	**Date and time vaccinated**: 21/5/21 **Dose number: 1** [redacted] **Treatment**: [redacted]	[redacted]
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review

Table 6: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	[redacted] 73	**Date and time vaccinated**: 3/5/21 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 54	**Date and time vaccinated**: 10/5/21 **Dose number: 1** [redacted] **Treatment:** **Medical History:**	[redacted]
[redacted]		[redacted] 57	**Date and time vaccinated**: 3/4/21 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 68	**Date and time vaccinated**: 18/5/21 **Dose number: 1** [redacted]	[redacted]
[redacted]	[redacted]	[redacted] - 55	**Date and time vaccinated**: 19/5/21 @ 15.57 **Dose number: 1** [redacted]	[redacted]

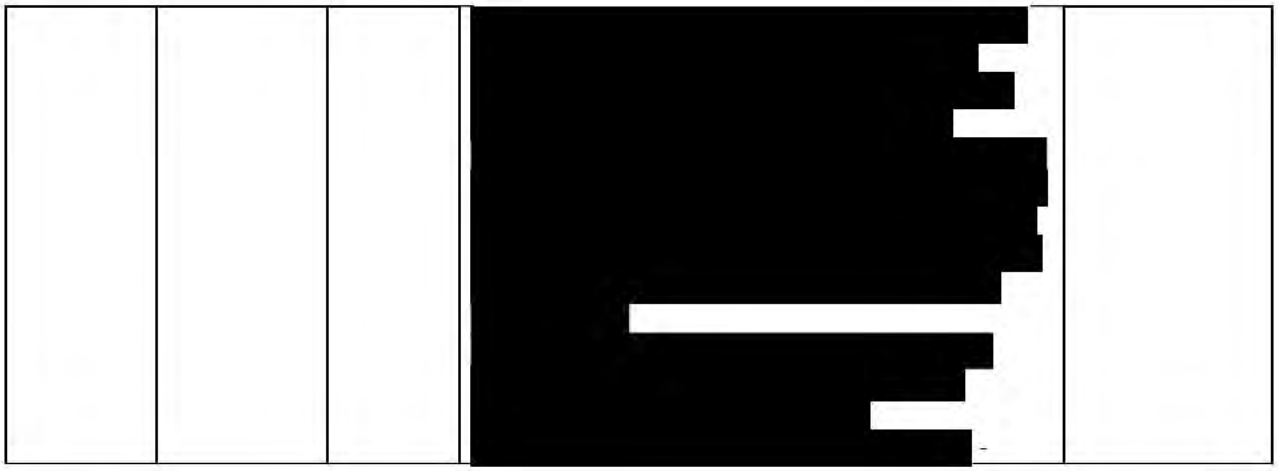


Table 7: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-27-05-2021

6.1	22,031	3,613,053
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
15,273	6652	198
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	5.2	New South Wales	4.2
Northern Territory	6.2	Queensland	5.5
South Australia	5.2	Tasmania	7.9
Victoria	9.4	Western Australia	4.2

Summary

The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.

Nine additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, six cases are confirmed TTS and three are probable.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 17-23 May 2021 we received 1609 AEFI reports for COVID-19 vaccines.

Total adverse event reports to 23 May 2021

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 13

Meeting date: 03 June 2021

Report period: 26 May 2021 to 02 June 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 01/06/2021*

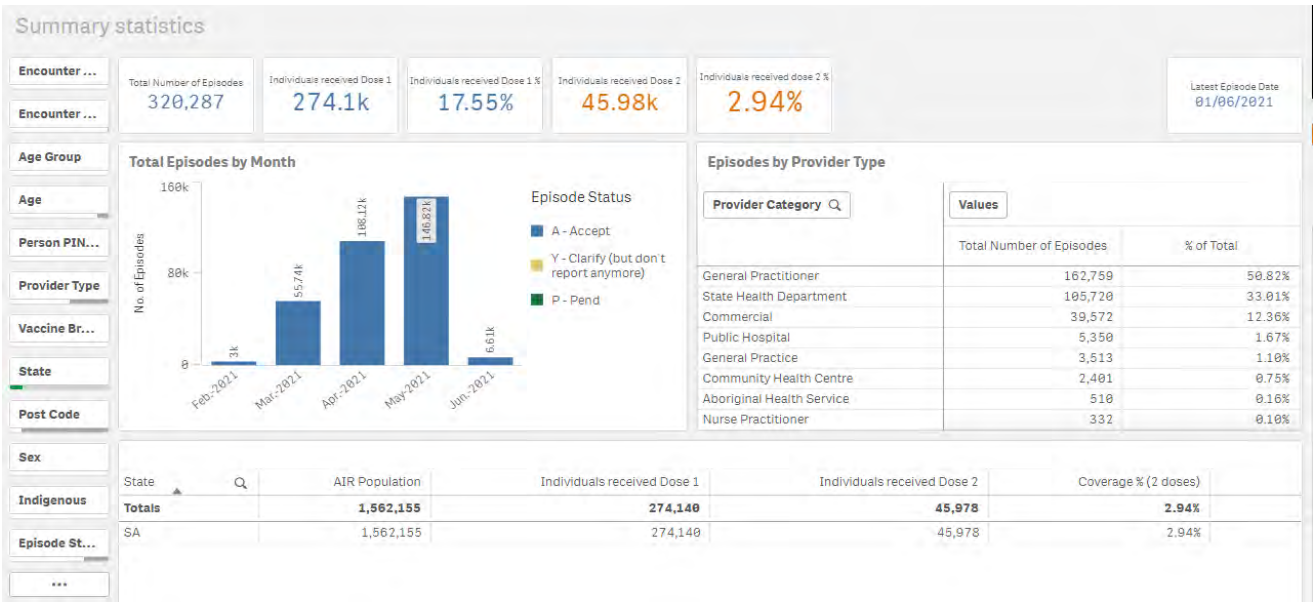
Total doses/episodes: 320,287

Individuals received dose 1 = 274,140

Individuals received dose 2 = 45,978

Pfizer doses = 116,184 (Dose 1: 71,404 – Dose 2: 44,683)

AstraZeneca doses = 204,103 (Dose 1: 202,804 – Dose 2: 1,297)



*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 02 June 2021 YTD

Number of Reports		**1,287**
Gender	Male	328
	Female	955
Indigenous	Yes	17
	No	1,183
	Unknown	58
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**312**
General reactions Total number of COVID-19 Vaccines Reports		**1200**

Astra Zeneca **Total General Reactions:**	**814**
Headache	306
Myalgia	222
Chills	156
Fever not recorded	145
Nausea	142
Lethargy	93
Fatigue	86
Arthralgia	84
Vomiting	51
Fever mild	47
Dizziness - see vertigo	41
Diarrhoea	39
Abdominal Pain	38
Dyspnoea	34
Clot	31
Rash	31
Injection-site pain	30
Chest Pain	28
Rigors	27
Tachycardia	26
Malaise	25
Vertigo	24
Pain	21
Confusion	20
Fever high	20
Light headedness	19
Visual disturbance	19
Hypertension	18
Coughing	17

Influenza-like illness	16
Flushing	15
Rash unspecified	15
Insomnia	14
Sweating	14
Injection site pain restricting limb mobility	13
Migraine	13
Paresthesia	13
Anorexia	12
Urticaria	12
Vasovagal episode (syncope, faint) +/-tonic clonic movements	11
Deep vein thrombosis	10
Death	9

Pfizer **Total General Reactions**	 **386**
Headache	105
Myalgia	80
Nausea	65
Fatigue	40
Lymphadenopathy	38
Lethargy	33
Arthralgia	31
Fever not recorded	29
Chills	27
Dizziness - see vertigo	25
Paresthesia	22
Abdominal Pain	21
Rash	21
Chest Pain	20
Hypertension	18
Vomiting	18
Rash unspecified	17
Pain	16
Light headedness	15
Diarrhoea	14
Dyspnoea	14
Flushing	14
Urticaria	14
Fever mild	13
Death	12
Tachycardia	12
Coughing	11

Injection-site pain	10
Itching	10

Table 2: Special Interest AEFI Topics as at 02 June 2021 YTD:

Total Number of reports	YTD	Week 13
	740	67
Myalgia	441	35
Arthralgia	219	19
Abdominal Pain (pancreatitis)	99 (2 pancreatitis)	7
Chest Pain (chest tightness, angina)	77	10
Pain	50	0
Clot	48	4
Visual disturbance	38	8
Epistaxis	20	1
Death	28	2
Deep vein thrombosis	11	5
Stroke	12	0
CVA	5	0
Atrial fibrillation	11	1
Cellulitis at the injection site	5	0
Thrombocytopenia	4	1
Hyperglycaemia	10	0
Miscarriage	1	0
Pericaditis	4	0
Vertigo	41	2
Arthritis	4	1
Herpes Zoster	7	2
Varicella like rash	2	0
Angina Pectoris	2	2
Pulmonary Embolus	5	2
Anaphylaxis	4	1

Table 3: TGA reported TTS Summary as at 02 June 2021 YTD:

Confirmed	Probable (deemed to meet criteria*, awaiting TGA determination)	Possible	Total
1	1	0	0

Summary of cases:

[redacted]	Age[redacted]r	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 02 June 2021:

Number unmatched reports: 6 *Reporter contacted to submit SAVSS report	81 [redacted] – [redacted]*
	76 [redacted] – [redacted]*

Table 5: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review
			Date and time vaccinated: **Dose number:** **Details:** **Treatment**: **Medical History:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting Specialist review

Table 6: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	[redacted] 26	**Date and time vaccinated:** 16/4/21 @ 14:30 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 51	**Date and time vaccinated:** 26/5/2021 11:40 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 81	**Date and time vaccinated:** 30/5/2021 @ 0915 **Dose number:** 1 [redacted] **Treatment:** [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 74	**Date and time vaccinated:** 21/05/2021 **Dose number:** 1 [redacted] **Medical History:** [redacted]	[redacted]

[redacted]	[redacted]	[redacted] 91	**Date and time vaccinated**: 21/5/21 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 82	**Date and time vaccinated**: 7/4/21 **Dose number:** ? [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 78	**Date and time vaccinated**: 25/03/2021 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 67	**Date and time vaccinated**: 17/5/21 @ 09.28 **Dose number:** 1 [redacted]	[redacted]

Table 7: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-27-05-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Nine additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, six cases are confirmed TTS and three are probable.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 17-23 May 2021 we received 1609 AEFI reports for COVID-19 vaccines.

Total adverse event reports to 23 May 2021

6.1	22,031	3,613,053
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

15,273	6652	198
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	5.2	New South Wales	4.2
Northern Territory	6.2	Queensland	5.5
South Australia	5.2	Tasmania	7.9
Victoria	9.4	Western Australia	4.2

Most commonly reported COVID-19 vaccine side effects

The AEFI most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally. They include headache, muscle and joint pain, fever and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 17-23 May 2021 were headache, muscle pain, fever, chills and fatigue.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 17-23 May 2021 were headache, muscle pain, lethargy, fever and injection site reactions.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

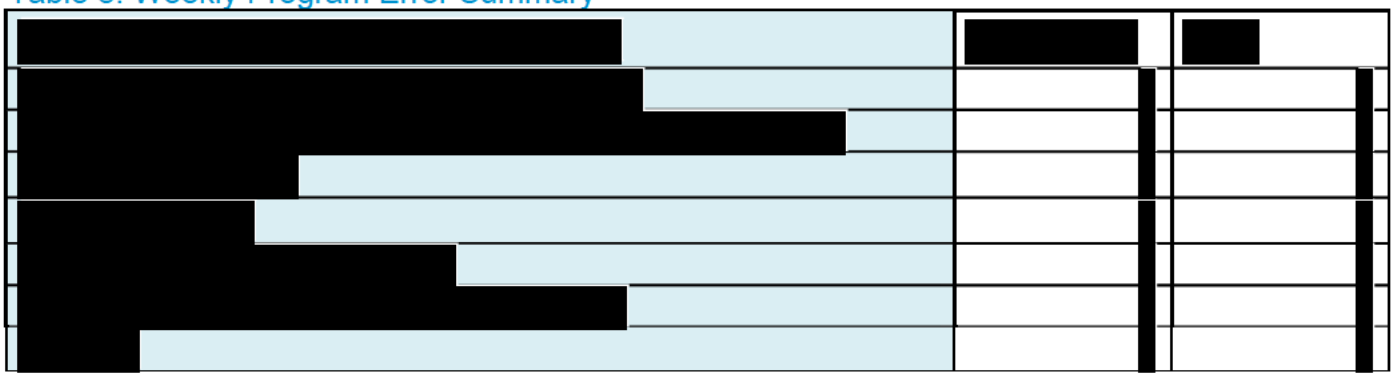
They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

Non-Critical Errors

- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 14

Meeting date: 10 June 2021

Report period: 02 June 2021 to 09 June 2021

Government of South Australia
SA Health

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Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 09/06/2021*

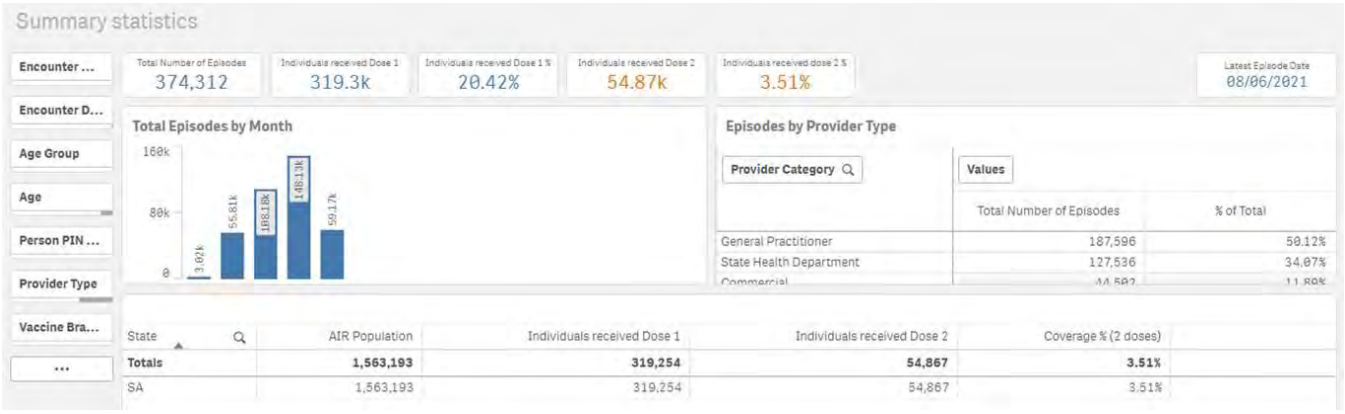
Total doses/episodes: 374,312

Individuals received dose 1 = 319,254

Individuals received dose 2 = 54,867

Pfizer doses = 135,674 (Dose 1: 83,968 – Dose 2: 51,601)

AstraZeneca doses = 238,638 (Dose 1: 235,367 – Dose 2: 3,268)



*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 09 June 2021 YTD to be updated from SAVSS

Number of Reports		**1,425**
Gender	Male	358
	Female	1,063
Indigenous	Yes	17
	No	1,319
	Unknown	60
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**353**
General reactions Total number of COVID-19 Vaccines Reports		**1,312**

Astra Zeneca **Total General Reactions:**	**882**	**% of Total**
Headache	329	37%
Myalgia	234	27%
Chills	172	20%
Fever not recorded	154	17%
Nausea	151	17%
Lethargy	99	11%
Arthralgia	95	11%
Fatigue	93	11%
Vomiting	55	6%
Fever mild	48	5%
Dizziness - see vertigo	44	5%
Diarrhoea	42	5%
Abdominal Pain	41	5%
Dyspnoea	35	4%
Rash	35	4%
Clot	31	4%
Chest Pain	29	3%
Injection-site pain	29	3%
Malaise	28	3%
Rigors	28	3%
Pain	26	3%
Tachycardia	26	3%
Vertigo	26	3%
Fever high	22	2%
Light headedness	21	2%
Confusion	20	2%
Visual disturbance	20	2%
Coughing	18	2%
Hypertension	18	2%

Influenza-like illness	17	2%
Flushing	16	2%
Rash unspecified	16	2%
Sweating	16	2%
Injection site pain restricting limb mobility	15	2%
Insomnia	15	2%
Urticaria	15	2%
Migraine	14	2%
Paresthesia	14	2%
Anorexia	13	1%
Deep vein thrombosis	13	1%
Death	11	1%
Vasovagal episode (syncope, faint) +/-tonic clonic movements	11	1%
Dysgeusia	10	1%
Palpitations	10	1%
Pruritus	10	1%

Pfizer **Total General Reactions**	**430**	**% of Total**
Headache	116	27%
Myalgia	84	20%
Nausea	69	16%
Fatigue	41	10%
Lymphadenopathy	40	9%
Chills	36	8%
Fever not recorded	36	8%
Lethargy	35	8%
Arthralgia	34	8%
Dizziness - see vertigo	25	6%
Chest Pain	24	6%
Paresthesia	23	5%
Pain	22	5%
Rash	22	5%
Abdominal Pain	21	5%
Vomiting	20	5%
Hypertension	19	4%
Light headedness	18	4%
Rash unspecified	18	4%
Coughing	16	4%
Urticaria	16	4%
Dyspnoea	15	3%
Fever mild	15	3%
Injection-site pain	15	3%

Death	14	3%
Diarrhoea	14	3%
Flushing	14	3%
Tachycardia	13	3%
Vertigo	13	3%
Itching	11	3%
Menstrual Irregularity	11	3%

Table 2: Special Interest AEFI Topics as at 09 June 2021 YTD

Total Number of reports	YTD	Week 14
	651	48
Myalgia	467	19
Arthralgia	241	18
Abdominal Pain (pancreatitis)	102 (2 pancreatitis)	1
Chest Pain (chest tightness, angina)	86	7
Pain	63	9
Clot	49	1
Visual disturbance	40	0
Epistaxis	21	1
Death	31	1
Deep vein thrombosis	15	3
Stroke	12	0
CVA	5	0
Atrial fibrillation	12	1
Cellulitis at the injection site	5	0
Thrombocytopenia	4	0
Hyperglycaemia	10	0
Miscarriage	1	0
Pericaditis	4	0
Vertigo	50	4
Arthritis	4	0
Herpes Zoster	12	5
Varicella like rash	2	0
Angina Pectoris	2	0
Pulmonary Embolus	8	3
Anaphylaxis	4	0
Hypertension	50	1
Menstrual Irregularity	10	6
Bells Palsy	2	2

Table 3: TGA reported TTS Summary as at 09 June 2021 YTD:

Confirmed	Probable (deemed to meet criteria*, awaiting TGA determination)	Possible	Total
1	1	0	0

Summary of cases:

[redacted]	Age [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	73 [redacted]	[redacted]	[redacted]	Astra Zeneca -1	[redacted]
[redacted]	91 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	26 [redacted]	[redacted]	[redacted]	TBC Astra Zeneca-1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]

[redacted]	73 [redacted]	[redacted]	[redacted]	Astra Zeneca -1	[redacted]
[redacted]	89 [redacted]	[redacted]	[redacted]	Astra Zenca 1	[redacted]
[redacted]	47 [redacted]	[redacted]	[redacted]	Astra Zenca 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 09 June 2021:

Number unmatched reports: 6 *Reporter contacted to submit SAVSS report	81 [redacted]
	76 [redacted]*

Table 5: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	33yo [redacted]	**Date and time vaccinated:** **Dose number:** 29/04/2021 – D 1 19/05/2021 – D 2 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 33	**Date and time vaccinated:** 22/05/2021@ 0900hrs **Dose number:** Pfizer D1 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 93	**Date and time vaccinated:** 21/5/21 @ 14:00hrs **Dose number: Pfizer D1** [redacted]	[redacted]

			First dose Pfizer on 21/05 [redacted]	

Table 6: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	[redacted] - 96	**Date and time vaccinated:** 29/05/2021 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	[redacted] 80	**Date and time vaccinated:** 30/04/2021 **Dose number:** AZ D1 [redacted]	[redacted]

Table 7: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 03/06/2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-03-06-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Eight additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, four cases are confirmed and four are deemed probable TTS. This brings the total number of confirmed and probable TTS cases in Australia to 41.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 24-30 May 2021 we received 1825 AEFI reports for COVID-19 vaccines.

Total adverse event reports to 30 May 2021

5.8	24,402	4,243,600
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

16,983	7205	217
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	5.1	New South Wales	4.0
Northern Territory	5.8	Queensland	5.3
South Australia	5.2	Tasmania	7.9
Victoria	8.4	Western Australia	4.0

Most commonly reported vaccine side effects

The AEFI most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally. They include headache, muscle and joint pain, fever and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 24-30 May 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 24-30 May 2021 were headache, muscle pain, lethargy, joint pain and nausea.

This week we focus on dizziness and fainting as side effects relating to COVID-19 vaccination.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

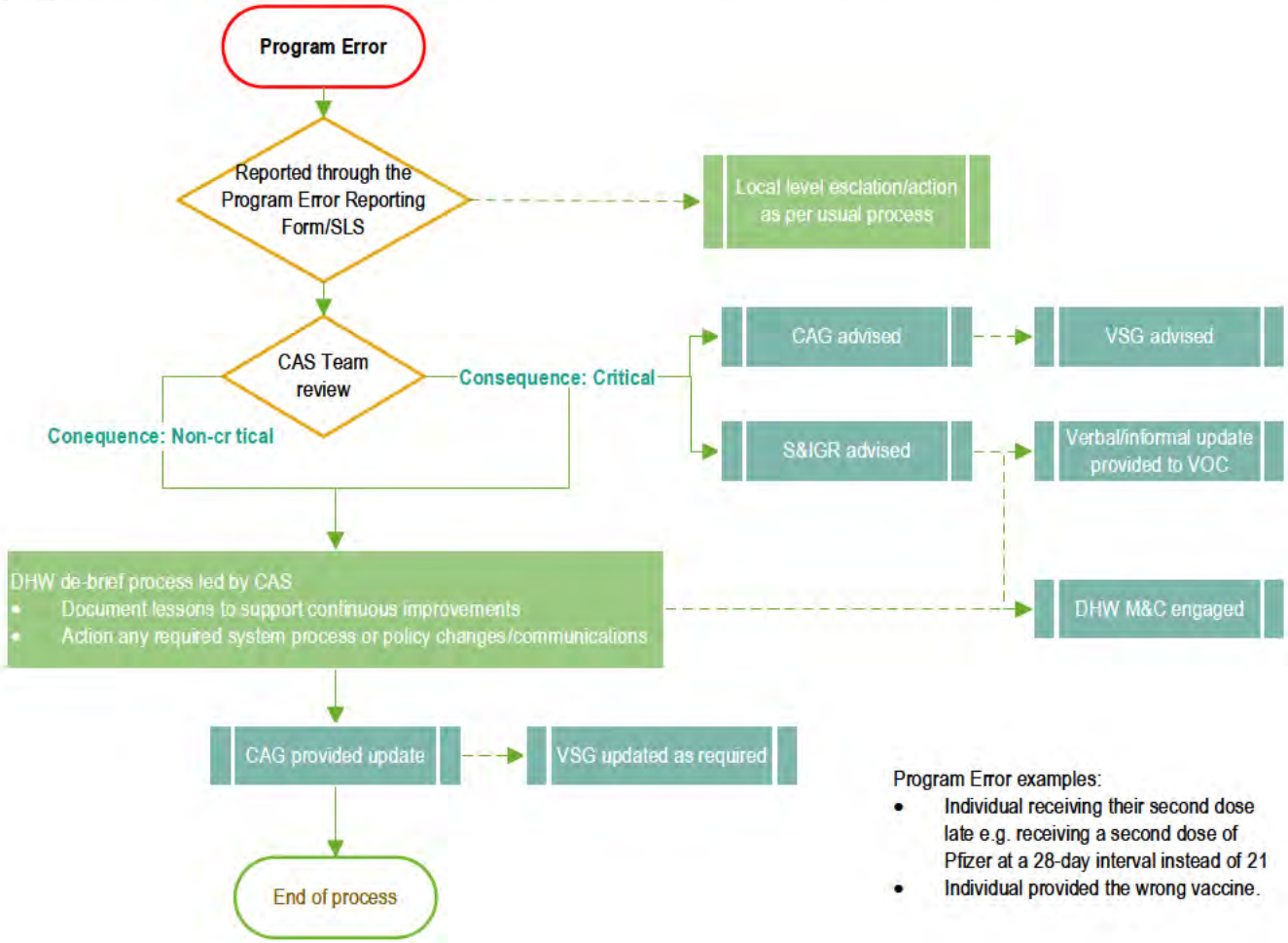
[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

Appendix 4.

INCIDENT ESCALATION AND COMMUNICATION PROCESS FLOW - CLINICAL



Program Error examples:

- Individual receiving their second dose late e.g. receiving a second dose of Pfizer at a 28-day interval instead of 21
- Individual provided the wrong vaccine.

DHW: Department for Health and Wellbeing
VOC: Vaccine Operations Centre
CAS: Clinical Advisory Service Team
CAG: Clinical Advisory Group

M&C: Media and Communications team
S&IGR: Strategy and Intergovernment Relations team
VSG: Vaccine Strategy Group
SLS: Safety Learning System

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OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 15

Meeting date: 17 June 2021

Report period: 09 June 2021 to 16 June 2021

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 3 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine and (3) frequency of AEFI associated with the Astra Zeneca vaccines (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 1706/2021*

Total doses/episodes: 449,329
Individuals received dose 1 = 377,295
Individuals received dose 2 = 71,794
Pfizer doses = 167,361 (Dose 1: 106,299– Dose 2: 60,948)
AstraZeneca doses = 281,968 (Dose 1:271,100 – Dose 2: 10,848)

*Latest available data from Australian Immunisation Regsiter report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 16 June 2021 YTD

Number of Reports		**1,518**
Gender	Male	378
	Female	1,136
Indigenous	Yes	17
	No	1,411
	Unknown	60
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**369**
General reactions Total number of COVID-19 Vaccines Reports		**1,402**

Astra Zeneca **Total General Reactions:**	**938**	**% of Total**
Headache	349	37%
Myalgia	239	25%
Chills	183	20%
Nausea	163	17%
Fever not recorded	160	17%
Lethargy	100	11%
Arthralgia	99	11%
Fatigue	99	11%
Vomiting	59	6%
Fever mild	49	5%
Diarrhoea	48	5%
Abdominal Pain	46	5%
Dizziness - see vertigo	44	5%
Rash	38	4%
Dyspnoea	35	4%
Malaise	34	4%
Pain	33	4%
Chest Pain	32	3%
Clot	32	3%
Rigors	30	3%
Tachycardia	30	3%
Injection-site pain	29	3%
Vertigo	29	3%
Light headedness	24	3%
Fever high	23	2%
Confusion	20	2%
Coughing	20	2%
Visual disturbance	20	2%
Hypertension	19	2%

Flushing	18	2%
Influenza-like illness	17	2%
Rash unspecified	16	2%
Sweating	16	2%
Deep vein thrombosis	15	2%
Injection site pain restricting limb mobility	15	2%
Insomnia	15	2%
Paresthesia	15	2%
Urticaria	15	2%
Migraine	14	1%
Anorexia	13	1%
Death	12	1%
Shivering	12	1%
Epistaxis	11	1%
Palpitations	11	1%
Vasovagal episode (syncope, faint) +/-tonic clonic movements	11	1%
Dysgeusia	10	1%
Herpes zoster	10	1%
Lymphadenopathy	10	1%
Pain in extremity	10	1%
Pruritus	10	1%

Pfizer **Total General Reactions**	**464**	**% of Total**
Headache	129	28%
Myalgia	87	19%
Nausea	72	16%
Fatigue	44	9%
Lymphadenopathy	43	9%
Lethargy	40	9%
Fever not recorded	39	8%
Chills	37	8%
Arthralgia	36	8%
Paresthesia	28	6%
Chest Pain	26	6%
Dizziness - see vertigo	25	5%
Vomiting	25	5%
Rash	24	5%
Pain	23	5%
Abdominal Pain	22	5%
Hypertension	20	4%
Light headedness	20	4%
Coughing	19	4%

Rash unspecified	18	4%
Urticaria	18	4%
Dyspnoea	16	3%
Fever mild	16	3%
Flushing	16	3%
Injection-site pain	16	3%
Tachycardia	15	3%
Vertigo	15	3%
Death	14	3%
Diarrhoea	14	3%
Menstrual Irregularity	12	3%
Itching	11	2%
Vasovagal episode (syncope, faint) +/-tonic clonic movements	11	2%
Visual disturbance	10	2%

Table 2: Special Interest AEFI Topics as at 16 June 2021 YTD:

Total Number of reports	YTD	Week 15
	699	43
Myalgia	478	11
Arthralgia	250	9
Abdominal Pain (pancreatitis)	111 (2 pancreatitis)	6
Chest Pain (chest tightness, angina)	95	9
Pain	71	8
Clot	53	4
Visual disturbance	43	2
Epistaxis	24	1
Death	32	1
Deep vein thrombosis	19	4
Stroke	12	0
CVA	5	0
Atrial fibrillation	12	0
Cellulitis at the injection site	5	0
Thrombocytopenia	5	1
Hyperglycaemia	10	0
Miscarriage	1	0
Pericaditis	6	2
Vertigo	55	5
Arthritis	4	0
Herpes Zoster	13	0
Varicella like rash	2	0
Angina Pectoris	2	0
Pulmonary Embolus	11	2
Anaphylaxis	4	0
Hypertension	53	3
Menstrual Irregularity	12	2
Bells Palsy	5	3

Myocarditis	0	0

Table 3: TGA reported TTS Summary as at 16 June 2021 YTD:

Confirmed	Probable (deemed to meet criteria*, awaiting TGA determination)	Possible	Unlikely	Unclassified on TGA listing	Total
3	2	3	3	1	12

Summary of cases:

[redacted]	Age [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Astra Zeneca - 1	[redacted]
[redacted]	70 [redacted]	[redacted]	[redacted]	Astra Zeneca – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	26 [redacted]	[redacted]	[redacted]	Astra Zeneca-1	[redacted]
[redacted]	47 [redacted]	[redacted]	[redacted]	Astra Zeneca 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Astra Zeneca -1	[redacted]

	58			Astra Zeneca – 1	
	89			Astra Zeneca 1	
	73			Astra Zeneca -1	
	71			Astra Zeneca 1	
	91			Astra Zeneca 1	-

Table 4: TGA unmatched AEFI reports as at 16 June 2021:

Number unmatched reports: 2 *Reporter contacted to submit SAVSS report	81
	76 *

Table 5: Events received following Pfizer's Comirnaty vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	53[redacted]	**Date and time vaccinated:** 29/04/2021 @ [redacted] **Dose number:** 2 [redacted]	[redacted]
[redacted]	[redacted]	58[redacted]	**Date and time vaccinated:** 31/5/21 **Dose number:** 2 [redacted]	[redacted]
[redacted]	[redacted]	75[redacted]	**Date and time vaccinated:** 8/6/21 @ 11:15 **Dose number:** 1 [redacted]	[redacted]

[redacted]	[redacted]	42[redacted]	**Date and time vaccinated**: 27/5/21 @ 12:15 **Dose number:** 2 [redacted]	[redacted]

Table 6: Events received following AstraZeneca's COVID-19 Vaccine

Event ID Number	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation from Committee
[redacted]	[redacted]	65 [redacted]	**Date and time vaccinated**: 21/5/21 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	21 [redacted]	**Date and time vaccinated**: 16/3/21 @ 15:53 **Dose number:** 1 [redacted]	[redacted]
[redacted]	[redacted]	70 M	**Date and time vaccinated**: 14/5/21 **Dose number**: AZ dose 1 [redacted]	[redacted]

Table 7: Summary of the TGA COVID-19 vaccine updates

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 10/06/2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Seven additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. Sadly, in one of these cases the patient has died, and we extend our sincerest condolences to her family. This brings the total number of confirmed and probable TTS cases in Australia to 48. When assessed using the United Kingdom (UK) case definition, 35 cases were confirmed and 13 were deemed probable TTS.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the week of 31 May-6 June 2021 we received 2198 AEFI reports for COVID-19 vaccines.

To 6 June 2021, the TGA has received 272 reports of death following vaccination for COVID-19 vaccines.

By chance, some people will experience new illnesses or die from a pre-existing condition shortly after vaccination, especially if they are elderly. We review all deaths reported after vaccination and compare the expected natural death rates in a similar case group to observed death rates following immunisation to distinguish between possible side effects of the vaccines and coincidental events.

For reports of death other than TTS, our review of cases and analysis of reporting patterns does not suggest that the vaccine caused these deaths

Total adverse event reports to 6 June 2021

5.3	27,072	5,076,413
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

18,810	8031	234
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.7	New South Wales	3.8
Northern Territory	5.2	Queensland	5.3
South Australia	4.9	Tasmania	7.4
Victoria	7.0	Western Australia	4.2

Most commonly reported vaccine side effects

The AEFI most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally. They include headache, muscle and joint pain, fever and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 31 May-6 June 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 31 May-6 June 2021 were headache, muscle pain, fatigue, nausea and dizziness.

This week we focus on reports of herpes zoster reactivation (also known as shingles) following COVID-19 vaccination.

2. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted].

Non-Critical Errors

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty COVID-19 vaccine[#]

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		
Nervous system disorders	Headache			Acute peripheral facial paralysis†	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

Information sourced from the Therapeutic Goods Administration - Australian product information – Comirnaty™ (bnt162b2 [mRNA]) COVID-19 vaccine.

*A higher frequency of pyrexia was observed after the 2nd dose.

†Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

Appendix 3: TGA published AEFI definitions AstraZeneca COVID-19 vaccines*

MedDRA SOC	Adverse reaction[b]	COVID-19 Vaccine AstraZeneca (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
MedDRA SOC	**Adverse reaction[b]**	**COVID-19 Vaccine AstraZeneca (N= 10, 069)**	**Control[c] (N= 9, 902)**
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

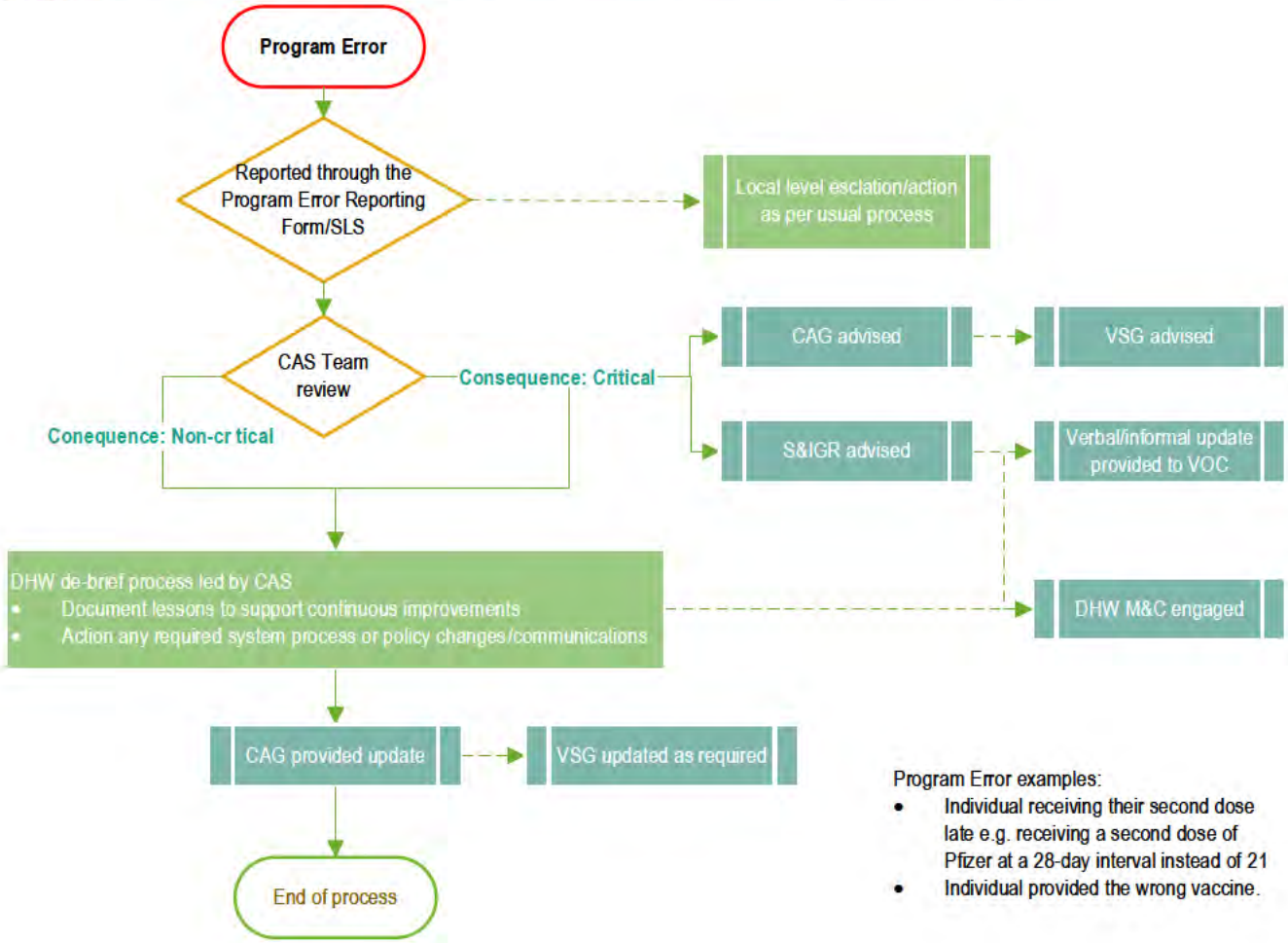
[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

* Product information for AusPAR - COVID-19 VACC NE ASTRAZENECA – ChAdOx1-S - AstraZeneca Pty Ltd – PM-2020-06115-1- 2 FINAL 15 February 2021

Appendix 4.

INCIDENT ESCALATION AND COMMUNICATION PROCESS FLOW - CLINICAL



Program Error examples:

- Individual receiving their second dose late e.g. receiving a second dose of Pfizer at a 28-day interval instead of 21
- Individual provided the wrong vaccine.

DHW: Department for Health and Wellbeing
VOC: Vaccine Operations Centre
CAS: Clinical Advisory Service Team
CAG: Clinical Advisory Group

M&C: Media and Communications team
S&IGR: Strategy and Intergovernment Relations team
VSG: Vaccine Strategy Group
SLS: Safety Learning System

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 32

Meeting date: 19 October 2021

Report period:

06 October 2021 to 12 October 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

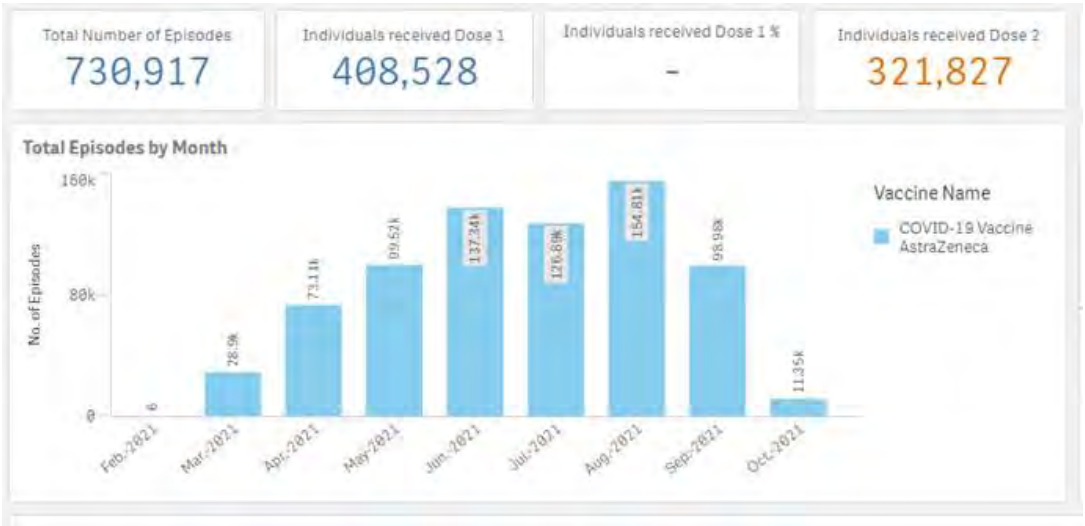
These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

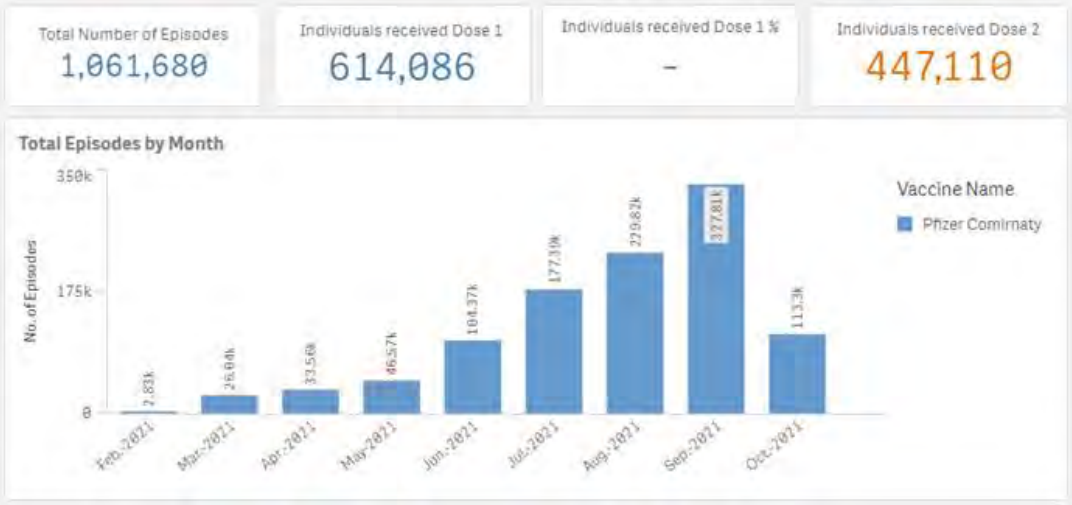
Vaccination recorded to the Australian Immunisation Register as at 12/10/2021*

Total vaccines:

Vaxzevria:



Pfizer:



Moderna:

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 12/10/2021 YTD:

Number of Reports		**3,808**
Gender	Male	1,030
	Female	2,770
Indigenous	Yes	51
	No	3,561
	Unknown	133
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**911**
General reactions Total number of COVID-19 Vaccines Reports		**3,405**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,821**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	591	32.45	0.081
Myalgia	381	20.92	0.052
Chills	275	15.10	0.038
Nausea	248	13.62	0.034
Fever not recorded	236	12.96	0.032
Fatigue	195	10.71	0.027
Lethargy	169	9.28	0.023
Arthralgia	153	8.40	0.021
Abdominal Pain	105	5.77	0.014
Vomiting	102	5.60	0.014
Dizziness - see vertigo	86	4.72	0.012
Diarrhoea	84	4.61	0.011
Chest Pain	77	4.23	0.011
Rash	75	4.12	0.010
Dyspnoea	72	3.95	0.010
Malaise	64	3.51	0.009
Pain	64	3.51	0.009
Fever mild	62	3.40	0.008
Paresthesia	47	2.58	0.006
Vertigo	47	2.58	0.006
Pulmonary embolism	45	2.47	0.006
Visual disturbance	45	2.47	0.006
Rigors	44	2.42	0.006
Deep vein thrombosis	43	2.36	0.006
Tachycardia	42	2.31	0.006
Light headedness	41	2.25	0.006
Coughing	40	2.20	0.005
Sweating	39	2.14	0.005
Exacerbation of existing medical condition	37	2.03	0.005

Rash unspecified	37	2.03	0.005
Injection-site pain	36	1.98	0.005
Shivering	36	1.98	0.005
Urticaria	36	1.98	0.005
Clot	34	1.87	0.005
Fever high	34	1.87	0.005
Hypertension	33	1.81	0.005
Migraine	30	1.65	0.004
Influenza-like illness	28	1.54	0.004
Confusion	26	1.43	0.004
Pain in extremity	26	1.43	0.004
Palpitations	26	1.43	0.004
Herpes zoster	25	1.37	0.003
Epistaxis	24	1.32	0.003
Anorexia	23	1.26	0.003
Flushing	22	1.21	0.003
Lymphadenopathy	22	1.21	0.003
Death	21	1.15	0.003
Injection site pain restricting limb mobility	21	1.15	0.003
Pruritus	21	1.15	0.003
Oedema	20	1.10	0.003
Thrombosis with thrombocytopenia syndrome TTS	4	0.22	0.001

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**1,968**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	476	24.19	0.045
Myalgia	339	17.23	0.032
Nausea	287	14.58	0.027
Fatigue	267	13.57	0.025
Chest Pain	256	13.01	0.024
Fever not recorded	184	9.35	0.017
Lymphadenopathy	180	9.15	0.017
Chills	179	9.10	0.017
Lethargy	154	7.83	0.015
Arthralgia	149	7.57	0.014
Dizziness - see vertigo	142	7.22	0.013
Vomiting	111	5.64	0.010
Paresthesia	109	5.54	0.010
Palpitations	101	5.13	0.010
Dyspnoea	96	4.88	0.009
Pain	89	4.52	0.008
Abdominal Pain	85	4.32	0.008
Rash	84	4.27	0.008

Diarrhoea	82	4.17	0.008
Light headedness	79	4.01	0.007
Rash unspecified	70	3.56	0.007
Tachycardia	65	3.30	0.006
Menstrual Irregularity	56	2.85	0.005
Hypertension	53	2.69	0.005
Oedema	49	2.49	0.005
Coughing	47	2.39	0.004
Urticaria	46	2.34	0.004
Vertigo	46	2.34	0.004
Malaise	44	2.24	0.004
Pericaditis	43	2.18	0.004
Throat soreness	42	2.13	0.004
Exacerbation of existing medical condition	41	2.08	0.004
Itching	41	2.08	0.004
Sweating	41	2.08	0.004
Lymphadenopathy localized to the region of the injection site	40	2.03	0.004
Tinnitus	40	2.03	0.004
Vasovagal episode (syncope, faint) +/-tonic clonic movements	39	1.98	0.004
Fever mild	38	1.93	0.004
Visual disturbance	38	1.93	0.004
Flushing	35	1.78	0.003
Migraine	33	1.68	0.003
Shivering	33	1.68	0.003
Numbness	30	1.52	0.003
Injection-site pain	27	1.37	0.003
Fever high	26	1.32	0.002
Pain in extremity	25	1.27	0.002
Altered breathing	24	1.22	0.002
Anxious	22	1.12	0.002
Insomnia	22	1.12	0.002
Throat irritation	21	1.07	0.002
Herpes zoster	20	1.02	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Spikevax **Total Reactions Reported:**	**19**	**% of total Spikevax AEFI reported***	**% of Total Spikevax vaccines administered****
Chills	3	15.79	0.02
Pain	3	15.79	0.02
Chest Pain	2	10.53	0.01
Coughing	2	10.53	0.01
Dyspnoea	2	10.53	0.01

Lethargy	2	10.53	0.01
Pain in extremity	2	10.53	0.01
Pericaditis	2	10.53	0.01
Altered breathing	1	5.26	0.01
Blister	1	5.26	0.01
Clammy	1	5.26	0.01
Confusion	1	5.26	0.01
Dizziness - see vertigo	1	5.26	0.01
Fatigue	1	5.26	0.01
Fever mild	1	5.26	0.01
Fever not recorded	1	5.26	0.01
Headache	1	5.26	0.01
Hives- see urticaria	1	5.26	0.01
Hypotension	1	5.26	0.01
injection site mass (>50mm)	1	5.26	0.01
Insomnia	1	5.26	0.01
Light headedness	1	5.26	0.01
Myalgia	1	5.26	0.01
Nasal congestion	1	5.26	0.01
Nausea	1	5.26	0.01
Numbness	1	5.26	0.01
Palpitations	1	5.26	0.01
Paresthesia	1	5.26	0.01
Rhinorrhoea	1	5.26	0.01
Shivering	1	5.26	0.01
Sweating	1	5.26	0.01
Tachycardia	1	5.26	0.01
Throat irritation	1	5.26	0.01
Throat soreness	1	5.26	0.01
Toothache	1	5.26	0.01
Upper respiratory tract infection	1	5.26	0.01
Urticaria	1	5.26	0.01
Vasovagal episode (syncope, faint) +/-tonic clonic movements	1	5.26	0.01
Visual disturbance	1	5.26	0.01

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 12/10/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 32		
Total Number of reports	**1,821**	**% of Total AZ vacc admin***	**30**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	105	0.014	4	3.81	0.001
Chest Pain	77	0.011	1	1.30	0.000
Clot	34	0.005	0	0.000	0.000
Vertigo	47	0.006	2	4.26	0.000
Visual disturbance	45	0.006	2	4.44	0.000
Hypertension	33	0.005	1	3.030	0.000
Epistaxis	24	0.003	0	0.000	0.000
Deep vein thrombosis	43	0.006	1	2.326	0.000
Death	21	0.003	0	0.000	0.000
Herpes zoster	25	0.003	1	4.00	0.000
Pulmonary embolism	45	0.006	1	2.22	0.000
Cerebral vascular accident see Stroke	8	0.001	0	0.000	0.000
Stroke	11	0.002	0	0.000	0.000
Thrombocytopenia	8	0.001	0	0.00	0.000
Bells Palsy	7	0.001	1	14.286	0.000
Anaphylaxis	3	0.000	0	0.000	0.000
Pericarditis	5	0.001	0	0.000	0.000
Menstrual Irregularity	7	0.001	0	0.000	0.000
Guillain Barré syndrome	4	0.001	0	0.000	0.000
Myocarditis	4	0.001	0	0.000	0.000
Exacerbation of existing medical condition	37	0.005	0	0.000	0.000
Thrombosis with thrombocytopenia syndrome TTS	4	0.001	0	0.000	0.000
Cerebral Venous Sinus Thrombosis	4	0.001	0	0.000	0.000
Dyskinesia	2	0.000	0	0.000	0.000
Idiopathic thrombocytopenic purpura	5	0.001	0	0.000	0.000
Multiple sclerosis	1	0.000	0	0.000	0.000
Purpura	11	0.002	0	0.000	0.000

Dysgeusia	18	0.002	0	0.000	0.000
Thrombophlebitis	11	0.002	0	0.000	0.000
Lymphadenopathy	22	0.003	0	0.000	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 32**		
Total Number of reports	**1,968**	**% of Total Pfizer vacc admin.***	**118**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	85	0.008	7	8.24	0.001
Chest Pain	256	0.024	30	11.72	0.003
Vertigo	46	0.004	0	0.00	0.000
Dizziness – see Vertigo	142	0.013	0	0.00	0.000
Visual disturbance	38	0.004	2	5.26	0.000
Hypertension	53	0.005	6	11.32	0.001
Death	17	0.002	1	5.88	0.000
Herpes zoster	20	0.002	0	0.00	0.000
Pulmonary embolism	11	0.001	0	0.00	0.000
Bells Palsy	6	0.001	0	0.00	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	28	0.003	0	0.00	0.000
Pericarditis	43	0.004	3	6.98	0.000
Myocarditis	7	0.001	0	0.00	0.000
Menstrual Irregularity	56	0.005	10	17.86	0.001
Exacerbation of existing medical condition	41	0.004	2	4.88	0.000
Miscarriage	3	0.000	0	0.00	0.000
Tinnitus	40	0.004	5	12.50	0.000
Paresthesia	109	0.010	7	6.42	0.001
Oedema Eyelid	15	0.001	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax Total Number of reports	YTD		Week 32		
	19	% of Total Spikevax vacc admin*	12	% of YTD AESI reported**	% of Total Spikevax vacc admin***
Chest Pain	2	0.012	0	0.000	0.000
Death	0	0.000	0	0.000	0.000
Pericarditis	2	0.012	2	100	0.012
Myocarditis	0	0.000	0	0.000	0.000

Table 3: TGA reported TTS Summary as at 12/10/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]			[redacted]		
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 12/10/2021 YTD:

Number unmatched reports:11 *Reporter contacted to submit SAVSS report	83 [redacted]
	76 [redacted]
	35 [redacted]
	86 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]
	76 [redacted]

Table 5: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	21 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 28/09/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	20 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:**29/9/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** none [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 6: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	57 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 23/08/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

[redacted]	[redacted]	19 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 1/10/2021 **Dose number:** Unknown **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	45 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:**10/07/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	30 [redacted]	**Diagnosis:** [redacted] **Date vaccinated:** 01/10/2021 **Dose number:** 2	[redacted]	

			Details: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** **GP contacted/notified:** **Classification:** [redacted]	[redacted]	

Table 7: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	73 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 1st dose- 20/5/2021, 2nd dose- 12/8/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	69 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 10/9/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	74 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 10/8/21 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted]	[redacted]	No Change Change/Review rationale:

			Medical History: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 07 October 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-07-10-2021

Summary

- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.
- To 3 October 2021, approximately 28.8 million vaccine doses have been given in Australia 17 million first doses and 11.8 million second doses.
- The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials. They include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) linked to Vaxzevria (AstraZeneca).
- In the last week, an additional 3 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS, bringing the total number of cases to 151.
- We continue to carefully monitor reports of suspected myocarditis and/or pericarditis following the Comirnaty (Pfizer)and Spikevax (Moderna) vaccines, particularly in the younger age groups.
- The Spikevax (Moderna) vaccine is now being rolled out in Australia. To 3 October 2021, we have received 65 reports of suspected adverse events.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

In the general population (16 years of age and over), the most frequently reported side effects suspected to be associated with the vaccines include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle and joint pain, and fever and chills.

Now the vaccines are being rolled out more widely, we are receiving more reports in younger individuals. The TGA is monitoring these reports closely. We know from the Comirnaty (Pfizer) and Spikevax (Moderna) clinical trials that the most common adverse reactions in adolescents are similar to those in older people and include injection-site pain, fatigue and headache. Most of these side effects were mild and resolved within a day or two. For both vaccines, they were more common after the second vaccine dose than the first.

Review of the TGA adverse event database to 3 October 2021 indicates that the most commonly reported reactions in adolescents after vaccination with Comirnaty and Spikevax are dizziness, headache, fainting (syncope), feeling faint (pre-syncope) and nausea. These are expected reactions based on what was seen in the clinical trials. However, at this point they are early observations based on limited data as we continue to closely monitor safety in this age group.

To help us monitor the safety of the COVID-19 vaccines, we encourage people to report suspected side effects even if it is not certain that the vaccine caused them. Anyone can report a suspected side effect including members of the public, nurses, pharmacists, doctors, health authorities and pharmaceutical companies. A report can be made directly to the TGA, through a health professional, or by calling the NPS MedicineWise Adverse Medicine Events phone line for consumers. Reporting can be anonymous if preferred. For more information click Report a suspected side effect.

Total adverse event reports to 3 October 2021

2.3	66,829	28,769,273
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
37,774	**28,667**	**65**
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax

To 3 October 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 369.

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	1.6	New South Wales	1.6
Northern Territory	2.2	Queensland	2.3
South Australia	2.3	Tasmania	4.2
Victoria	3.2	Western Australia	2.3

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

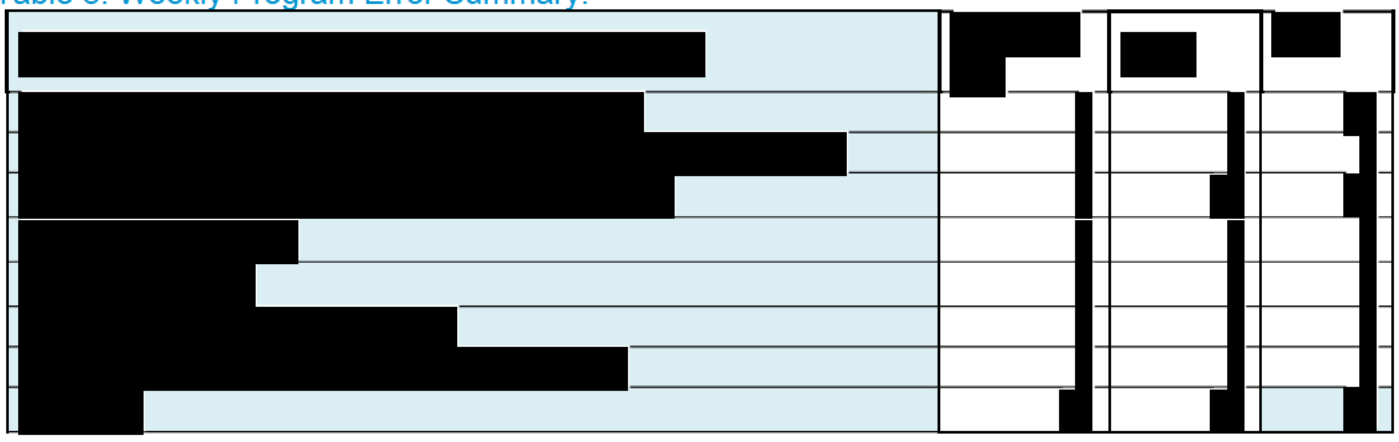
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

[redacted]

apart

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 33

Meeting date: 26 October 2021

Report period:

13 October 2021 to 19 October 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

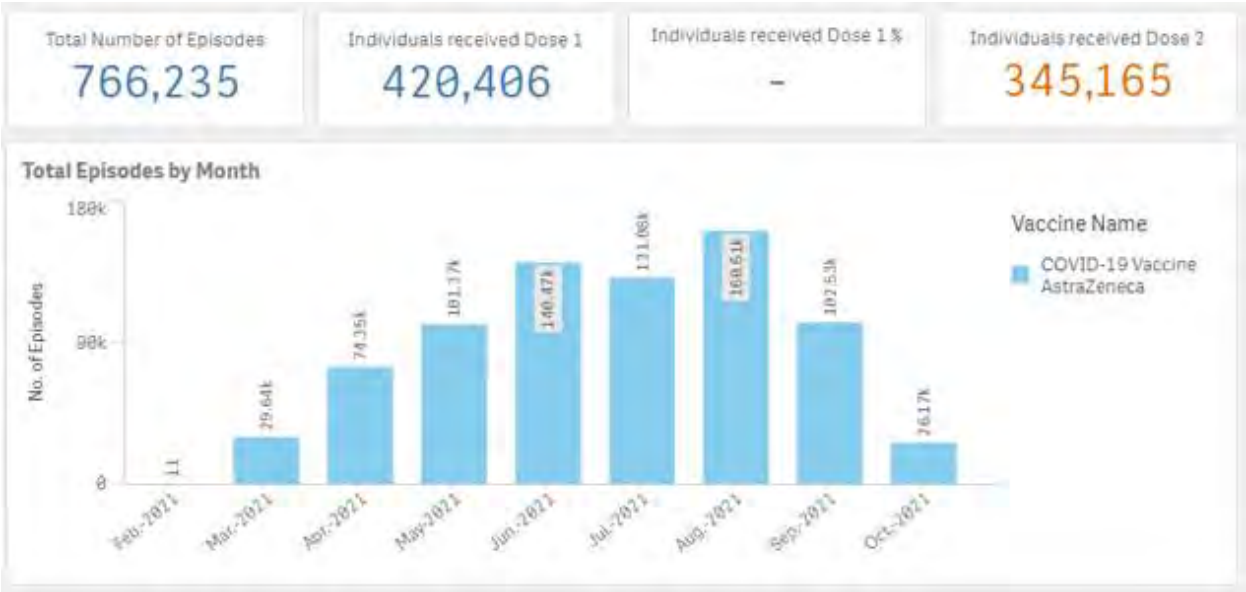
These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 19/10/2021*

Total vaccines:

Vaxzevria:



Pfizer:

Moderna:

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 19/10/2021 YTD:

Number of Reports		**3,968**
Gender	Male	1,096
	Female	2,859
Indigenous	Yes	52
	No	3,708
	Unknown	141
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**940**
General reactions Total number of COVID-19 Vaccines Reports		**3,533**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,838**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	593	32.26	0.077
Myalgia	382	20.78	0.050
Chills	275	14.96	0.036
Nausea	249	13.55	0.032
Fever not recorded	236	12.84	0.031
Fatigue	197	10.72	0.026
Lethargy	170	9.25	0.022
Arthralgia	154	8.38	0.020
Abdominal Pain	106	5.77	0.014
Vomiting	102	5.55	0.013
Dizziness - see vertigo	86	4.68	0.011
Diarrhoea	84	4.57	0.011
Chest Pain	77	4.19	0.010
Dyspnoea	76	4.13	0.010
Rash	76	4.13	0.010
Malaise	65	3.54	0.008
Pain	64	3.48	0.008
Fever mild	62	3.37	0.008
Paresthesia	47	2.56	0.006
Vertigo	47	2.56	0.006
Pulmonary embolism	46	2.50	0.006
Visual disturbance	45	2.45	0.006
Deep vein thrombosis	44	2.39	0.006
Rigors	44	2.39	0.006
Light headedness	42	2.29	0.005
Tachycardia	42	2.29	0.005
Rash unspecified	41	2.23	0.005
Coughing	40	2.18	0.005
Sweating	39	2.12	0.005

Exacerbation of existing medical condition	38	2.07	0.005
Urticaria	37	2.01	0.005
Injection-site pain	36	1.96	0.005
Shivering	36	1.96	0.005
Hypertension	35	1.90	0.005
Clot	34	1.85	0.004
Fever high	34	1.85	0.004
Migraine	30	1.63	0.004
Influenza-like illness	28	1.52	0.004
Confusion	26	1.41	0.003
Pain in extremity	26	1.41	0.003
Palpitations	26	1.41	0.003
Herpes zoster	25	1.36	0.003
Epistaxis	24	1.31	0.003
Anorexia	23	1.25	0.003
Flushing	23	1.25	0.003
Death	22	1.20	0.003
Lymphadenopathy	22	1.20	0.003
Injection site pain restricting limb mobility	21	1.14	0.003
Oedema	21	1.14	0.003
Pruritus	21	1.14	0.003

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**2,087**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	503	24.10	0.041
Myalgia	364	17.44	0.030
Nausea	304	14.57	0.025
Fatigue	280	13.42	0.023
Chest Pain	270	12.94	0.022
Fever not recorded	194	9.30	0.016
Chills	187	8.96	0.015
Lymphadenopathy	187	8.96	0.015
Arthralgia	168	8.05	0.014
Lethargy	163	7.81	0.013
Dizziness - see vertigo	150	7.19	0.012
Paresthesia	131	6.28	0.011
Vomiting	115	5.51	0.009
Palpitations	110	5.27	0.009
Dyspnoea	101	4.84	0.008
Pain	96	4.60	0.008
Abdominal Pain	94	4.50	0.008
Rash	87	4.17	0.007
Diarrhoea	84	4.02	0.007

Light headedness	83	3.98	0.007
Rash unspecified	77	3.69	0.006
Tachycardia	69	3.31	0.006
Menstrual Irregularity	57	2.73	0.005
Urticaria	57	2.73	0.005
Hypertension	53	2.54	0.004
Oedema	51	2.44	0.004
Itching	50	2.40	0.004
Vertigo	48	2.30	0.004
Coughing	47	2.25	0.004
Malaise	46	2.20	0.004
Pericaditis	45	2.16	0.004
Exacerbation of existing medical condition	43	2.06	0.004
Fever mild	43	2.06	0.004
Sweating	42	2.01	0.003
Tinnitus	42	2.01	0.003
Throat soreness	41	1.96	0.003
Visual disturbance	41	1.96	0.003
Lymphadenopathy localized to the region of the injection site	40	1.92	0.003
Vasovagal episode (syncope, faint) +/-tonic clonic movements	39	1.87	0.003
Migraine	37	1.77	0.003
Flushing	35	1.68	0.003
Shivering	34	1.63	0.003
Numbness	30	1.44	0.002
Injection-site pain	27	1.29	0.002
Fever high	26	1.25	0.002
Pain in extremity	26	1.25	0.002
Altered breathing	25	1.20	0.002
Herpes zoster	24	1.15	0.002
Anxious	22	1.05	0.002
Insomnia	22	1.05	0.002
Throat irritation	22	1.05	0.002

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Spikevax **Total Reactions Reported:**	**43**	**% of total Spikevax AEFI reported***	**% of Total Spikevax vaccines administered****
Chest Pain	5	11.63	0.02
Headache	5	11.63	0.02
Pain	5	11.63	0.02
Injection-site erythema	4	9.30	0.02
Nausea	4	9.30	0.02
Chills	3	6.98	0.01

Hives- see urticaria	3	6.98	0.01
Injection-site swelling	3	6.98	0.01
Lethargy	3	6.98	0.01
Light headedness	3	6.98	0.01
Vomiting	3	6.98	0.01
Clammy	2	4.65	0.01
Coughing	2	4.65	0.01
Dizziness - see vertigo	2	4.65	0.01
Dyspnoea	2	4.65	0.01
Fever not recorded	2	4.65	0.01
Injection-site pruritus	2	4.65	0.01
Itching	2	4.65	0.01
Lymphadenopathy	2	4.65	0.01
Pain in extremity	2	4.65	0.01
Pericaditis	2	4.65	0.01

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 19/10/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 33		
Total Number of reports	**1,838**	**% of Total AZ vacc admin***	**17**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	106	0.014	1	0.94	0.0001
Chest Pain	77	0.010	0	0.00	0.000
Clot	34	0.004	0	0.000	0.000
Vertigo	47	0.006	0	0.00	0.000
Visual disturbance	45	0.006	0	0.00	0.000
Hypertension	35	0.005	2	5.714	0.0003
Epistaxis	24	0.003	0	0.000	0.000
Deep vein thrombosis	44	0.006	1	2.273	0.0001
Death	22	0.003	1	4.545	0.0001
Herpes zoster	25	0.003	0	0.00	0.000
Pulmonary embolism	46	0.006	1	2.17	0.000
Cerebral vascular accident see Stroke	8	0.001	0	0.000	0.000
Stroke	12	0.002	0	0.000	0.000
Thrombocytopenia	8	0.001	0	0.00	0.000
Bells Palsy	7	0.001	0	0.000	0.000
Anaphylaxis	3	0.000	0	0.000	0.000
Pericarditis	5	0.001	0	0.000	0.000
Menstrual Irregularity	7	0.001	0	0.000	0.000
Guillain Barré syndrome	4	0.001	0	0.000	0.000
Myocarditis	4	0.001	0	0.000	0.000
Exacerbation of existing medical condition	38	0.005	0	0.000	0.000
Thrombosis with thrombocytopenia syndrome TTS	4	0.001	0	0.000	0.000
Cerebral Venous Sinus Thrombosis	4	0.001	0	0.000	0.000
Dyskinesia	2	0.000	0	0.000	0.000
Idiopathic thrombocytopenic purpura	5	0.001	0	0.000	0.000
Multiple sclerosis	1	0.000	0	0.000	0.000
Purpura	11	0.001	0	0.000	0.000

Dysgeusia	18	0.002	0	0.000	0.000
Thrombophlebitis	11	0.001	0	0.000	0.000
Lymphadenopathy	22	0.003	0	0.000	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 33**		
Total Number of reports	**2,087**	**% of Total Pfizer vacc admin.***	**109**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Abdominal Pain	94	0.008	9	9.57	0.001
Chest Pain	270	0.022	12	4.44	0.001
Vertigo	48	0.004	1	2.08	0.0001
Dizziness – see Vertigo	150	0.012	7	4.67	0.001
Visual disturbance	41	0.003	3	7.32	0.0002
Hypertension	53	0.004	0	0.00	0.000
Death	17	0.001	0	0.00	0.000
Herpes zoster	24	0.002	4	16.67	0.0003
Pulmonary embolism	12	0.001	1	8.33	0.0001
Bells Palsy	6	0.000	0	0.00	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	34	0.003	5	14.71	0.0004
Pericarditis	45	0.004	2	4.44	0.0002
Myocarditis	8	0.001	1	12.50	0.0001
Myopericarditis	3	0.000	2	66.67	0.0002
Menstrual Irregularity	57	0.005	1	1.75	0.0001
Exacerbation of existing medical condition	43	0.004	2	4.65	0.0002
Miscarriage	3	0.000	0	0.00	0.000
Tinnitus	42	0.003	2	4.76	0.000
Paresthesia	131	0.011	22	0.00	0.002
Oedema Eyelid	14	0.001	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax Total Number of reports	YTD		Week 33		
	43	% of Total Spikevax vacc admin*	21	% of YTD AESI reported**	% of Total Spikevax vacc admin***
Bells Palsy	1	0.004	1	100.000	0.004
Chest Pain	5	0.019	3	60.000	0.011
Death	0	0.000	0	0.000	0.000
Lymphadenopathy	2	0.008	2	100.000	0.008
Pericarditis	2	0.008	0	0.000	0.000
Meningitis Aseptic	1	0.004	1	100.000	0.004
Myocarditis	0	0.000	0	0.000	0.000
Myopericarditis	0	0.000	0	0.000	0.000
Menstrual Irregularity	1	0.004	1	100.000	0.004
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	0	0.000	0	0.000	0.000

Table 3: TGA reported TTS Summary as at 19/10/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Summary of TGA Line Listing cases:

[redacted]	Age / [redacted]	[redacted]	[redacted]	Vaccine	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria (Astra Zeneca) – 1	[redacted]
[redacted]	53 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	87 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]

[redacted]					
[redacted]	68 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	58 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	71 [redacted]	[redacted]	[redacted]	Vaxzevria – 1	[redacted]
[redacted]	72 [redacted]	[redacted]	[redacted]	Vaxzevria - 1	[redacted]

Table 4: TGA unmatched AEFI reports as at 19/10/2021 YTD:

Number unmatched reports:10 *Reporter contacted to submit SAVSS report	83 [redacted] *
	35 [redacted]
	86 [redacted]
	76 [redacted]
	49 [redacted]
	65 [redacted]
	71 [redacted]
	85 [redacted]
	56 [redacted]
	76 [redacted]

Table 5: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	50 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 06/10/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	21 [redacted]	**Diagnosis:** Aseptic [redacted] **Date and time vaccinated:** 09/10/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 6: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	29 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 8/10/2021 **Dose number:** 2	[redacted]	No Change

			Details: [redacted] **Laboratory Results:** [redacted] > **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	Change/Review rationale:
[redacted]	[redacted]	35 M	**Diagnosis:** [redacted] **Date and time vaccinated:** 09/10/2021 **Dose number:** 2 **Details:** 3[redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

[redacted]	[redacted]	25 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 08/10/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	20 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 22/09/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	36 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 03/09/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted]	[redacted]	No Change Change/Review rationale:

			PT for left sided weakness. **Medical History**: Current smoker **GP contacted/notified:** Yes **Classification: Neurology**		

Table 7: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	74 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 16/9/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** **Imaging & Findings:** **Treatment**: **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:**	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 14 October 2021:

Summary

- The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.
- To 10 October 2021, approximately 31 million vaccine doses have been given in Australia – 18 million first doses and 13 million second doses.
- The most frequently reported side effects suspected to be associated with the vaccines reflect what was seen in the clinical trials. They include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle pain, fever and chills.
- We are closely monitoring rare reports of blood clots with low blood platelets (also called thrombosis with thrombocytopenia syndrome or TTS) linked to Vaxzevria (AstraZeneca). In the last week, 2 additional reports of blood clots and low blood platelets have been assessed as probable TTS, bringing the total number of cases to 152.
- We continue to carefully monitor reports of suspected myocarditis and pericarditis following the Comirnaty (Pfizer) and Spikevax (Moderna) vaccines, particularly in younger age groups. For Comirnaty (Pfizer), to 10 October 2021, we have received 269 reports of suspected myocarditis alone or in combination with pericarditis, and an additional 725 reports of suspected pericarditis alone. In the same period for Spikevax (Moderna), we have received one report of suspected myocarditis and 13 reports of suspected pericarditis. These events can occur due to other causes, including common viral infections, so it is expected that not all cases are related to vaccination.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

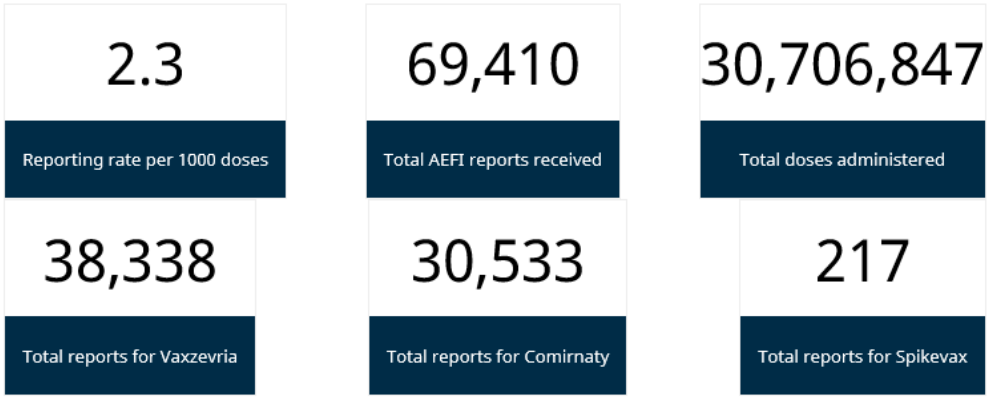
In the general population (16 years of age and over), the most frequently reported side effects suspected to be associated with the vaccines include injection-site reactions such as a sore arm, and more general symptoms such as headache, muscle and joint pain, and fever and chills.

Now the vaccines are being rolled out more widely, we are receiving more reports in younger individuals under 18 years. The TGA is monitoring these reports closely. We know from the Comirnaty (Pfizer) and Spikevax (Moderna) clinical trials that the most common adverse reactions in adolescents are similar to those in older people and include injection-site pain, fatigue and headache. Most of these side effects were mild and resolved within a day or two. For both vaccines, they were more common after the second vaccine dose than the first.

To 10 October 2021, we have received 856 reports in individuals under 18 years old after vaccination with Comirnaty (Pfizer) and Spikevax (Moderna). The most commonly reported reactions are dizziness, fainting (syncope) and feeling faint (pre-syncope), nausea and chest pain. However, at this point they are early observations based on limited data as we continue to closely monitor safety in this age group.

To help us assess the safety of the COVID-19 vaccines, we encourage people to report suspected side effects even if it is not certain that the vaccine caused them. Anyone can report a suspected side effect including members of the public, nurses, pharmacists, doctors, health authorities and pharmaceutical companies. A report can be made directly to the TGA, through a health professional, or by calling the NPS MedicineWise Adverse Medicine Events phone line for consumers. Reporting can be anonymous if preferred. For more information click Report a suspected side effect.

Total adverse event reports to 10 October 2021



To 10 October 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 372.

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	1.5	New South Wales	1.5
Northern Territory	2.3	Queensland	2.2
South Australia	2.3	Tasmania	4.0
Victoria	3.1	Western Australia	2.2

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

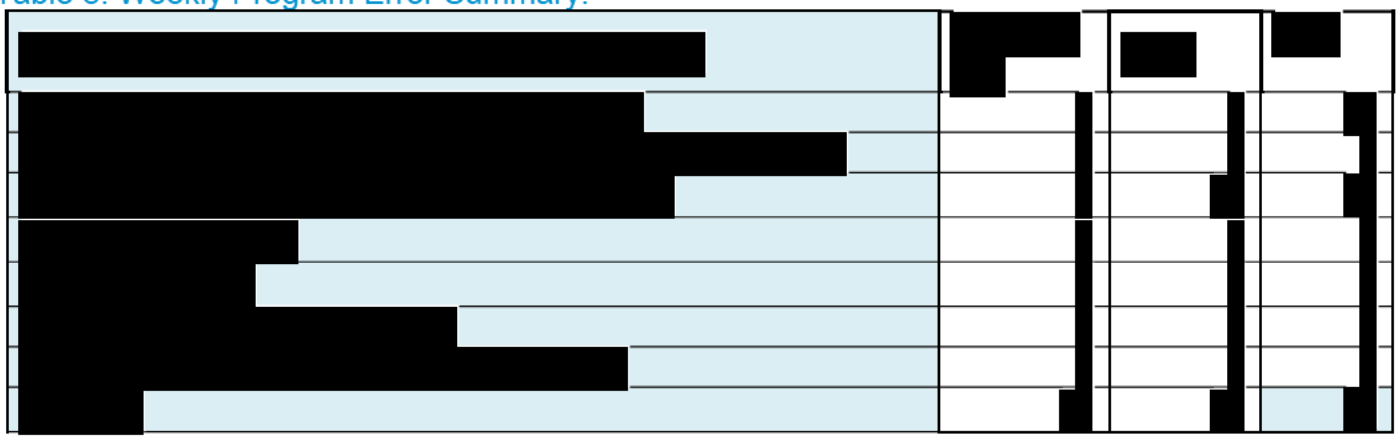
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

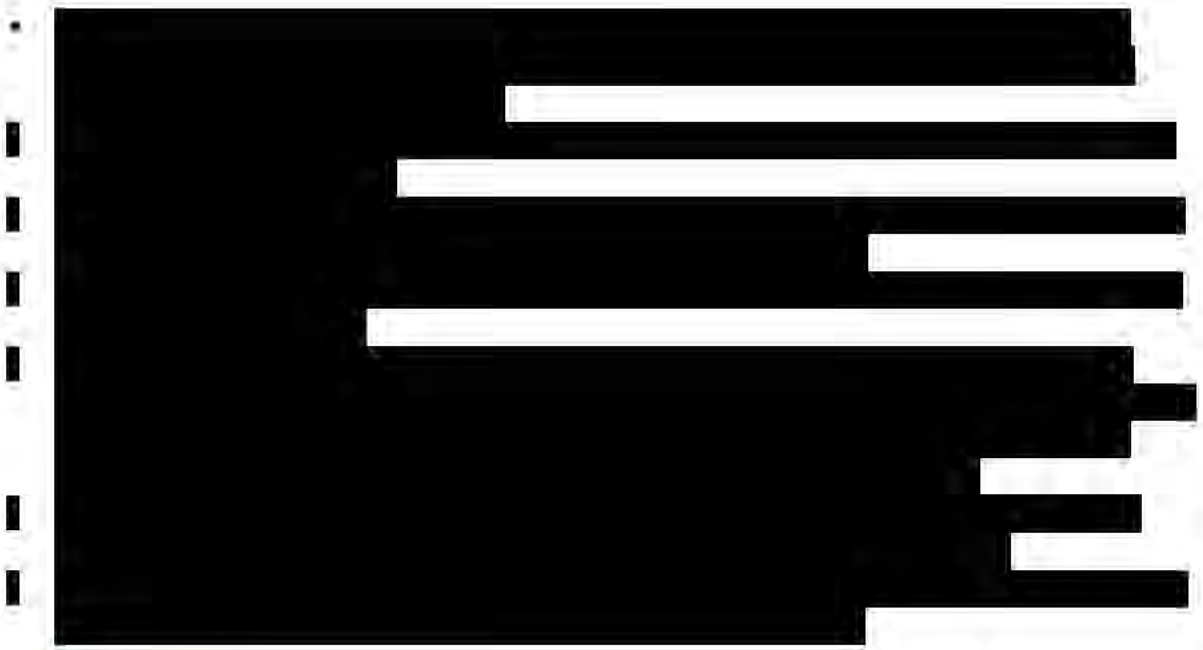
Table 8: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

- [redacted]



Non-Critical Errors

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 34

Meeting date: 2 November 2021

Report period:

20 October 2021 to 26 October 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 02/11/2021*

Total vaccines:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2	Coverage % (2 doses)
Totals	**1,683,039**	**1,190,179**	**926,964**	**55.08%**
SA	1,683,039	1,190,179	926,964	55.08%

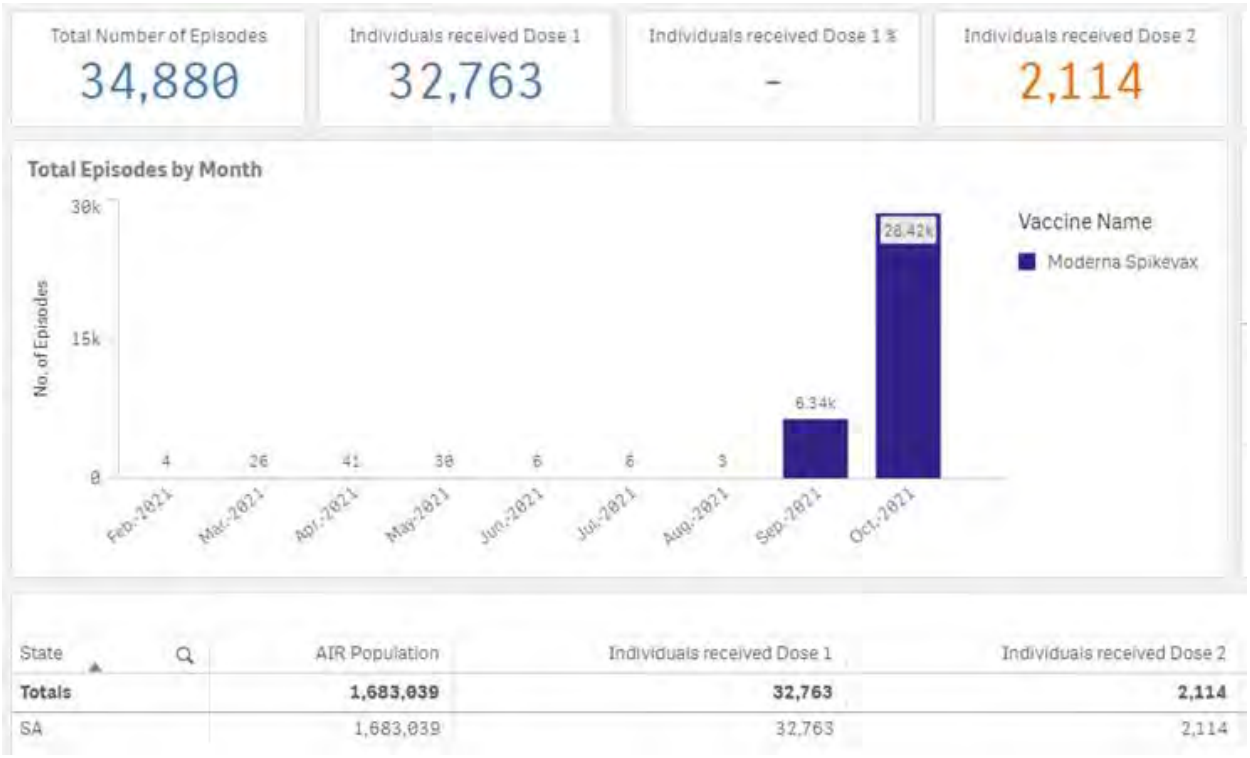
Vaxzevria:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,683,039**	**421,237**	**355,964**
SA	1,683,039	421,237	355,964

Pfizer:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2	Coverage % (2 doses)
Totals	**1,683,039**	**737,882**	**568,938**	**-**
SA	1,683,039	737,882	568,938	-

Moderna:



State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,683,039**	**32,763**	**2,114**
SA	1,683,039	32,763	2,114

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 02/11/2021 YTD:

Number of Reports		**4,110**
Gender	Male	1,133
	Female	2,965
Indigenous	Yes	52
	No	3,853
	Unknown	139
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**979**
General reactions Total number of COVID-19 Vaccines Reports		**3,646**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,862**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	595	31.95	0.076
Myalgia	385	20.68	0.049
Chills	275	14.77	0.035
Nausea	249	13.37	0.032
Fever not recorded	237	12.73	0.030
Fatigue	199	10.69	0.026
Lethargy	170	9.13	0.022
Arthralgia	156	8.38	0.020
Abdominal Pain	106	5.69	0.014
Vomiting	102	5.48	0.013
Dizziness - see vertigo	86	4.62	0.011
Diarrhoea	84	4.51	0.011
Chest Pain	78	4.19	0.010
Dyspnoea	78	4.19	0.010
Rash	77	4.14	0.010
Malaise	66	3.54	0.008
Pain	64	3.44	0.008
Fever mild	62	3.33	0.008
Paresthesia	52	2.79	0.007
Pulmonary embolism	48	2.58	0.006

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**2,193**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	540	24.62	0.041
Myalgia	374	17.05	0.029
Nausea	322	14.68	0.025
Fatigue	296	13.50	0.023
Chest Pain	295	13.45	0.023

Fever not recorded	220	10.03	0.017
Chills	203	9.26	0.016
Lymphadenopathy	192	8.76	0.015
Arthralgia	180	8.21	0.014
Lethargy	171	7.80	0.013
Dizziness - see vertigo	157	7.16	0.012
Paresthesia	135	6.16	0.010
Vomiting	127	5.79	0.010
Palpitations	120	5.47	0.009
Dyspnoea	115	5.24	0.009
Pain	109	4.97	0.008
Abdominal Pain	98	4.47	0.007
Light headedness	91	4.15	0.007
Diarrhoea	89	4.06	0.007
Rash	88	4.01	0.007

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Spikevax **Total Reactions Reported:**	**43**	**% of total Spikevax AEFI reported***	**% of Total Spikevax vaccines administered****
Headache	8	14.55	0.02
Chest Pain	7	12.73	0.02
Nausea	7	12.73	0.02
Dizziness - see vertigo	5	9.09	0.01
Injection-site erythema	5	9.09	0.01
Lethargy	5	9.09	0.01
Pain	5	9.09	0.01
Chills	4	7.27	0.01
Dyspnoea	4	7.27	0.01
Fever not recorded	4	7.27	0.01
Injection-site swelling	4	7.27	0.01
Light headedness	4	7.27	0.01
Sweating	4	7.27	0.01
Diarrhoea	3	5.45	0.01
Hives- see urticaria	3	5.45	0.01
injection site warmth see warmth	3	5.45	0.01
Injection-site pain	3	5.45	0.01
Lymphadenopathy	3	5.45	0.01
Myalgia	3	5.45	0.01
Rash	3	5.45	0.01
Visual disturbance	3	5.45	0.01

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 02/11/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 34		
Total Number of reports	**1862**	**% of Total AZ vacc admin***	**16**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	106	0.014	0	0.00	0.000
Chest Pain	78	0.010	1	1.28	0.0001
Clot	34	0.004	0	0.00	0.000
Vertigo	47	0.006	0	0.00	0.000
Visual disturbance	45	0.006	0	0.00	0.000
Hypertension	36	0.005	1	2.78	0.0001
Epistaxis	24	0.003	0	0.00	0.000
Deep vein thrombosis	44	0.006	0	0.00	0.000
Death	22	0.003	0	0.00	0.000
Herpes zoster	27	0.003	7	25.93	0.0009
Pulmonary embolism	48	0.006	1	2.08	0.0001
Cerebral vascular accident see Stroke	8	0.001	0	0.00	0.000
Stroke	12	0.002	0	0.00	0.000
Thrombocytopenia	9	0.001	1	11.11	0.0001
Bells Palsy	7	0.001	0	0.00	0.000
Anaphylaxis	3	0.000	0	0.00	0.000
Pericarditis	5	0.001	0	0.00	0.000
Menstrual Irregularity	7	0.001	0	0.00	0.000
Guillain Barré syndrome	4	0.001	0	0.00	0.000
Myocarditis	4	0.001	0	0.00	0.000
Exacerbation of existing medical condition	40	0.005	2	5.00	0.0003
Thrombosis with thrombocytopenia syndrome TTS	4	0.001	0	0.00	0.0000
Cerebral Venous Sinus Thrombosis	4	0.001	0	0.00	0.000
Dyskinesia	2	0.000	0	0.00	0.000
Idiopathic thrombocytopenic purpura	5	0.001	0	0.00	0.000
Multiple sclerosis	1	0.000	0	0.00	0.000
Purpura	11	0.001	0	0.00	0.000

Dysgeusia	19	0.002	1	5.26	0.0001
Thrombophlebitis	11	0.001	0	0.00	0.000
Lymphadenopathy	23	0.003	1	4.35	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 34**		
Total Number of reports	**2,193**	**% of Total Pfizer vacc admin.***	**97**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Chest Pain	295	0.023	17	5.76	0.001
Vertigo	51	0.004	0	0.00	0.000
Dizziness – see Vertigo	157	0.012	7	4.46	0.0005
Visual disturbance	46	0.004	5	10.87	0.000
Death	17	0.001	0	0.00	0.0000
Herpes zoster	25	0.002	1	4.00	0.000
Pulmonary embolism	12	0.001	0	0.00	0.000
Bells Palsy	7	0.001	0	0.00	0.0000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	36	0.003	2	5.56	0.0002
Pericarditis	45	0.003	0	0.00	0.000
Myocarditis	10	0.001	2	20.00	0.0002
Myopericarditis	3	0.000	0	0.00	0.0000
Menstrual Irregularity	58	0.004	1	1.72	0.0001
Exacerbation of existing medical condition	47	0.004	4	8.51	0.0003
Miscarriage	3	0.000	0	0.00	0.0000
Tinnitus	46	0.004	4	4.35	0.0003

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax	YTD		Week 34		
Total Number of reports	55	% of Total Spikevax vacc admin*	11	% of YTD AESI reported**	% of Total Spikevax vacc admin***
Bells Palsy	1	0.003	0	0.00	0.00
Chest Pain	7	0.020	1	14.29	0.003
Death	0	0.000	0	0.00	0.00
Lymphadenopathy	3	0.009	1	33.33	0.003
Pericarditis	2	0.006	0	0.00	0.00
Meningitis Aseptic	1	0.003	0	0.00	0.00
Myocarditis	0	0.000	0	0.00	0.00
Myopericarditis	0	0.000	0	0.00	0.00
Menstrual Irregularity	2	0.006	1	50.00	0.003
Anaphylaxis	0	0.000	0	0.00	0.00

Table 3: TGA reported TTS Summary as at 02/11/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 4: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Diagnosis: **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	15 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated** [redacted] **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	13 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:**12/10/2021 **Dose number:** 1 **Details:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** **GP contacted/notified:** **Classification:**		

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	75	**Diagnosis:** **Date and time vaccinated:** 0/09/2021 **Dose number:** 2 **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	65	**Diagnosis:** **Date and time vaccinated:** 09/08/21 **Dose number:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 21 October 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-21-10-2021

Total adverse event reports to 17 October 2021

2.2	72,011	32,653,925
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
38,901	32,281	498
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax

To 17 October 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 386.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

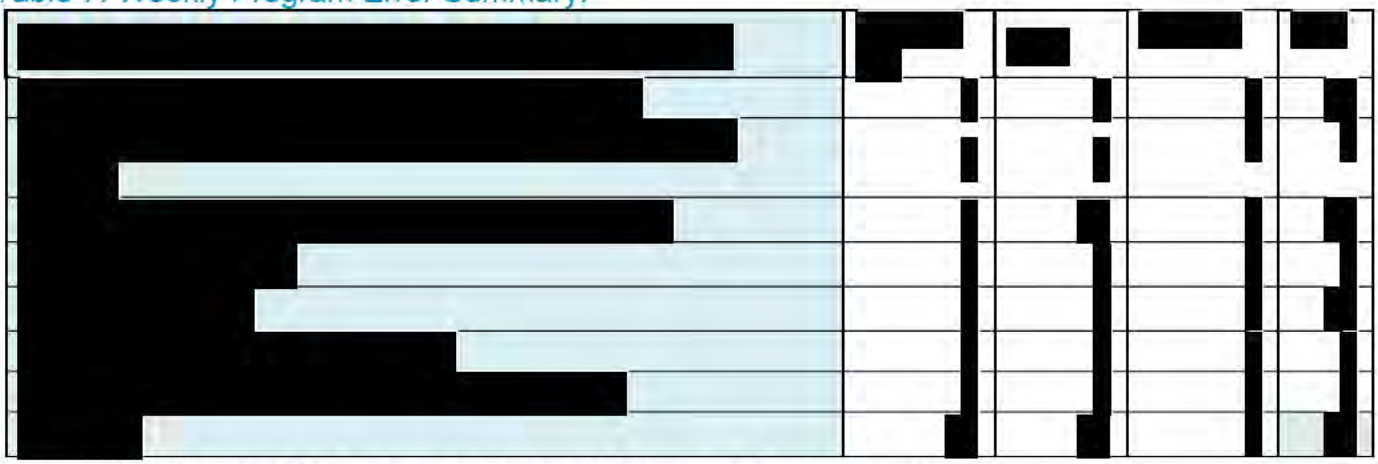
The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team,

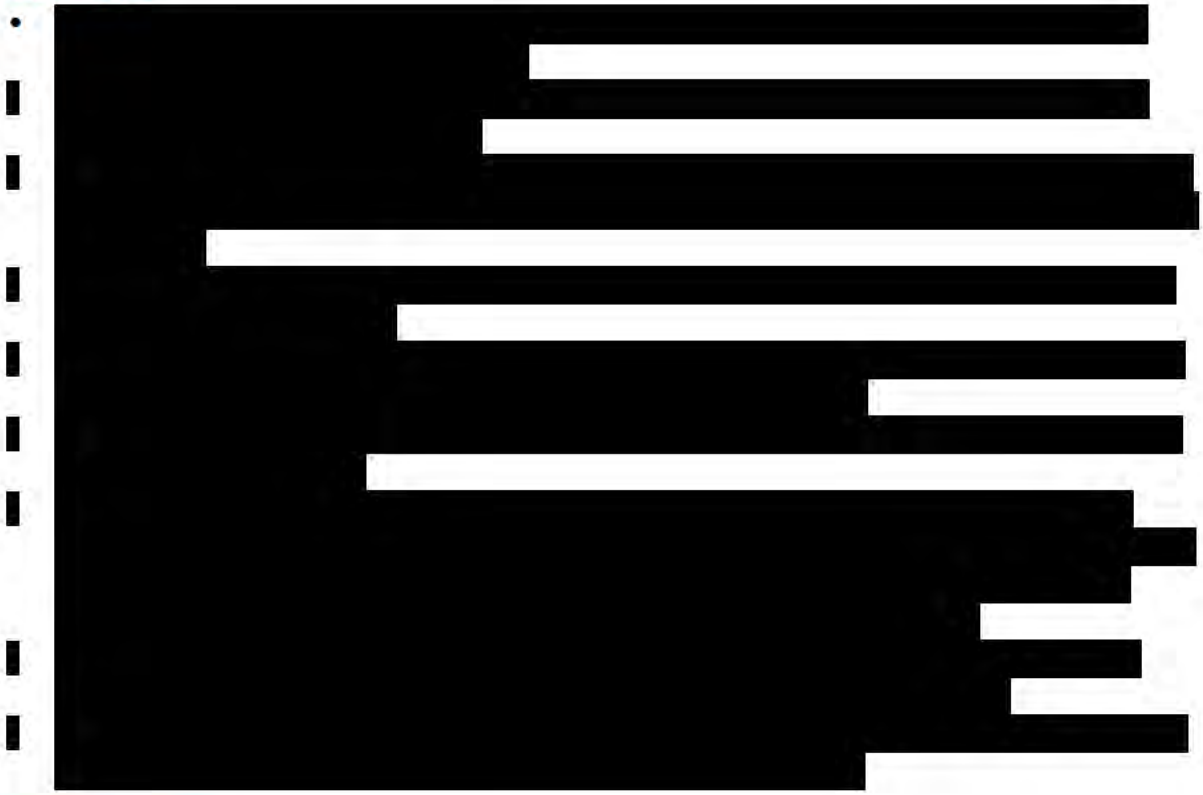
with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

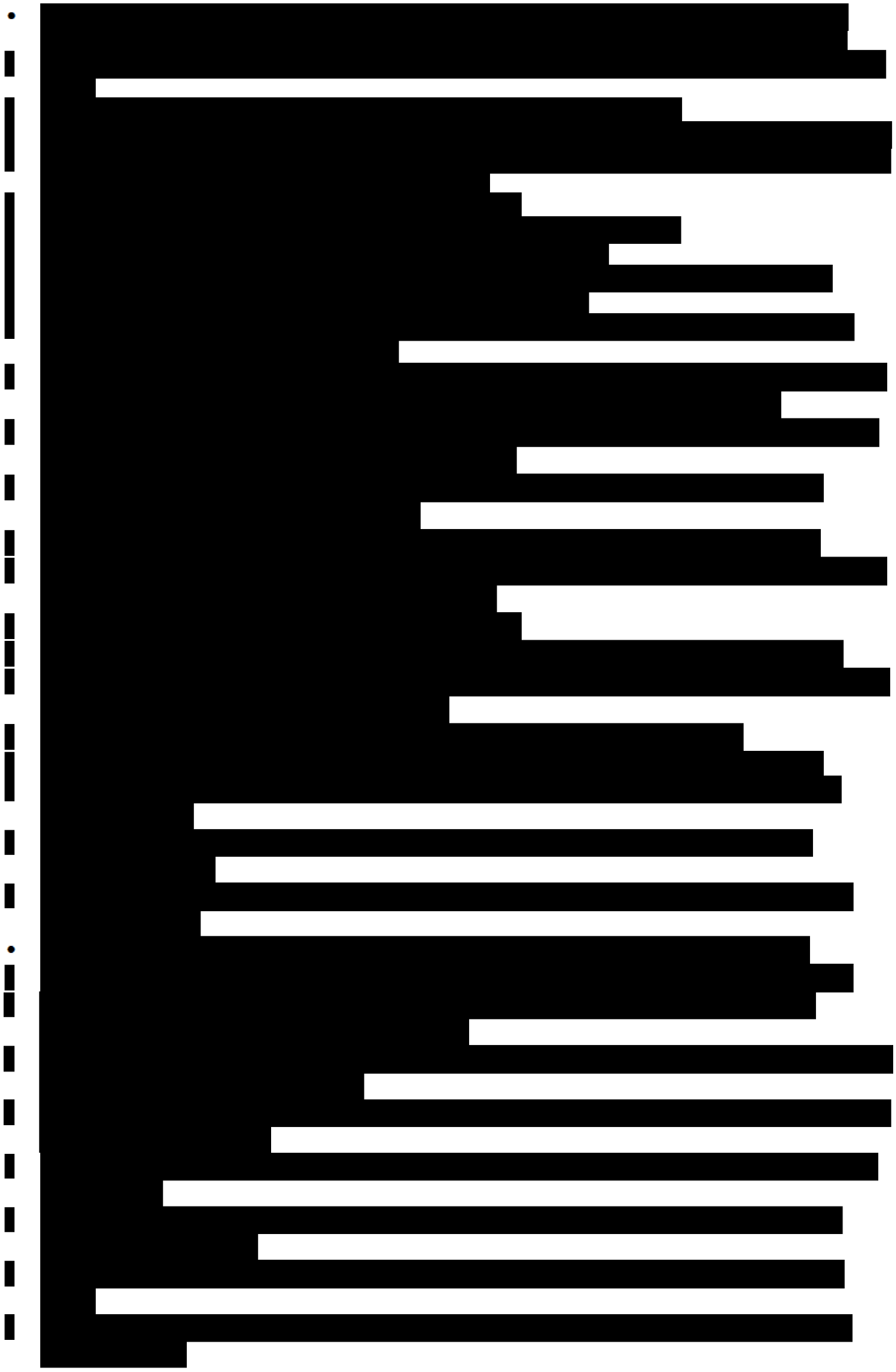


As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors



Non-Critical Errors



- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 35

Meeting date: 9 November 2021

Report period:

27 October 2021 to 2 November 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

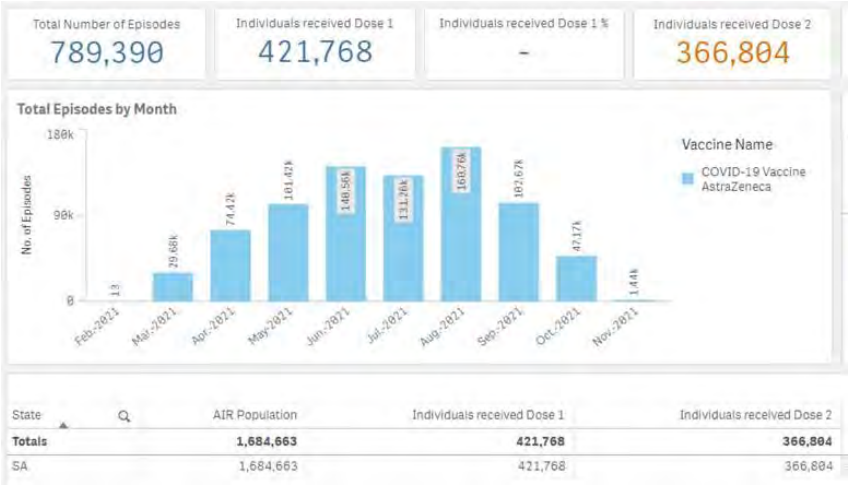
These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 02/11/2021*

Total vaccines:

Vaxzevria:



Pfizer:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,684,663**	**770,000**	**620,265**
SA	1,684,663	770,000	620,265

Moderna:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,684,663**	**39,511**	**7,405**
SA	1,684,663	39,511	7,405

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 02/11/2021 YTD:

Number of Reports		**4,236**
Gender	Male	1,185
	Female	3,040
Indigenous	Yes	54
	No	3,974
	Unknown	140
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**1,024**
General reactions Total number of COVID-19 Vaccines Reports		**3,749**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,880**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	599	31.86	0.076
Myalgia	386	20.53	0.049
Chills	276	14.68	0.035
Nausea	249	13.24	0.032
Fever not recorded	237	12.61	0.030
Fatigue	201	10.69	0.025
Lethargy	171	9.10	0.022
Arthralgia	162	8.62	0.021
Abdominal Pain	106	5.64	0.013
Vomiting	102	5.43	0.013
Dizziness - see vertigo	91	4.84	0.012
Diarrhoea	85	4.52	0.011
Chest Pain	80	4.26	0.010
Dyspnoea	79	4.20	0.010
Rash	77	4.10	0.010
Malaise	66	3.51	0.008
Pain	65	3.46	0.008
Fever mild	62	3.30	0.008
Paresthesia	53	2.82	0.007
Pulmonary embolism	49	2.61	0.006

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**2,280**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	553	24.25	0.040
Myalgia	390	17.11	0.028
Nausea	331	14.52	0.024
Chest Pain	309	13.55	0.022
Fatigue	307	13.46	0.022

Fever not recorded	226	9.91	0.016
Chills	204	8.95	0.015
Lymphadenopathy	195	8.55	0.014
Arthralgia	184	8.07	0.013
Lethargy	180	7.89	0.013
Dizziness - see vertigo	161	7.06	0.012
Paresthesia	138	6.05	0.010
Vomiting	131	5.75	0.009
Palpitations	129	5.66	0.009
Dyspnoea	121	5.31	0.009
Pain	114	5.00	0.008
Abdominal Pain	100	4.39	0.007
Light headedness	92	4.04	0.007
Rash	90	3.95	0.006
Diarrhoea	89	3.90	0.006

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Spikevax **Total Reactions Reported:**	**76**	**% of total Spikevax AEFI reported***	**% of Total Spikevax vaccines administered****
Headache	12	15.79	0.03
Chest Pain	10	13.16	0.02
Nausea	9	11.84	0.02
Fever not recorded	8	10.53	0.02
Injection-site erythema	8	10.53	0.02
Dizziness - see vertigo	7	9.21	0.01
Lethargy	7	9.21	0.01
Injection-site swelling	6	7.89	0.01
Lymphadenopathy	6	7.89	0.01
Myalgia	6	7.89	0.01
Chills	5	6.58	0.01
Dyspnoea	5	6.58	0.01
Pain	5	6.58	0.01
Vomiting	5	6.58	0.01
Diarrhoea	4	5.26	0.01
Injection-site pain	4	5.26	0.01
Light headedness	4	5.26	0.01
Rash	4	5.26	0.01
Sweating	4	5.26	0.01
Visual disturbance	4	5.26	0.01

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 02/11/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 35		
Total Number of reports	**1880**	**% of Total AZ vacc admin***	**18**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Abdominal Pain	106	0.013	0	0.00	0.000
Chest Pain	80	0.010	2	2.50	0.0003
Clot	34	0.004	0	0.00	0.000
Vertigo	48	0.006	1	2.08	0.0001
Visual disturbance	45	0.006	0	0.00	0.000
Epistaxis	24	0.003	0	0.00	0.000
Deep vein thrombosis	44	0.006	0	0.00	0.000
Death	22	0.003	0	0.00	0.000
Herpes zoster	27	0.003	7	25.93	0.0009
Pulmonary embolism	49	0.006	1	2.04	0.0001
Cerebral vascular accident see Stroke	8	0.001	0	0.00	0.000
Stroke	12	0.002	0	0.00	0.000
Thrombocytopenia	9	0.001	1	11.11	0.0001
Bells Palsy	8	0.001	0	0.00	0.000
Anaphylaxis	3	0.000	0	0.00	0.000
Pericarditis	5	0.001	0	0.00	0.000
Menstrual Irregularity	7	0.001	0	0.00	0.000
Guillain Barré syndrome	4	0.001	0	0.00	0.000
Myocarditis	4	0.001	0	0.00	0.000
Exacerbation of existing medical condition	40	0.005	0	0.00	0.000
Thrombosis with thrombocytopenia syndrome TTS	4	0.001	0	0.00	0.000
Cerebral Venous Sinus Thrombosis	4	0.001	0	0.00	0.000
Dyskinesia	2	0.000	0	0.00	0.000
Idiopathic thrombocytopenic purpura	5	0.001	0	0.00	0.000
Multiple sclerosis	1	0.000	0	0.00	0.000
Purpura	11	0.001	0	0.00	0.000
Dysgeusia	19	0.002	0	0.00	0.000

Thrombophlebitis	11	0.001	0	0.00	0.000
Lymphadenopathy	23	0.003	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 35**		
Total Number of reports	**2,280**	**% of Total Pfizer vacc admin.***	**90**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Chest Pain	309	0.022	13	4.21	0.001
Vertigo	53	0.004	2	3.77	0.000
Dizziness – see Vertigo	161	0.012	4	2.48	0.0003
Visual disturbance	46	0.003	0	0.00	0.000
Death	17	0.001	0	0.00	0.0000
Herpes zoster	26	0.002	1	3.85	0.000
Pulmonary embolism	12	0.001	0	0.00	0.000
Bells Palsy	7	0.001	0	0.00	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	43	0.003	1	2.33	0.0001
Pericarditis	51	0.004	6	11.76	0.0004
Myocarditis	14	0.001	4	28.57	0.0003
Myopericarditis	6	0.000	2	33.33	0.0001
Menstrual Irregularity	62	0.004	4	6.45	0.0003
Exacerbation of existing medical condition	53	0.004	6	11.32	0.0004
Miscarriage	3	0.000	0	0.00	0.000
Tinnitus	43	0.003	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax Total Number of reports	YTD		Week 35		
	76	% of Total Spikevax vacc admin*	18	% of YTD AESI reported**	% of Total Spikevax vacc admin***
Bells Palsy	1	0.002	0	0.000	0.000
Chest Pain	10	0.021	3	30.000	0.006
Death	0	0.000	0	0.000	0.000
Lymphadenopathy	6	0.013	3	50.000	0.006
Pericarditis	2	0.004	0	0.000	0.000
Meningitis Aseptic	1	0.002	0	0.000	0.000
Myocarditis	0	0.000	0	0.000	0.000
Myopericarditis	0	0.000	0	0.000	0.000
Menstrual Irregularity	2	0.004	0	0.000	0.000
Miscarriage	1	0.002	1	100.00	0.002
Anaphylaxis	0	0.000	0	0.000	0.000

Table 3: TGA reported TTS Summary as at 02/11/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 4: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Diagnosis: **Date and time vaccinated**: **Dose number:** **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	33 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 20/10/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	33 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 28/10 1630 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Medical History**: [redacted]	[redacted]	No Change Change/Review rationale:

			GP contacted/notified: [redacted] **Classification:** [redacted]	[redacted]	
[redacted]	[redacted]	22 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 15/10/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	18 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**:14/10/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	17 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 26/10/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted]	[redacted]	No Change Change/Review rationale:

			Imaging & Findings: [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	26 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 14/10/2021 **Dose number:** 2 **Details**: [redacted] **Laboratory Results: troponin** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	63 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**:9/10 **Dose number:** 1 **Details**: [redacted] **Laboratory Results** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 28 October 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-28-10-2021

Total adverse event reports to 24 October 2021

2.2	74,380	34,364,950
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
39,496	**33,878**	**670**
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax

To 24 October 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 397.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

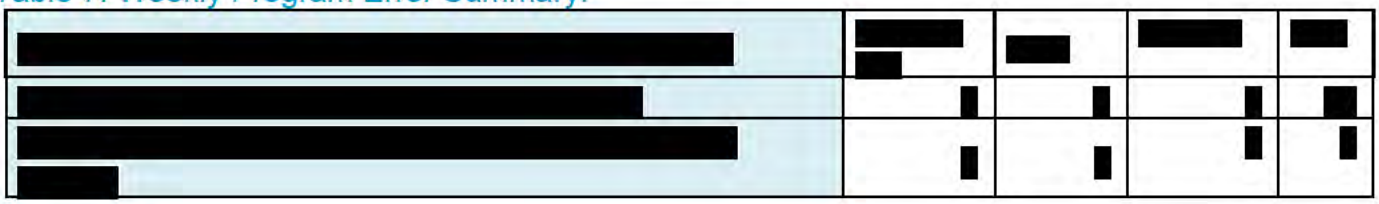
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

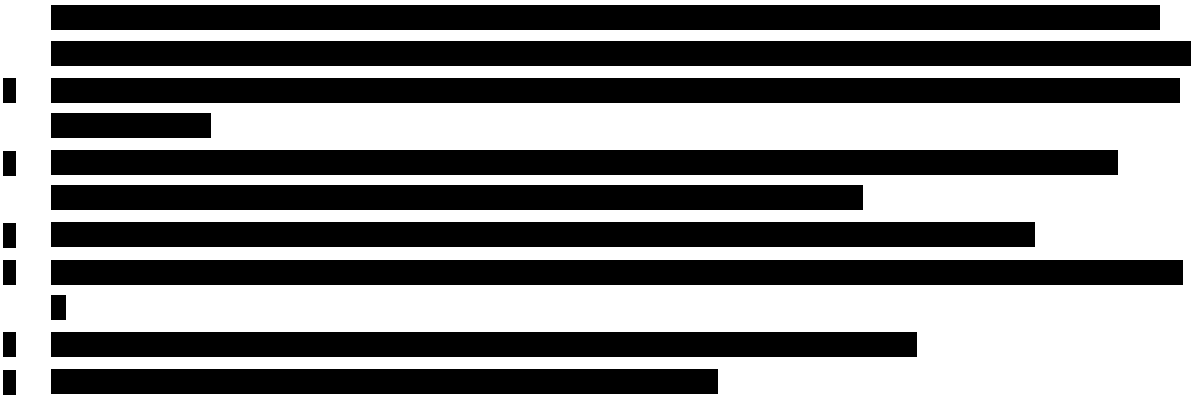
Critical Errors

- [redacted]

Non-Critical Errors

- [redacted]

[redacted]



Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 36

Meeting date: 16 November 2021

Report period:

3 November 2021 to 9 November 2021

Government of South Australia
SA Health

Contents

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 09/11/2021*

Total vaccines:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,685,630**	**1,260,424**	**1,048,084**
SA	1,685,630	1,260,424	1,048,084

Vaxzevria:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,685,630**	**422,246**	**374,115**
SA	1,685,630	422,246	374,115

Pfizer:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,685,630**	**794,551**	**661,773**
SA	1,685,630	794,551	661,773

Moderna:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,685,630**	**43,627**	**13,979**
SA	1,685,630	43,627	13,979

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 09/11/2021 YTD:

Number of Reports		**4,407**
Gender	Male	1,241
	Female	3,153
Indigenous	Yes	55
	No	4,130
	Unknown	146
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**1,061**
General reactions Total number of COVID-19 Vaccines Reports		**3,889**

Vaxzevria (Astra Zeneca) **Total Reports:**	**1,890**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	601	31.80	0.075
Myalgia	387	20.48	0.049
Chills	276	14.60	0.035
Nausea	249	13.17	0.031
Fever not recorded	237	12.54	0.030
Fatigue	201	10.63	0.025
Lethargy	171	9.05	0.021
Arthralgia	162	8.57	0.020
Abdominal Pain	106	5.61	0.013
Vomiting	103	5.45	0.013
Dizziness - see vertigo	92	4.87	0.012
Diarrhoea	85	4.50	0.011
Chest Pain	80	4.23	0.010
Dyspnoea	79	4.18	0.010
Rash	78	4.13	0.010
Malaise	68	3.60	0.009
Pain	66	3.49	0.008
Fever mild	62	3.28	0.008
Paresthesia	53	2.80	0.007
Pulmonary embolism	50	2.65	0.006

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer **Total Reactions Reported:**	**2,430**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	592	24.36	0.041
Myalgia	416	17.12	0.029
Nausea	350	14.40	0.024
Chest Pain	345	14.20	0.024
Fatigue	321	13.21	0.022

Fever not recorded	242	9.96	0.017
Chills	215	8.85	0.015
Lymphadenopathy	203	8.35	0.014
Lethargy	197	8.11	0.013
Arthralgia	194	7.98	0.013
Dizziness - see vertigo	170	7.00	0.012
Vomiting	149	6.13	0.010
Paresthesia	146	6.01	0.010
Palpitations	138	5.68	0.009
Dyspnoea	133	5.47	0.009
Pain	117	4.81	0.008
Abdominal Pain	105	4.32	0.007
Diarrhoea	102	4.20	0.007
Light headedness	95	3.91	0.007
Rash unspecified	95	3.91	0.007

* Number of symptoms reported against all AEFI's reported YTD
** Number of symptoms reported against all vaccinations administered YTD

Spikevax **Total Reactions Reported:**	**87**	**% of total Spikevax AEFI reported***	**% of Total Spikevax vaccines administered****
Headache	14	16.09	0.02
Chest Pain	13	14.94	0.02
Nausea	12	13.79	0.02
Myalgia	10	11.49	0.02
Fever not recorded	9	10.34	0.02
Injection-site erythema	9	10.34	0.02
Lethargy	8	9.20	0.01
Dizziness - see vertigo	7	8.05	0.01
Injection-site swelling	7	8.05	0.01
Lymphadenopathy	7	8.05	0.01
Chills	6	6.90	0.01
Dyspnoea	6	6.90	0.01
Vomiting	6	6.90	0.01
Epistaxis	5	5.75	0.01
Pain	5	5.75	0.01
Diarrhoea	4	4.60	0.01
Fatigue	4	4.60	0.01
Injection-site pain	4	4.60	0.01
Light headedness	4	4.60	0.01
Palpitations	4	4.60	0.01

* Number of symptoms reported against all AEFI's reported YTD
** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 09/11/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 36		
Total Number of reports	**1890**	**% of Total AZ vacc admin***	**7**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Chest Pain	80	0.010	0	0.00	0.0000
Clot	34	0.004	0	0.00	0.0000
Vertigo	48	0.006	0	0.00	0.0000
Visual disturbance	45	0.006	0	0.00	0.0000
Epistaxis	24	0.003	0	0.00	0.0000
Deep vein thrombosis	44	0.006	0	0.00	0.0000
Death	22	0.003	0	0.00	0.0000
Herpes zoster	28	0.004	1	3.57	0.0001
Pulmonary embolism	50	0.006	1	2.00	0.0001
Cerebral vascular accident see Stroke	8	0.001	0	0.00	0.0000
Stroke	12	0.002	0	0.00	0.0000
Thrombocytopenia	9	0.001	0	0.00	0.0000
Bells Palsy	8	0.001	0	0.00	0.0000
Anaphylaxis	3	0.000	0	0.00	0.0000
Pericarditis	5	0.001	0	0.00	0.0000
Menstrual Irregularity	8	0.001	0	0.00	0.0000
Guillain Barré syndrome	4	0.001	0	0.00	0.0000
Myocarditis	4	0.001	0	0.00	0.0000
Exacerbation of existing medical condition	41	0.005	1	2.44	0.0001
Thrombosis with thrombocytopenia syndrome TTS	4	0.001	0	0.00	0.0000
Cerebral Venous Sinus Thrombosis	4	0.001	0	0.00	0.0000
Dyskinesia	2	0.000	0	0.00	0.0000
Idiopathic thrombocytopenic purpura	5	0.001	0	0.00	0.0000
Multiple sclerosis	1	0.000	0	0.00	0.0000
Purpura	11	0.001	0	0.00	0.0000
Dysgeusia	19	0.002	0	0.00	0.0000
Thrombophlebitis	11	0.001	0	0.00	0.0000

Lymphadenopathy	23	0.003	0	0.00	0.0000
Acute disseminated encephalomyelitis	2	0.000	1	50.00	0.0001

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 36**		
Total Number of reports	**2,430**	**% of Total Pfizer vacc admin.***	**145**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Chest Pain	345	0.024	31	8.99	0.002
Vertigo	57	0.004	4	7.02	0.000
Dizziness – see Vertigo	170	0.012	8	4.71	0.0005
Visual disturbance	50	0.003	4	8.00	0.000
Death	17	0.001	0	0.00	0.0000
Herpes zoster	27	0.002	1	3.70	0.000
Pulmonary embolism	12	0.001	0	0.00	0.000
Bells Palsy	7	0.000	0	0.00	0.0000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	43	0.003	0	0.00	0.0000
Pericarditis	53	0.004	2	3.77	0.0001
Myocarditis	19	0.001	5	26.32	0.0003
Myopericarditis	8	0.001	1	12.50	0.0001
Menstrual Irregularity	67	0.005	4	5.97	0.0003
Exacerbation of existing medical condition	68	0.005	11	16.18	0.0008
Miscarriage	3	0.000	0	0.00	0.0000
Tinnitus	44	0.003	1	2.27	0.0001
Vasculitis	5	0.000	0	0.00	0.0000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax	YTD		Week 36		
Total Number of reports	**87**	**% of Total Spikevax vacc admin***	**11**	**% of YTD AESI reported****	**% of Total Spikevax vacc admin*****
Bells Palsy	1	0.002	0	0.000	0.000
Chest Pain	13	0.023	3	23.07	0.005
Death	0	0.000	0	0.000	0.000
Lymphadenopathy	7	0.012	1	14.28	0.002
Pericarditis	2	0.003	0	0.000	0.000
Meningitis Aseptic	1	0.002	0	0.000	0.000
Myocarditis	0	0.000	0	0.000	0.000
Myopericarditis	0	0.000	0	0.000	0.000
Menstrual Irregularity	2	0.003	0	0.000	0.000
Miscarriage	1	0.002	1	0.000	0.002
Anaphylaxis	0	0.000	0	0.000	0.000

Table 3: TGA reported TTS Summary as at 09/11/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 4: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	28[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 11/10/21 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	31[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 23/10/201 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

[redacted]	[redacted]	26 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 29/10/2021 **Dose number:** 2 **Details** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	32 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 13/10/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

[redacted]	[redacted]	16 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 26/10/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	20 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**:31/10/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	**No Letter required**	No Change Change/Review rationale:
[redacted]	[redacted]	17 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 19/10/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted]	[redacted]	No Change Change/Review rationale:

			Treatment: **Medical History:** **GP contacted/notified:** **Classification:**		
		22	**Diagnosis:** **Date and time vaccinated:** 26/10/2021 **Dose number:** 2 **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**		No Change Change/Review rationale:
		48	**Diagnosis:** **Date and time vaccinated:** 30/09/2021 **Dose number:** 1 **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**		No Change Change/Review rationale:
		15	**Diagnosis:** **Date and time vaccinated:** 4/11/2021 **Dose number:** 2 **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:**		No Change Change/Review rationale:

			Medical History: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	77 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 3/9/2021 **Dose number:** 1 **Details** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	88 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 1/10/21 **Dose number:** Dose 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted] [redacted]	[redacted]	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 4 November 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-04-11-2021

Summary

- Vaccination against COVID-19 is the most effective way to reduce deaths and severe illness from infection. The protective benefits of vaccination continue to far outweigh the potential risks.
- Like all medicines, COVID-19 vaccines may cause some side effects. The most frequently reported include injection-site reactions (such as a sore arm) and more general symptoms, like headache, muscle pain, fever and chills. This reflects what was seen in the clinical trials.
- We are carefully monitoring and reviewing reports of:
    - myocarditis and pericarditis following mRNA vaccines, particularly in younger age groups
    - thrombosis with thrombocytopenia syndrome (TTS) following Vaxzevria (AstraZeneca)
    - Guillain-Barre Syndrome (GBS) following Vaxzevria (AstraZeneca)
    - immune thrombocytopenia (ITP) following Vaxzevria (AstraZeneca)
- Myocarditis is a known but very rare side effect of Comirnaty (Pfizer) and Spikevax (Moderna). It is usually temporary with most people getting better within a few days. Myocarditis is reported in about one in of every 100,000 people who receive Comirnaty (Pfizer), although it is more common in young men and teenage boys after the second dose (3–7 cases per 100,000 doses).
    - To 31 October 2021, the TGA has received 253 reports which have been assessed as likely to be myocarditis from about 21.9 million doses of Comirnaty (Pfizer). This is an increase of 18 cases of likely myocarditis since last week.
- Thrombosis with thrombocytopenia syndrome (or TTS) is a very rare but serious side effect of Vaxzevria (AstraZeneca). Our analysis shows it is reported in about 2 in every 100,000 people following vaccination, although the risk is slightly higher in people under 60 years. The risk of TTS is much lower after the second vaccine dose.
    - One new case of TTS was reported this week, taking the total to 158 cases from about 13.1 million doses of Vaxzevria (AstraZeneca).

Total adverse event reports to 31 October 2021

2.1	76,587	35,715,731
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
39,965	35,386	891
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax

To 31 October 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 409.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

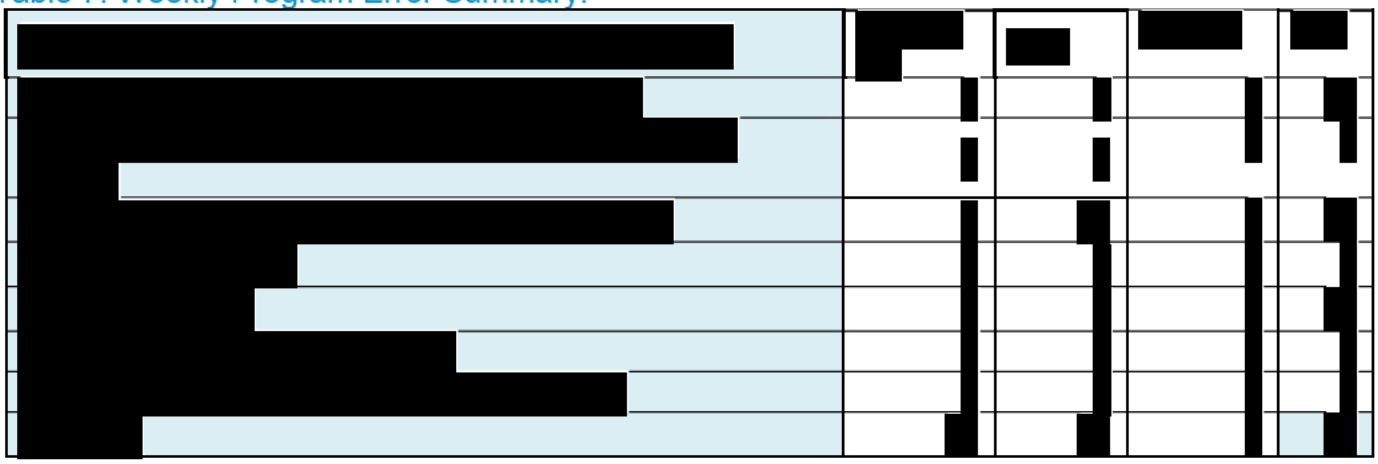
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



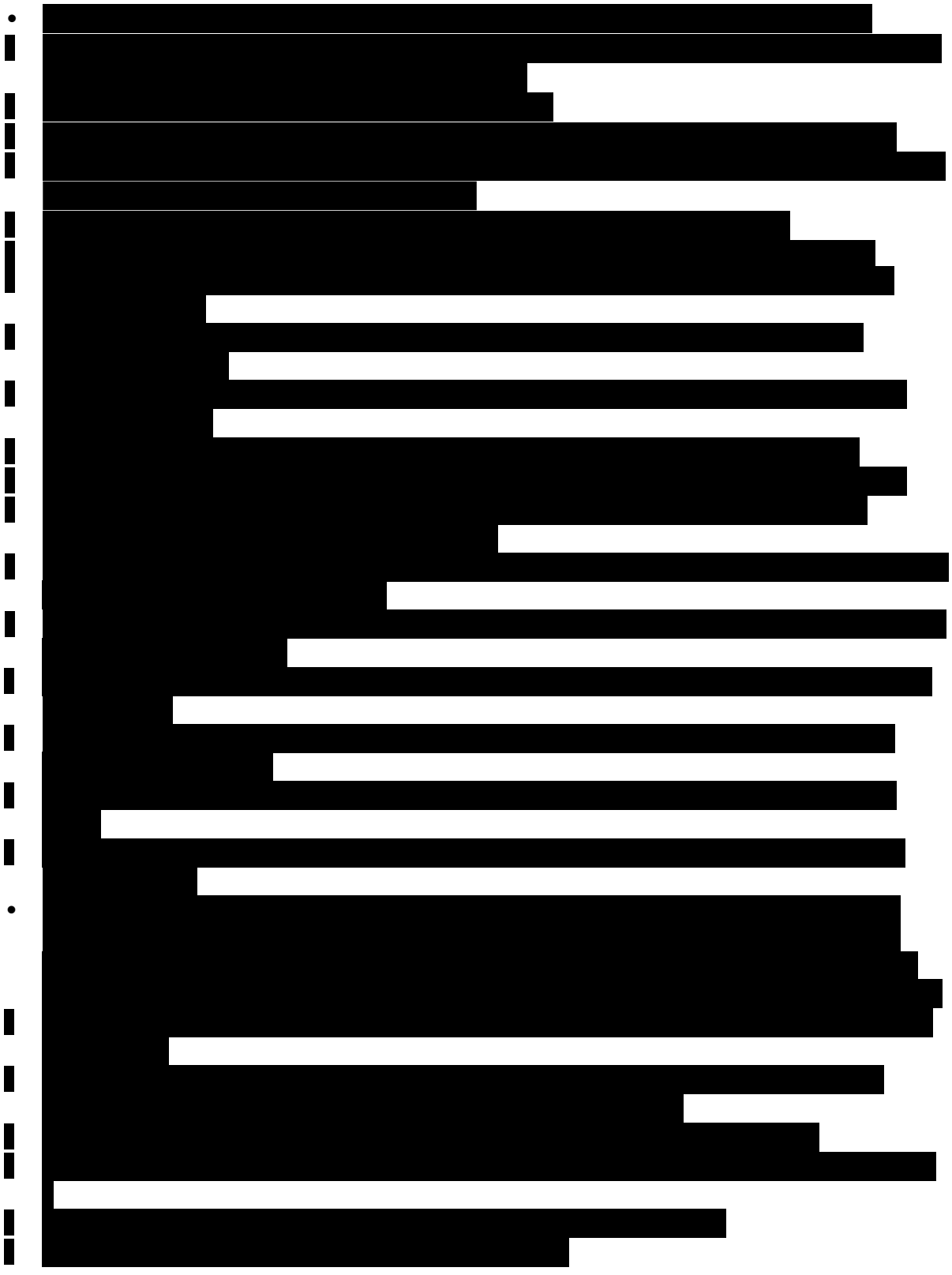
As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

[redacted]

Non-Critical Errors

[redacted]



Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 37

Meeting date: 23 November 2021

Report period:

10 November 2021 to 16 November 2021

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 16/11/2021*

Total vaccines:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,686,066**	**1,291,794**	**1,113,535**
SA	1,686,066	1,291,794	1,113,535

Vaxzevria:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,686,066**	**422,855**	**384,563**
SA	1,686,066	422,855	384,563

Pfizer:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,686,066**	**820,569**	**708,608**
SA	1,686,066	820,569	708,608

Moderna:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,686,066**	**48,370**	**23,035**
SA	1,686,066	48,370	23,035

*Latest available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 16/11/2021 YTD:

Number of Reports		**4,593**
Gender	Male	1,301
	Female	3,280
Indigenous	Yes	56
	No	4,298
	Unknown	159
Injection Site Reactions Total Number COVID-19 Vaccines Reports		**1,096**
General reactions Total number of COVID-19 Vaccines Reports		**4,043**

Vaxzevria (Astra Zeneca) Total Reports:	**1,904**	**% of total AZ AEFI reported***	**% of Total AZ vaccines administered****
Headache	602	31.62	0.07
Myalgia	389	20.43	0.05
Chills	277	14.55	0.03
Nausea	249	13.08	0.03
Fever not recorded	237	12.45	0.03
Fatigue	202	10.61	0.03
Lethargy	171	8.98	0.02
Arthralgia	162	8.51	0.02
Abdominal Pain	106	5.57	0.01
Vomiting	104	5.46	0.01
Dizziness - see vertigo	93	4.88	0.01
Diarrhoea	85	4.46	0.01
Chest Pain	82	4.31	0.01
Rash	81	4.25	0.01
Dyspnoea	80	4.20	0.01
Malaise	68	3.57	0.01
Pain	66	3.47	0.01
Fever mild	62	3.26	0.01
Paresthesia	53	2.78	0.01
Pulmonary embolism	50	2.63	0.01

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer Total Reactions Reported:	**2,574**	**% of total Pfizer AEFI reported***	**% of Total Pfizer vaccines administered****
Headache	622	24.16	0.04
Myalgia	448	17.40	0.03
Chest Pain	393	15.27	0.03
Nausea	371	14.41	0.02
Fatigue	345	13.40	0.02

Fever not recorded	261	10.14	0.02
Chills	228	8.86	0.02
Lymphadenopathy	223	8.66	0.01
Lethargy	205	7.96	0.01
Arthralgia	202	7.85	0.01
Dizziness - see vertigo	193	7.50	0.01
Vomiting	167	6.49	0.01
Palpitations	163	6.33	0.01
Dyspnoea	154	5.98	0.01
Paresthesia	151	5.87	0.01
Pain	119	4.62	0.01
Abdominal Pain	108	4.20	0.01
Diarrhoea	108	4.20	0.01
Rash	98	3.81	0.01
Rash unspecified	97	3.77	0.01

* Number of symptoms reported against all AEFI's reported YTD
** Number of symptoms reported against all vaccinations administered YTD

Spikevax **Total Reactions Reported:**	**87**	**% of total Spikevax AEFI reported***	**% of Total Spikevax vaccines administered****
Chest Pain	20	12.17	0.02
Headache	18	11.30	0.02
Nausea	18	10.43	0.02
Myalgia	16	8.70	0.01
Fever not recorded	10	7.83	0.01
Injection-site swelling	10	7.83	0.01
Dizziness - see vertigo	9	6.96	0.01
Injection-site erythema	9	6.09	0.01
Injection-site pain	9	6.09	0.01
Lethargy	9	6.09	0.01
Vomiting	9	5.22	0.01
Dyspnoea	8	5.22	0.01
Lymphadenopathy	8	5.22	0.01
Chills	7	4.35	0.01
Fatigue	7	4.35	0.01
Malaise	7	3.48	0.01
Fever high	6	3.48	0.01
Pain	6	3.48	0.01
Epistaxis	5	3.48	0.01
Injection site pain restricting limb mobility	5	12.17	0.01

* Number of symptoms reported against all AEFI's reported YTD
** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 16/11/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 37		
Total Number of reports	**1,904**	**% of Total AZ vacc admin***	**13**	**% of YTD AESI reported****	**% of Total AZ vacc admin*****
Chest Pain	82	0.010	0	0.00	0.000
Clot	34	0.004	0	0.00	0.000
Vertigo	48	0.006	0	0.00	0.000
Visual disturbance	45	0.006	0	0.00	0.000
Epistaxis	24	0.003	0	0.00	0.000
Deep vein thrombosis	45	0.006	1	2.22	0.0001
Death	22	0.003	0	0.00	0.000
Herpes zoster	28	0.003	0	0.00	0.000
Pulmonary embolism	50	0.006	0	0.00	0.000
Cerebral vascular accident see Stroke	8	0.001	0	0.00	0.000
Stroke	12	0.001	0	0.00	0.000
Thrombocytopenia	9	0.001	0	0.00	0.000
Bells Palsy	9	0.001	1	11.11	0.0001
Anaphylaxis	3	0.000	0	0.00	0.000
Pericarditis	5	0.001	0	0.00	0.000
Menstrual Irregularity	8	0.001	0	0.00	0.000
Guillain Barré syndrome	4	0.000	0	0.00	0.000
Myocarditis	4	0.000	0	0.00	0.000
Exacerbation of existing medical condition	41	0.005	0	0.00	0.000
Thrombosis with thrombocytopenia syndrome TTS	4	0.000	0	0.00	0.000
Cerebral Venous Sinus Thrombosis	4	0.000	0	0.00	0.000
Dyskinesia	2	0.000	0	0.00	0.000
Idiopathic thrombocytopenic purpura	5	0.001	0	0.00	0.000
Multiple sclerosis	1	0.000	0	0.00	0.000
Purpura	11	0.001	0	0.00	0.000
Dysgeusia	19	0.002	0	0.00	0.000
Thrombophlebitis	11	0.001	0	0.00	0.000

Lymphadenopathy	23	0.003	0	0.00	0.000
Acute disseminated encephalomyelitis	2	0.000	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	**YTD**		**Week 37**		
Total Number of reports	**2,574**	**% of Total Pfizer vacc admin.***	**124**	**% of YTD AESI reported****	**% of Total Pfizer vacc admin.*****
Chest Pain	393	0.027	40	10.18	0.003
Vertigo	59	0.004	0	0.00	0.000
Dizziness – see Vertigo	193	0.013	16	8.29	0.001
Visual disturbance	52	0.004	1	1.92	0.000
Death	17	0.001	0	0.00	0.000
Herpes zoster	28	0.002	1	3.57	0.000
Pulmonary embolism	12	0.001	0	0.00	0.000
Bells Palsy	8	0.001	1	12.50	0.0001
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	49	0.003	4	8.16	0.0003
Pericarditis	55	0.004	0	0.00	0.000
Myocarditis	20	0.001	1	5.00	0.0001
Myopericarditis	8	0.001	0	0.00	0.000
Menstrual Irregularity	68	0.005	1	1.47	0.0001
Exacerbation of existing medical condition	74	0.005	5	6.76	0.0003
Miscarriage	3	0.000	0	0.00	0.000
Tinnitus	48	0.003	3	6.25	0.0002
Vasculitis	5	0.000	0	0.00	0.000

* Number of Special Interest symptoms reported against all vaccinations administered YTD
** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD
***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax	YTD		Week 37		
Total Number of reports	115	% of Total Spikevax vacc admin*	25	% of YTD AESI reported**	% of Total Spikevax vacc admin***
Bells Palsy	1	0.001	0	0.000	0.000
Chest Pain	20	0.028	7	53.85	0.010
Death	0	0.000	0	0.000	0.000
Lymphadenopathy	8	0.011	1	14.29	0.001
Pericarditis	2	0.003	0	0.000	0.000
Meningitis Aseptic	1	0.001	0	0.000	0.000
Myocarditis	0	0.000	0	0.000	0.000
Myopericarditis	0	0.000	0	0.000	0.000
Menstrual Irregularity	3	0.004	1	50.00	0.001
Miscarriage	1	0.001	0	0.000	0.000
Anaphylaxis	0	0.000	0	0.000	0.000

Table 3: TGA reported TTS Summary as at 16/11/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 4: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Diagnosis: **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	[redacted] 25	**Diagnosis:** [redacted] **Date and time vaccinated:** 15/10/21 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/ AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Diagnosis: **Date and time vaccinated**: **Dose number:** **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 11 November 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-11-11-2021

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

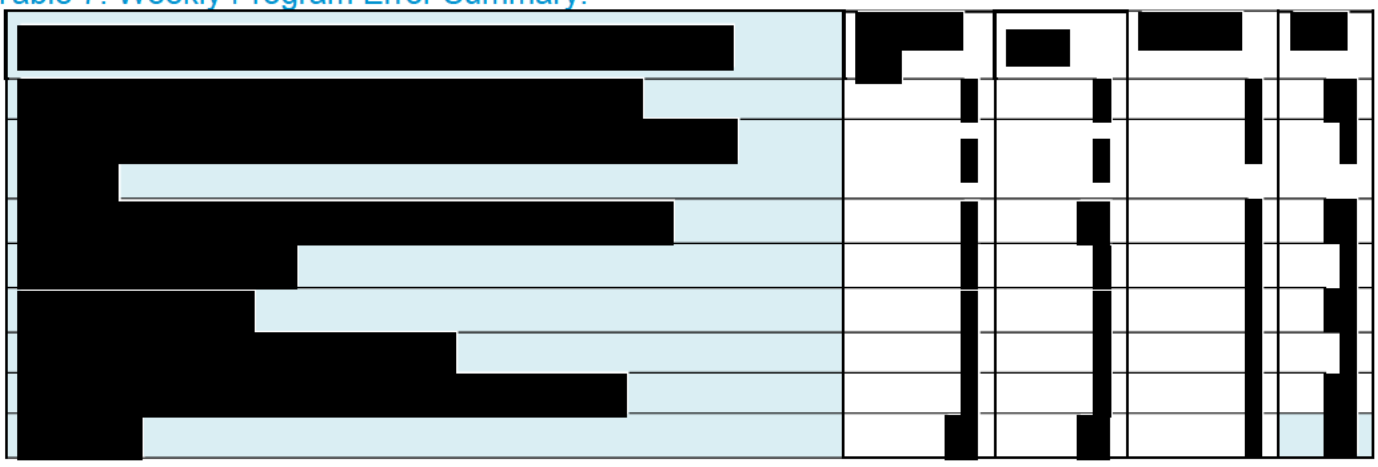
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

Non-Critical Errors

- [redacted]

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia

- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 38

Meeting date: 30 November 2021

Report period:

17 November 2021 to 23 November 2021

Government of South Australia
SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

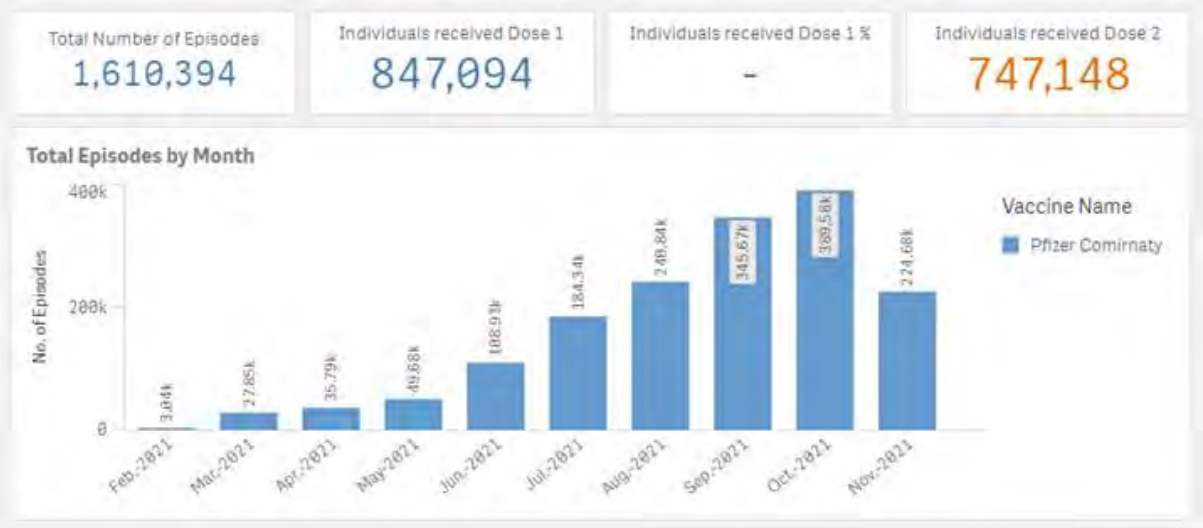
Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 23/11/2021*

Total vaccines:

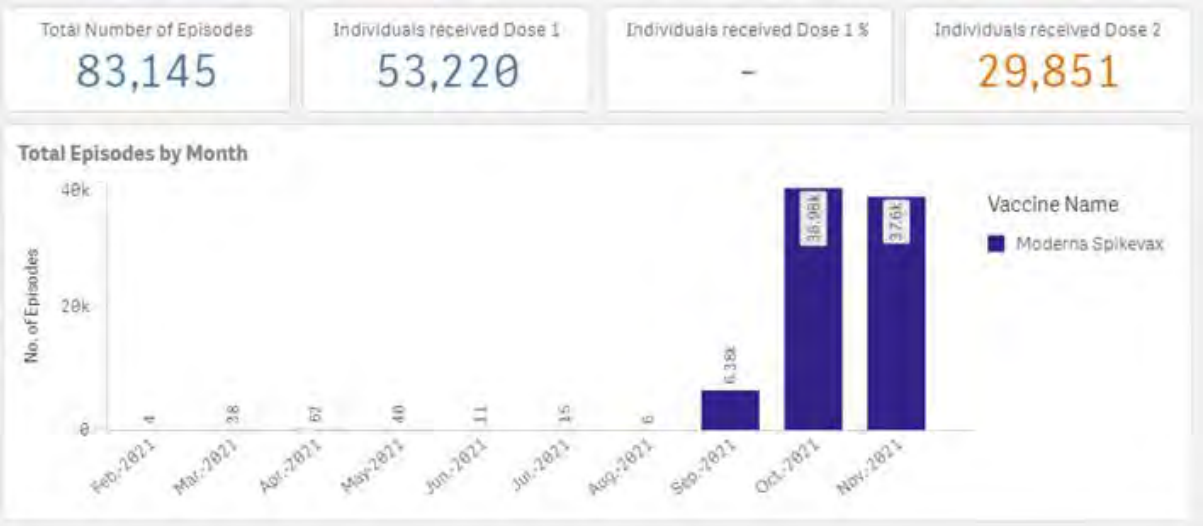
Vaxzevria:

Pfizer:



State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,687,032**	**847,094**	**747,148**
SA	1,687,032	847,094	747,148

Moderna:

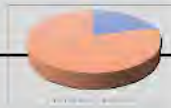


State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,687,032**	**53,220**	**29,851**
SA	1,687,032	53,220	29,851

available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 23/11/2021 YTD:

Number of Reports		**4,766**
Gender	Male	1366
	Female	3400
Indigenous	Yes	63
	No	4,476
	Unknown	162
Injection site reactions total number Covid-19 vaccines reports		**1,146**
General reactions total number of COVID-19 vaccines reports		**4,204**



Vaxzevria (Astra Zeneca) **Adverse events**	**1,911**	**% of total AZ AEFI reported***	**Rates/1000 doses of total AZ vaccines administered****
Headache	603	31.55	7.362
Myalgia	389	20.36	4.749
Chills	278	14.55	3.394
Nausea	251	13.13	3.064
Fever not recorded	237	12.40	2.893
Fatigue	203	10.62	2.478
Lethargy	172	9.00	2.100
Arthralgia	163	8.53	1.990
Abdominal Pain	106	5.55	1.294
Vomiting	104	5.44	1.270
Dizziness - see vertigo	93	4.87	1.135
Diarrhoea	85	4.45	1.038
Chest Pain	83	4.34	1.013
Rash	82	4.29	1.001
Dyspnoea	81	4.24	0.989
Malaise	68	3.56	0.830
Pain	67	3.51	0.818
Fever mild	62	3.24	0.757
Paraesthesia	53	2.77	0.647
Pulmonary embolism	50	2.62	0.610

* Number of symptoms reported against all total AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Pfizer Adverse events	2,709	% of total Pfizer AEFI reported*	Rates/1000 doses of total Pfizer vaccines administered**
Headache	651	24.03	4.042
Myalgia	466	17.20	2.894
Nausea	388	14.32	2.409
Chest Pain	437	16.13	2.714
Fatigue	364	13.44	2.260
Fever not recorded	267	9.86	1.658
Chills	232	8.56	1.441
Lymphadenopathy	229	8.45	1.422
Arthralgia	211	7.79	1.310
Lethargy	219	8.08	1.360
Dizziness - see vertigo	206	7.60	1.279
Paraesthesia	169	6.24	1.049
Vomiting	173	6.39	1.074
Palpitations	169	6.24	1.049
Dyspnoea	172	6.35	1.068
Pain	114	4.21	0.708
Abdominal Pain	108	3.99	0.671
Light headedness	96	3.54	0.596
Rash	103	3.80	0.640
Diarrhoea	111	4.10	0.689

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Spikevax Adverse events	160	% of total Spikevax AEFI reported*	Rates/1000 doses of total Spikevax vaccines administered**
Headache	29	18.13	3.49
Chest Pain	29	18.13	3.49
Nausea	31	19.38	3.73
Fever not recorded	10	6.25	1.20
Injection-site erythema	11	6.88	1.32
Dizziness - see vertigo	15	9.38	1.80
Lethargy	13	8.13	1.56
Injection-site swelling	11	6.88	1.32
Lymphadenopathy	10	6.25	1.20
Myalgia	22	13.75	2.65
Lethargy	13	8.13	1.56
Arthralgia	12	7.50	1.44
Chills	12	7.50	1.44
Dyspnoea	11	6.88	1.32
Palpitation	8	5.00	0.96

Pain	6	3.75	0.72
Vomiting	11	6.88	1.32
Diarrhoea	9	5.63	1.08
Injection-site pain	15	9.38	1.80
Light headedness	6	3.75	0.72
Rash	5	3.13	0.60
Sweating	6	3.75	0.72
Visual disturbance	5	3.13	0.60

* Number of symptoms reported against all AEFI's reported YTD

** Number of symptoms reported against all vaccinations administered YTD

Table 2: Special Interest AEFI Topics as at 23/11/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 38		
Adverse events	1,911	Rates/1000 doses of total AZ vacc admin*	7	% of YTD AESI reported**	Rates/1000 doses of total AZ vacc admin***
Abdominal Pain	106	1.294	0	0.00	0.000
Chest Pain	83	1.013	1[a]	1.20	0.012
Clot	34	0.415	0	0.00	0.000
Vertigo	48	0.586	0	0.00	0.000
Visual disturbance	45	0.549	0	0.00	0.000
Epistaxis	24	0.293	0	0.00	0.000
Deep vein thrombosis	46	0.562	1[a]	2.17	0.012
Death	22	0.269	0	0.00	0.000
Herpes zoster	28	0.342	0	0.00	0.000
Pulmonary embolism	50	0.610	0	0.00	0.000
Cerebral vascular accident see Stroke	8	0.098	0	0.00	0.000
Stroke	12	0.147	0	0.00	0.000
Thrombocytopenia	9	0.110	0	0.00	0.000
Bell's Palsy	9	0.110	0	0.00	0.000
Anaphylaxis	3	0.037	0	0.00	0.000
Pericarditis	5	0.061	0	0.00	0.000
Menstrual Irregularity	8	0.098	0	0.00	0.000
Guillain Barré syndrome	4	0.049	0	0.00	0.000
Myocarditis	4	0.049	0	0.00	0.000

Exacerbation of existing medical condition	41	0.501	0	0.00	0.000
Thrombosis with thrombocytopenia syndrome TTS	4	0.049	0	0.00	0.000
Cerebral Venous Sinus Thrombosis	4	0.049	0	0.00	0.000
Dyskinesia	2	0.024	0	0.00	0.000
Idiopathic thrombocytopenic purpura	5	0.061	0	0.00	0.000
Multiple sclerosis	1	0.012	0	0.00	0.000
Purpura	11	0.134	0	0.00	0.000
Dysgeusia	19	0.232	0	0.00	0.000
Thrombophlebitis	11	0.134	0	0.00	0.000
Lymphadenopathy	23	0.281	0	0.00	0.000

a: Chest pain: 1st dose and DVT: 2nd dose

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	YTD		Week 38		
Adverse events	2,709	% of total Pfizer vacc admin.*	115	% of YTD AESI reported**	Rates/1000 doses of total Pfizer vacc admin.***
Chest Pain	437	2.714	35(17 after the 1st dose)	8.01	0.217
Vertigo	59	0.366	0	0.00	0.000
Dizziness – see Vertigo	206	1.279	10(6 after the 1st dose)	4.85	0.062
Visual disturbance	55	0.342	1[a]	1.82	0.006
Death	17	0.106	0	0.00	0.000
Herpes zoster	28	0.174	0	0.00	0.000
Pulmonary embolism	12	0.075	0	0.00	0.000
Bell's Palsy	9	0.056	1[a]	11.11	0.006
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	28	0.174	1[a]	3.57	0.006
Pericarditis	57	0.354	0	0.00	0.000
Myocarditis	21	0.130	1[a]	4.76	0.006

Myopericarditis	9	0.056	1[a]	11.11	0.006
Menstrual Irregularity	71	0.441	4(2 after the 1st dose)	5.63	0.025
Exacerbation of existing medical condition	85	0.528	10(6 after the 1st dose)	11.76	0.062
Miscarriage	4	0.025	0	0.00	0.000
Tinnitus	51	0.317	3(1 after the 1st dose)	5.88	0.019

a: Visual, anaphylactic reactions: 1st dose and Bell's palsy, myocarditis and myopericarditis: 2nd dose.

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax	YTD		Week 38		
Adverse events	160	Rates/1000 doses of total Spikevax vacc admin*	39	% of YTD AESI reported**	Rates/1000 doses of total Spikevax vacc admin***
Bells Palsy	1	0.120	0	0.000	0.000
Chest Pain	29	3.488	9(6 after the 1st dose)	31.034	1.082
Death	0	0.000	0	0.000	0.000
Lymphadenopathy	10	1.203	1[a]	10.000	0.120
Pericarditis	2	0.241	0	0.000	0.000
Meningitis Aseptic	1	0.120	0	0.000	0.000
Myocarditis	0	0.000	0	0.000	0.000
Myopericarditis	0	0.000	0	0.000	0.000
Menstrual Irregularity	4	0.481	1[a]	25.000	0.120
Anaphylaxis	1	0.120	0	0.000	0.000
Miscarriage	1	0.120	0	0.000	0.000

a: Menstrual Irregularity, Lymphadenopathy: 1st dose and, Miscarriage: 2nd dose.

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 23/11/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 4: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	27 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 9/11/21 **Dose number:** 2 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification: Haematology**	No Letter required	No Change Change/Review rationale:
			Diagnosis: **Date and time vaccinated**: **Dose number:** **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	52 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 3/5/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	22 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 11/11/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
			Diagnosis: **Date and time vaccinated**: **Dose number:**	Uncommon – refer back to GP for review Uncommon – refer back to GP	No Change Change/Review rationale:

			Details: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	**TGA AEFI/A ESI Cat**	**Age and Gender**	**Incident details**	**Recommendation for client from Committee**	**Vaccination Program Implications**
			Diagnosis: **Date and time vaccinated**: **Dose number:** **Details**: **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:
			Diagnosis: **Date and time vaccinated**: **Dose number:** **Details**: **Laboratory Results:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review	No Change Change/Review rationale:

			Imaging & Findings: **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP suggesting Specialist review No Letter required	

2. Summary of the TGA COVID-19 vaccine updates:

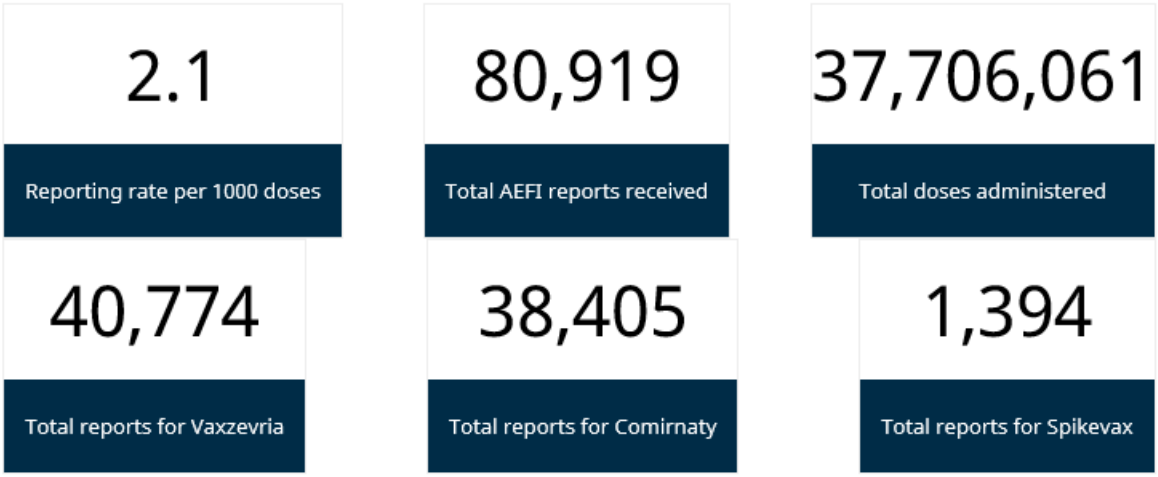
Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 18 November 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-18-11-2021

Summary

- Vaccination against COVID-19 is the most effective way to reduce deaths and severe illness from infection. The protective benefits of vaccination continue to far outweigh the potential risks.
- Like all medicines, COVID-19 vaccines may cause some side effects. The most frequently reported include injection-site reactions (such as a sore arm) and more general symptoms, like headache, muscle pain, fever and chills. This reflects what was seen in the clinical trials.
- We are carefully monitoring and reviewing reports of:
  - myocarditis and pericarditis following mRNA vaccines, particularly in younger age groups
  - thrombosis with thrombocytopenia syndrome (TTS) following Vaxzevria (AstraZeneca)
  - Guillain-Barre Syndrome (GBS) following Vaxzevria (AstraZeneca)
  - immune thrombocytopenia (ITP) following Vaxzevria (AstraZeneca)
- Myocarditis is a known but very rare side effect of Comirnaty (Pfizer) and Spikevax (Moderna). It is usually temporary, with most people getting better within a few days. Myocarditis is reported in about one in every 100,000 people who receive Comirnaty (Pfizer), although it is more common in young men and teenage boys after the second dose (4–9 cases per 100,000 doses).
  - To 14 November 2021, the TGA has received 315 reports which have been assessed as likely to be myocarditis from about 23.4 million doses of Comirnaty (Pfizer).
- Thrombosis with thrombocytopenia syndrome (or TTS) is a very rare but serious side effect of Vaxzevria (AstraZeneca). Our analysis shows it is reported in about 2 in every 100,000 vaccinated people following the first dose. The risk of TTS is much lower after the second dose (0.3 in every 100,000 vaccinated people).
  - Three new cases of probable TTS were reported this week, taking the total to 163 cases from about 13.4 million doses of Vaxzevria (AstraZeneca).

Total adverse event reports to 14 November 2021



To 14 November 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 420.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.

- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:

As the COVID-19 vaccination program is increasing, frequency of receipt of program errors is also increasing.

Critical Errors

-

Non-Critical Errors

-

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis

- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

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Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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Document 33

OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 39

Meeting date: 7 December 2021

Report period:

24 November 2021 to 30 November 2021

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 30/11/2021*

Total vaccines:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2	Coverage % (2 doses)
Totals	**1,688,362**	**1,353,238**	**1,213,929**	**71.90%**
SA	1,688,362	1,353,238	1,213,929	71.90%

Vaxzevria:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,688,362**	**424,395**	**402,951**
SA	1,688,362	424,395	402,951

Moderna Spikevax:

State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,688,362**	**57,589**	**36,819**
SA	1,688,362	57,589	36,819

Pfizer Comirnaty:

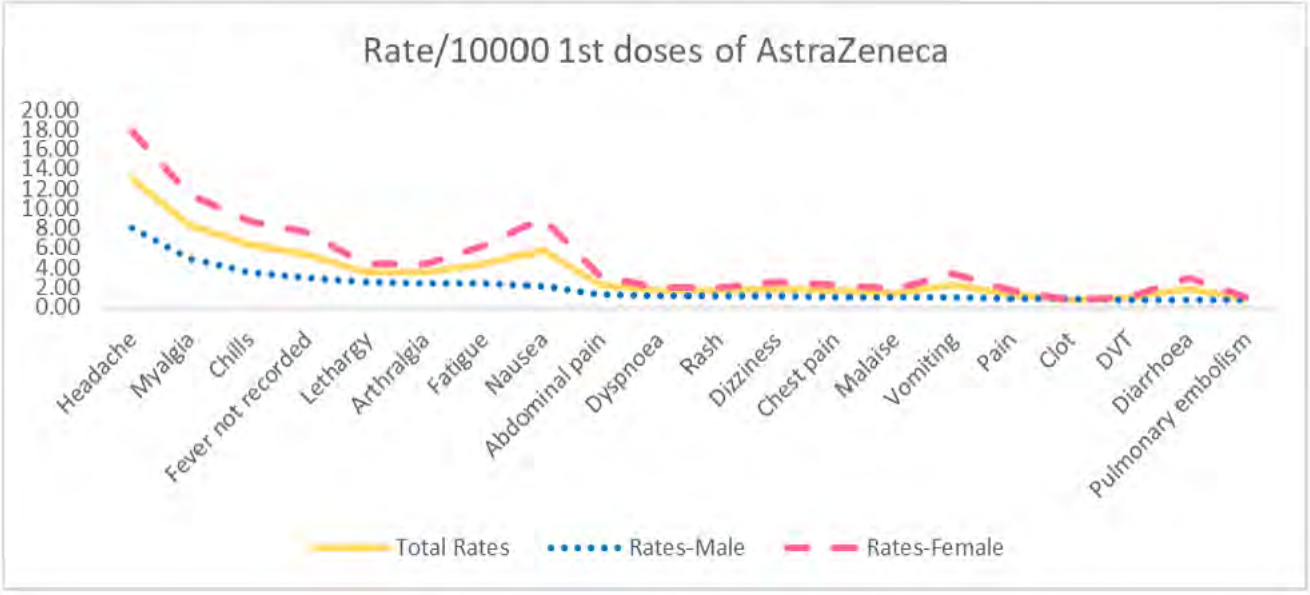
State	AIR Population	Individuals received Dose 1	Individuals received Dose 2
Totals	**1,688,362**	**871,254**	**779,399**
SA	1,688,362	871,254	779,399

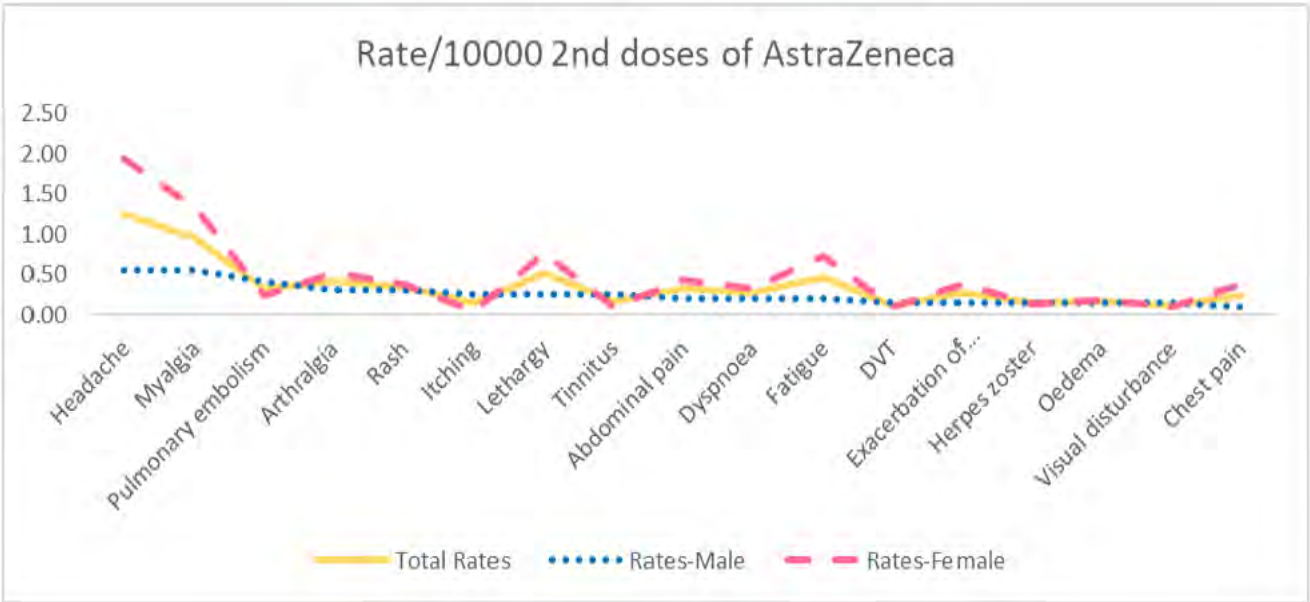
available data from Australian Immunisation Register report

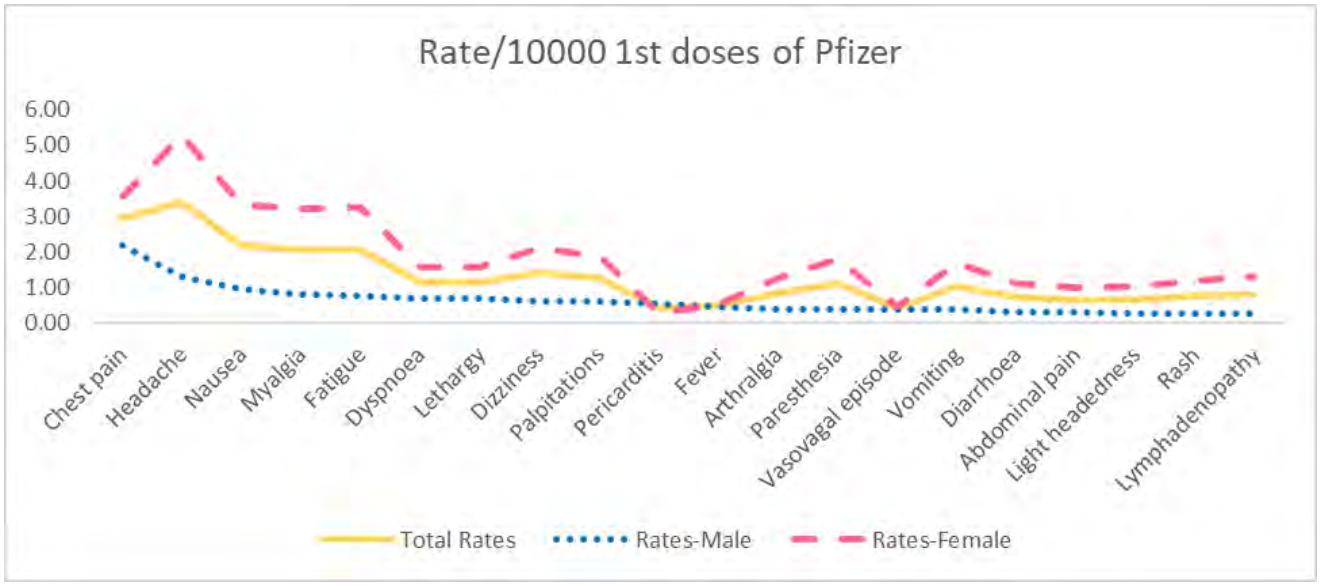
Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 30/11/2021 YTD:

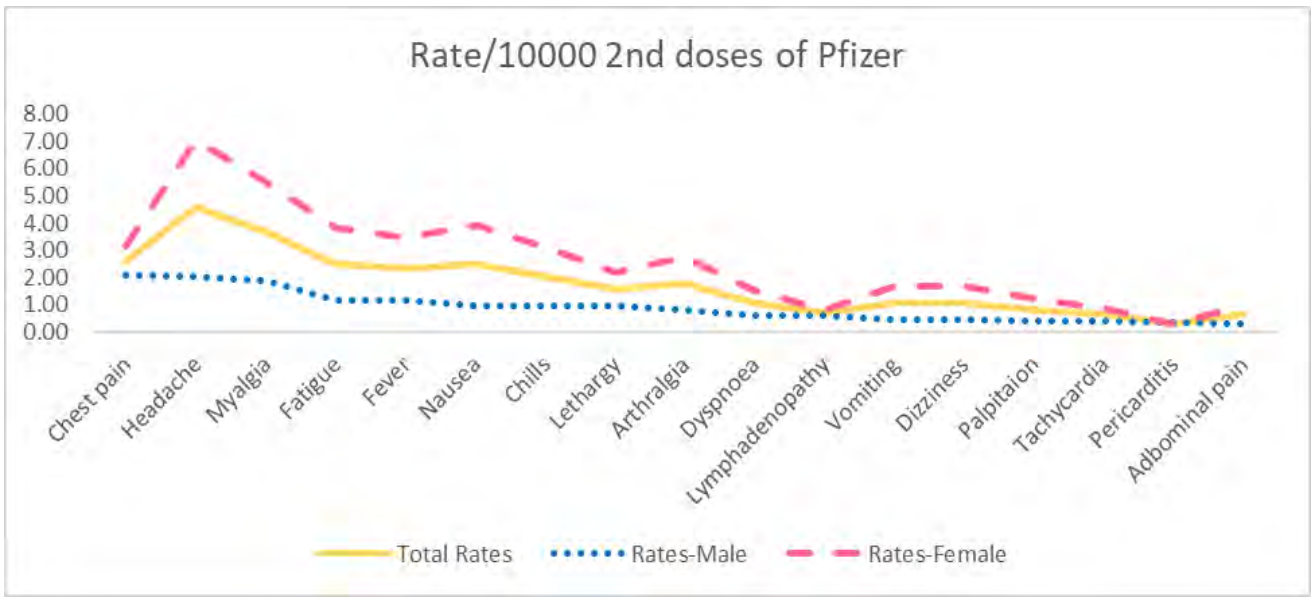
Number of Reports			**4937**
Gender	**Male**		**1403**
	Female		**3520**
Indigenous	**Yes**		**66**
Injection site reactions total number Covid-19 vaccines reports			**1186**
General reactions total number of COVID-19 vaccines reports			**4332**
Vaccine	**Reports**	**Injection site reaction**	**General Reaction**
AstraZeneca	1922	424	1752
Pfizer	2837	680	2428
Moderna	178	72	152

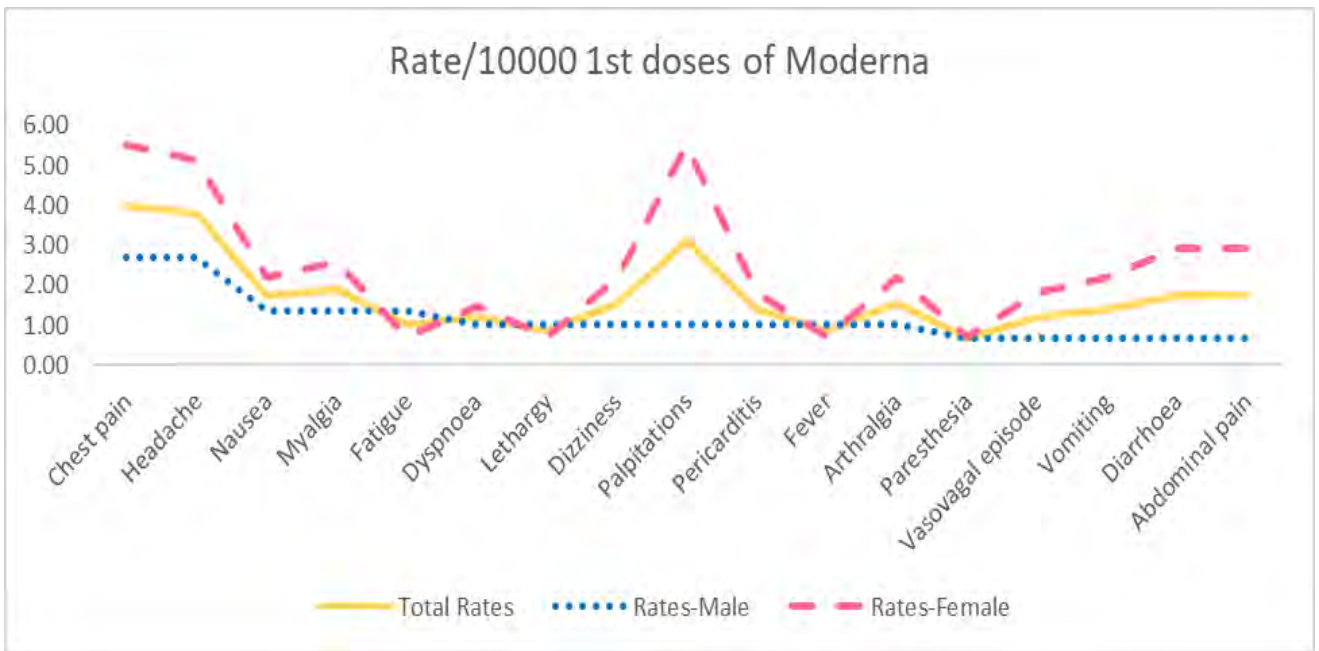
Figure 1: YTD Rates of common AEFI by vaccination, dose and gender






Rate/10000 1st doses of Pfizer
6.00
5.00
4.00
3.00
2.00
1.00
0.00
Chest pain
Headache
Nausea
Myalgia
Fatigue
Dyspnoea
Lethargy
Dizziness
Palpitations
Pericarditis
Fever
Arthralgia
Paresthesia
Vasovagal episode
Vomiting
Diarrhoea
Abdominal pain
Light headedness
Rash
Lymphadenopathy
Total Rates
Rates-Male
Rates-Female


Rate/10000 2nd doses of Pfizer
8.00
7.00
6.00
5.00
4.00
3.00
2.00
1.00
0.00
Chest pain
Headache
Myalgia
Fatigue
Fever
Nausea
Chills
Lethargy
Arthralgia
Dyspnoea
Lymphadenopathy
Vomiting
Dizziness
Palpitaion
Tachycardia
Pericarditis
Adbominal pain
Total Rates
Rates-Male
Rates-Female


Rate/10000 1st doses of Moderna
6.00
5.00
4.00
3.00
2.00
1.00
0.00
Chest pain
Headache
Nausea
Myalgia
Fatigue
Dyspnoea
Lethargy
Dizziness
Palpitations
Pericarditis
Fever
Arthralgia
Paresthesia
Vasovagal episode
Vomiting
Diarrhoea
Abdominal pain
Total Rates
Rates-Male
Rates-Female

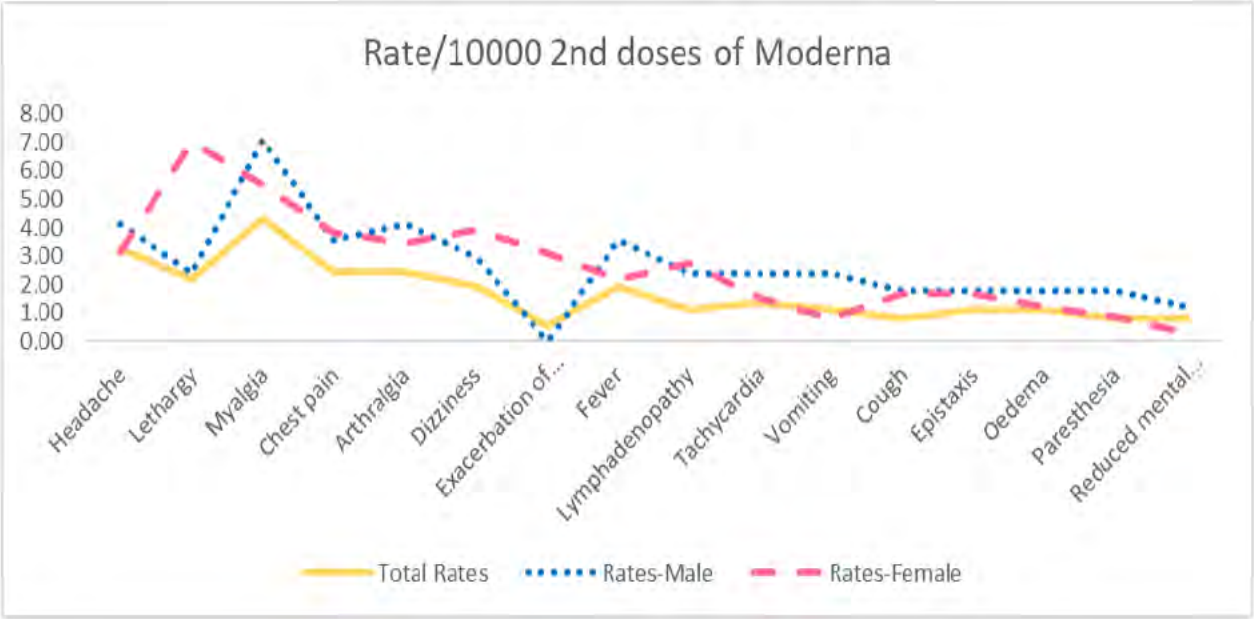


Table 2: Special Interest AEFI Topics as at 30/11/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 39		
Adverse events	**1922**	**Rates/1000 doses of total AZ vacc admin***	**8**	**% of YTD AESI reported****	**Rates/1000 doses of total AZ vacc admin*****
Abdominal Pain	107	0.129	0	0	0
Chest Pain	84	0.101	1(1: F, 1st dose	1.19	0.001
Clot	34	0.041	0	0	0
Vertigo	48	0.058	1(1: F, 1st dose)	2.08	0.001
Visual disturbance	45	0.054	0	0	0
Epistaxis	24	0.029	0	0	0
Deep vein thrombosis	46	0.056	0	0	0
Death	22	0.027	0	0	0
Herpes zoster	28	0.034	0	0	0
Pulmonary embolism	50	0.060	0	0	0
Cerebral vascular accident see Stroke	8	0.010	0	0	0
Stroke	12	0.014	0	0	0
Thrombocytopenia	9	0.011	0	0	0
Bell's Palsy	9	0.011	0	0	0

Anaphylaxis	3	0.004	0	0	0
Pericarditis	5	0.006	0	0	0
Menstrual Irregularity	8	0.010	0	0	0
Guillain Barré syndrome	4	0.005	0	0	0
Myocarditis	4	0.005	0	0	0
Exacerbation of existing medical condition	41	0.049	0	0	0
Thrombosis with thrombocytopenia syndrome TTS	4	0.005	0	0	0
Cerebral Venous Sinus Thrombosis	4	0.005	0	0	0
Dyskinesia	2	0.002	0	0	0
Idiopathic thrombocytopenic purpura	5	0.006	0	0	0
Multiple sclerosis	1	0.001	0	0	0
Purpura	11	0.013	0	0	0
Dysgeusia	19	0.023	0	0	0
Thrombophlebitis	11	0.013	0	0	0
Lymphadenopathy	23	0.028	0	0	0

a: Chest pain: 2nd dose(F) and DVT: 2nd dose

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	YTD		Week 39		
Adverse events	2837	Rates/1000 doses of total PZ vacc admin*	120	% of YTD AESI reported**	Rates/1000 doses of total Pfizer vacc admin.***
Chest Pain [a]	475	5.027	31(6: F & M, 2nd dose), (8: F 7:M, 1st dose	6.52	0.328
Vertigo	61	0.646	0	0	0
Dizziness – see Vertigo	208	2.201	0	0	0
Visual disturbance	62	0.656	0	0	0
Death	17	0.180	0	0	0
Herpes zoster	28	0.296	0	0	0
Pulmonary embolism	12	0.127	0	0	0

Bell's Palsy	14	0.148	5(2: F, 2nd dose), (2: F 1: M, 1st dose)	35.71	0.053
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	41	0.434	2(2: F, 1st dose)	4.87	0.021
Pericarditis	61	0.646	2 (1: F 1: M, 1st dose)	3.27	0.021
Myocarditis	22	0.233	0	0	0
Myopericarditis	9	0.095	0	0	0
Menstrual Irregularity	74	0.783	2(2 F, 2nd dose)	2.70	0.021
Exacerbation of existing medical condition	91	0.963	5(2: F, 2nd dose, 3: F, 1st dose	5.49	0.053
Miscarriage	4	0.042	0	0	0
Tinnitus	51	0.540	0	0	0

a: Chest pain: gender not available for 4 patients (1 after dose 1 and 3 after dose 2)

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax	YTD		Week 39		
Adverse events	178	Rates/1000 doses of total Spikevax vacc admin*	16	% of YTD AESI reported**	Rates/1000 doses of total Spikevax vacc admin***
Bells Palsy	1	0.001	0	0	0
Chest Pain [a]	33	0.020	4(1: F, 2nd dose, 2: F, 1st dose)	12.12	0.002
Death	0	0.000	0	0	0
Lymphadenopathy	14	0.008	4(2: F, 2nd dose, 2: F, 1st dose)	28.5	0.002
Pericarditis	2	0.001	0	0	0
Meningitis Aseptic	1	0.001	0	0	0
Myocarditis	0	0.000	0	0	0
Myopericarditis	0	0.000	0	0	0
Menstrual Irregularity	4	0.002	0	0	0

Anaphylaxis	1	0.001	0	0	0
Miscarriage	1	0.001	0	0	0

a: Chest pain: Dosage and gender not available

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 30/11/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 4: Events received following Moderna Spikevax vaccine:

Event ID #	**TGA AEFI/AESI Cat**	**Age and Gender**	**Incident details**	**Recommendation for client from Committee**	**Vaccination Program Implications**
			Diagnosis: **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	14[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** [redacted] **Dose number:** [redacted] **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	17[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** [redacted] **Dose number:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	30[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 21/10/2021 **Dose number:** 2	[redacted]	No Change

			Details: . **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History**: **GP contacted/notified:** **Classification:**		Change/Review rationale:
		35	**Diagnosis:** **Date and time vaccinated:** 12/11/2021 **Dose number:** 1 **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**		
		15	**Diagnosis:** **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:**		

			[redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	58 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 18/10 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings** [redacted] **Treatment:** [redacted] **Medical History** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	

[redacted]	[redacted] 1	41 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 3/11/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings** [redacted] **Treatment:** [redacted] **Medical History** [redacted] **GP contacted/notified**: [redacted] **Classification:** [redacted]	[redacted]	
[redacted]	[redacted]	35 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 21/11/2021 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted]	[redacted]	No Change Change/Review rationale:

			Treatment: [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Diagnosis: **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 25 November 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-25-11-2021

Summary

- Vaccination against COVID-19 is the most effective way to reduce deaths and severe illness from infection. The protective benefits of vaccination continue to far outweigh the potential risks.
- Like all medicines, COVID-19 vaccines may cause some side effects. The most frequently reported include injection-site reactions (such as a sore arm) and more general symptoms, like headache, muscle pain, fever and chills. This reflects what was seen in the clinical trials.
- We are carefully monitoring and reviewing reports of:
    - myocarditis and pericarditis following mRNA vaccines, particularly in younger age groups
    - thrombosis with thrombocytopenia syndrome (TTS) following Vaxzevria (AstraZeneca)
    - Guillain-Barre Syndrome (GBS) following Vaxzevria (AstraZeneca)
    - immune thrombocytopenia (ITP) following Vaxzevria (AstraZeneca)
- Myocarditis is a known but very rare side effect of Comirnaty (Pfizer) and Spikevax (Moderna). It is usually temporary, with most people getting better within a few days. Myocarditis is reported in 1–2 in every 100,000 people who receive Comirnaty (Pfizer), although it is more common in young men and teenage boys after the second dose (5–11 cases per 100,000 doses).
    - To 21 November 2021, the TGA has received 341 reports which have been assessed as likely to be myocarditis from about 23.9 million doses of Comirnaty (Pfizer).
- Thrombosis with thrombocytopenia syndrome (or TTS) is a very rare but serious side effect of Vaxzevria (AstraZeneca). Our analysis shows it is reported in about 2 in every 100,000 vaccinated people following the first dose. The risk of TTS is much lower after the second dose (0.3 in every 100,000 vaccinated people).
    - One new case of TTS was reported this week, taking the total to 164 cases from about 13.4 million doses of Vaxzevria (AstraZeneca).

Total adverse event reports to 21 November 2021

2.2	83,301	38,454,860
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
41,163	40,086	1,711
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax

To 21 November 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 425.

Myocarditis and pericarditis with mRNA vaccines

Details of Australian cases to 21 November 2021

Like other countries, we have observed a higher-than-expected number of cases of myocarditis in vaccinated compared to unvaccinated individuals for Comirnaty (Pfizer). The Global Advisory Committee on Vaccine Safety at the World Health Organization has recently stated that current evidence suggests a likely causal association between myocarditis and the mRNA vaccines.

In some countries, higher rates of myocarditis and pericarditis have been reported with Spikevax (Moderna) than with Comirnaty (Pfizer). Because the number of cases of myocarditis reported after Spikevax (Moderna) in Australia is small, we are not yet able to calculate reliable reporting rates for it or to see any difference in risk between the 2 vaccines. The current overall estimated rates (for the entire population) of myocarditis for Comirnaty and Spikevax are similar (1.4 cases per 100,000 Comirnaty doses versus 1.6 cases per 100,000 Spikevax doses). However, statistical analysis shows that there is more uncertainty around the reporting rate for Spikevax (likely to be between 1.1 and 2.4 cases per 100,000 doses) than for Comirnaty (likely to be between 1.3 and 1.6 cases per 100,000 doses).

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

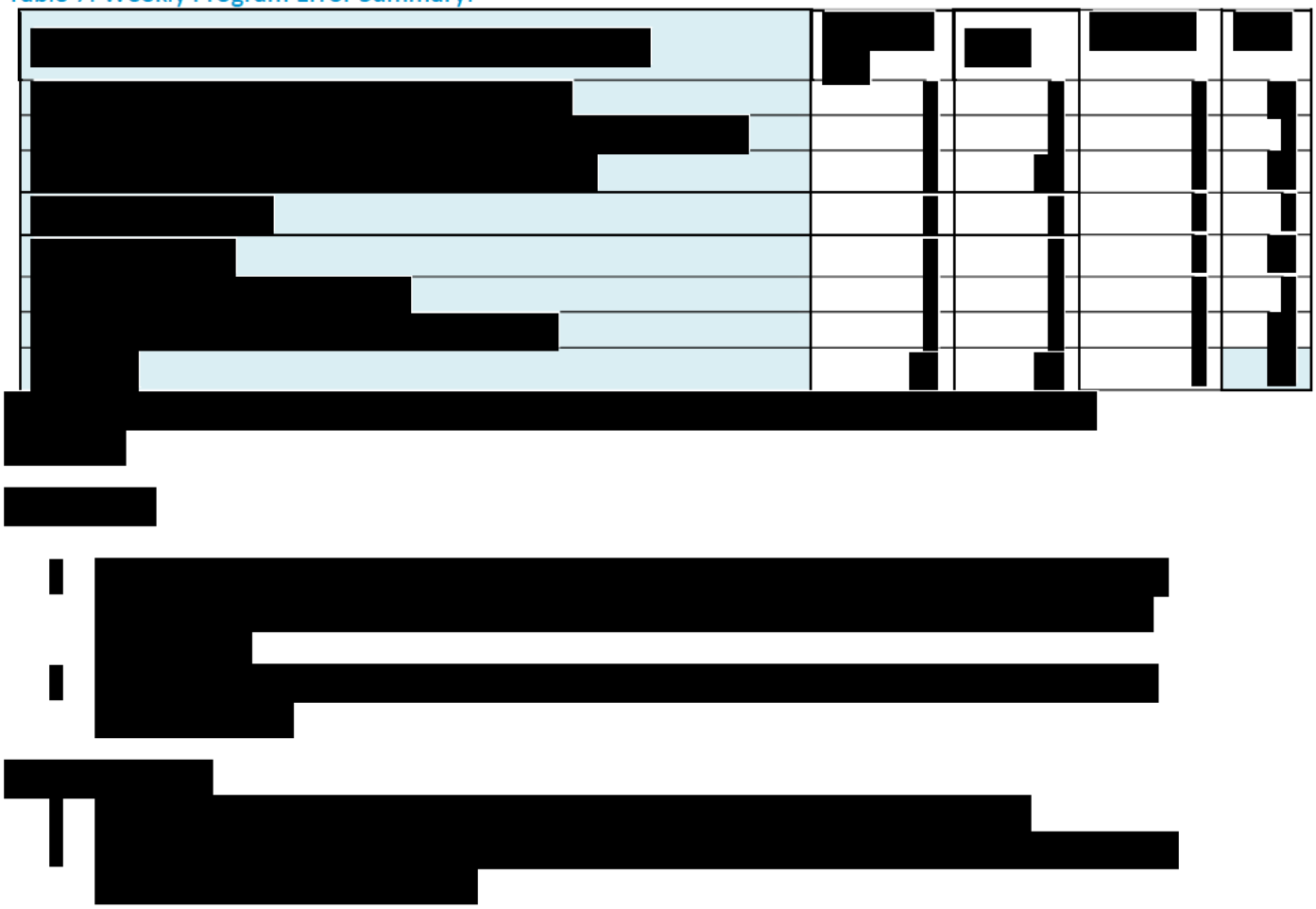
The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team,

with documented feedback and recommendations to the provider, patients and/or public as required.

Table 7: Weekly Program Error Summary:



Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- **Very common (≥ 1/10)**
- **Common (≥ 1/100 to < 1/10)**
- **Uncommon (≥ 1/1,000 to < 1/100)**
- **Rare (≥ 1/10,000 to < 1/1,000)**
- **Very rare (< 1/10,000)**

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis

- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 40

Meeting date: 14 December 2021

Report period:

1 December 2021 to 7 December 2021

Government of South Australia
SA Health

Contents

List of Tables

Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 07/12/2021*

Total vaccines:

Vaxzevria:

Pfizer:

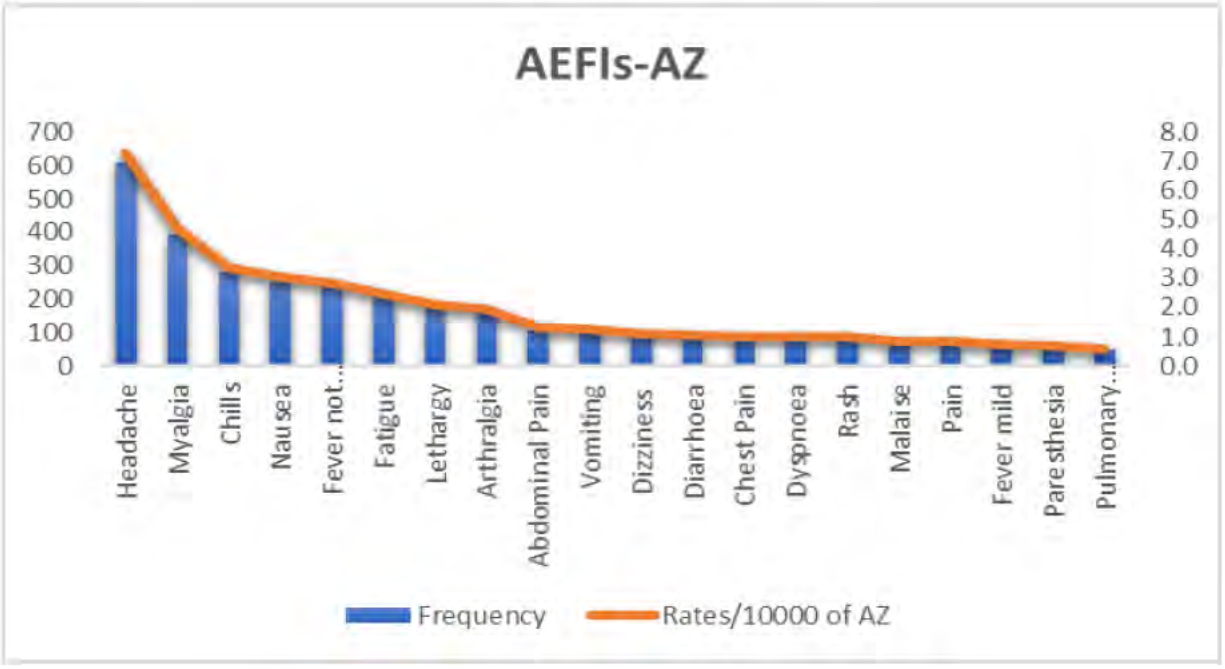
Moderna:

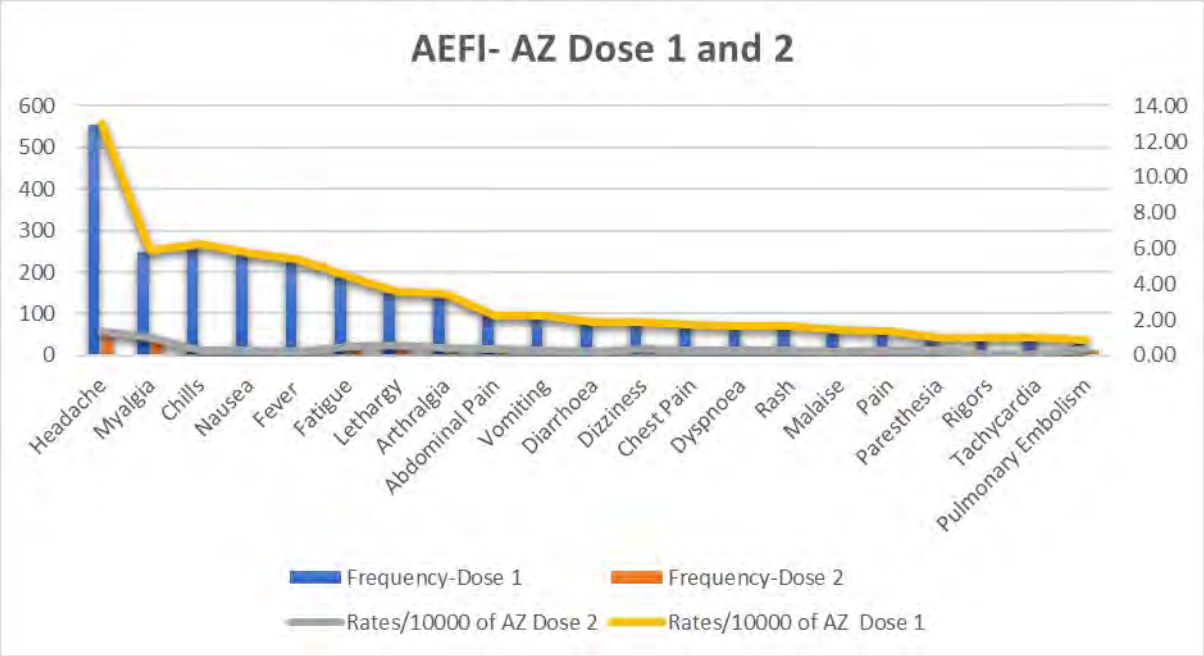
available data from Australian Immunisation Register report

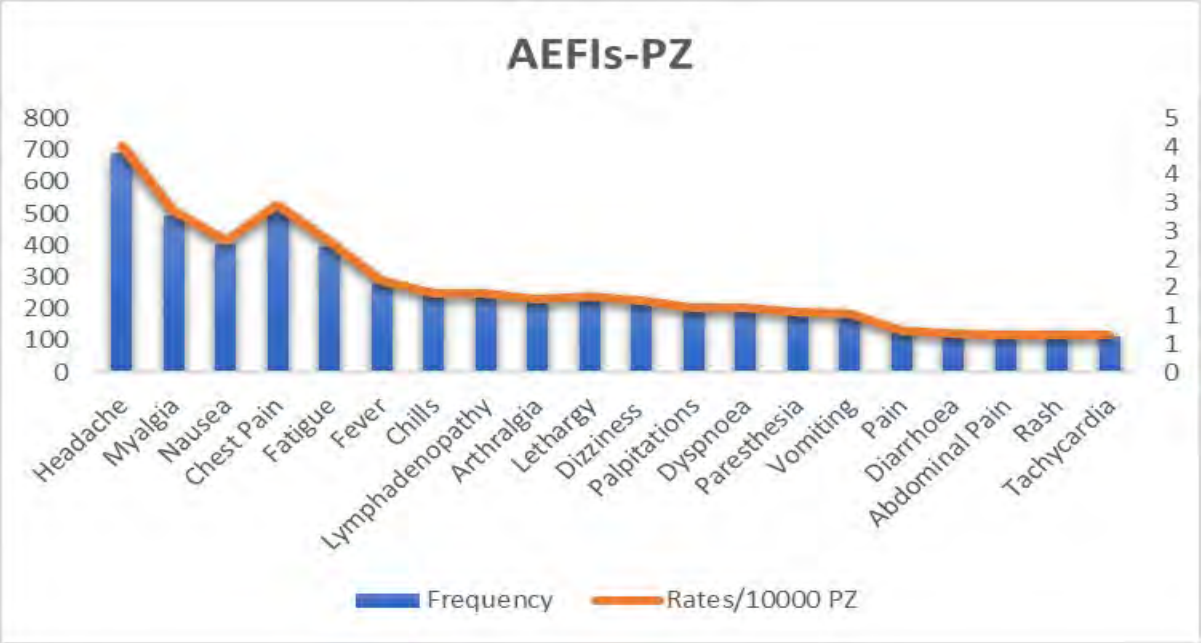
Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 07/12/2021 YTD:

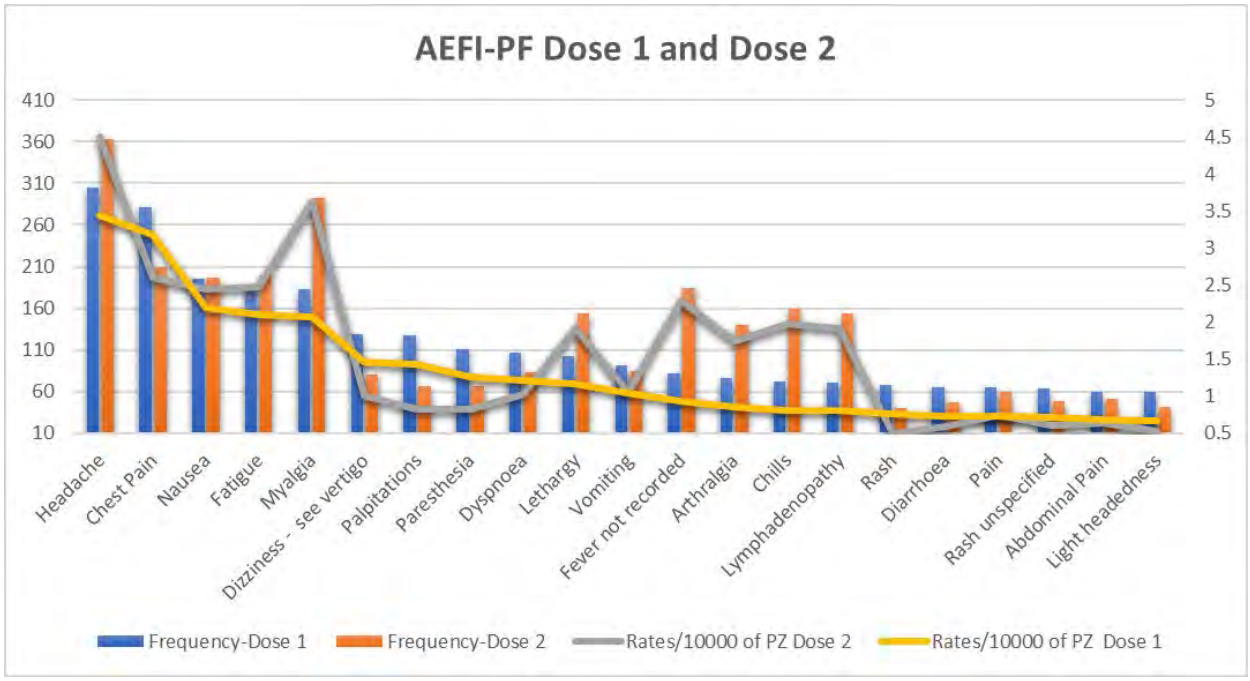
Number of Reports			**5073**
Gender	**Male**		**1445**
	Female		**3614**
Indigenous	**Yes**		**67**
Injection site reactions total number Covid-19 vaccines reports			**1212**
General reactions total number of COVID-19 vaccines reports			**4448**
Vaccine	**Reports**	**Injection site reaction**	**General Reaction**
AstraZeneca	1933	437	1765
Pfizer	2942	701	2518
Moderna	198	74	165

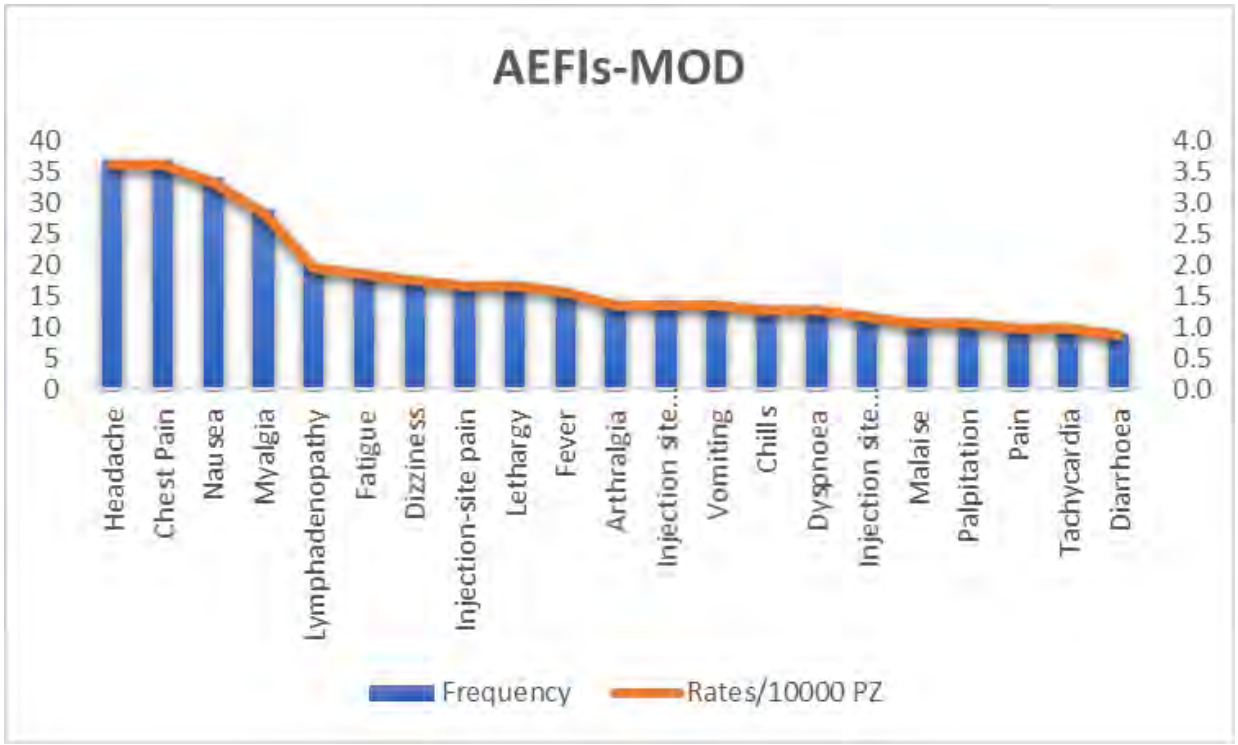
Figure 1: YTD Rates of common AEFI by vaccination, dose and gender




AEFI- AZ Dose 1 and 2
600
500
400
300
200
100
0
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
Headache
Myalgia
Chills
Nausea
Fever
Fatigue
Lethargy
Arthralgia
Abdominal Pain
Vomiting
Diarrhoea
Dizziness
Chest Pain
Dyspnoea
Rash
Malaise
Pain
Paresthesia
Rigors
Tachycardia
Pulmonary Embolism
Frequency-Dose 1
Frequency-Dose 2
Rates/10000 of AZ Dose 2
Rates/10000 of AZ Dose 1


AEFIs-PZ
800
700
600
500
400
300
200
100
0
5
4
4
3
3
2
2
1
1
0
Headache
Myalgia
Nausea
Chest Pain
Fatigue
Fever
Chills
Lymphadenopathy
Arthralgia
Lethargy
Dizziness
Palpitations
Dyspnoea
Paresthesia
Vomiting
Pain
Diarrhoea
Abdominal Pain
Rash
Tachycardia
Frequency
Rates/10000 PZ


AEFI-PF Dose 1 and Dose 2
410
360
310
260
210
160
110
60
10
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
Headache
Chest Pain
Nausea
Fatigue
Myalgia
Dizziness - see vertigo
Palpitations
Paresthesia
Dyspnoea
Lethargy
Vomiting
Fever not recorded
Arthralgia
Chills
Lymphadenopathy
Rash
Diarrhoea
Pain
Rash unspecified
Abdominal Pain
Light headedness
Frequency-Dose 1
Frequency-Dose 2
Rates/10000 of PZ Dose 2
Rates/10000 of PZ Dose 1


AEFIs-MOD
40
35
30
25
20
15
10
5
0
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
Headache
Chest Pain
Nausea
Myalgia
Lymphadenopathy
Fatigue
Dizziness
Injection-site pain
Lethargy
Fever
Arthralgia
Injection site...
Vomiting
Chills
Dyspnoea
Injection site...
Malaise
Palpitation
Pain
Tachycardia
Diarrhoea
Frequency
Rates/10000 PZ

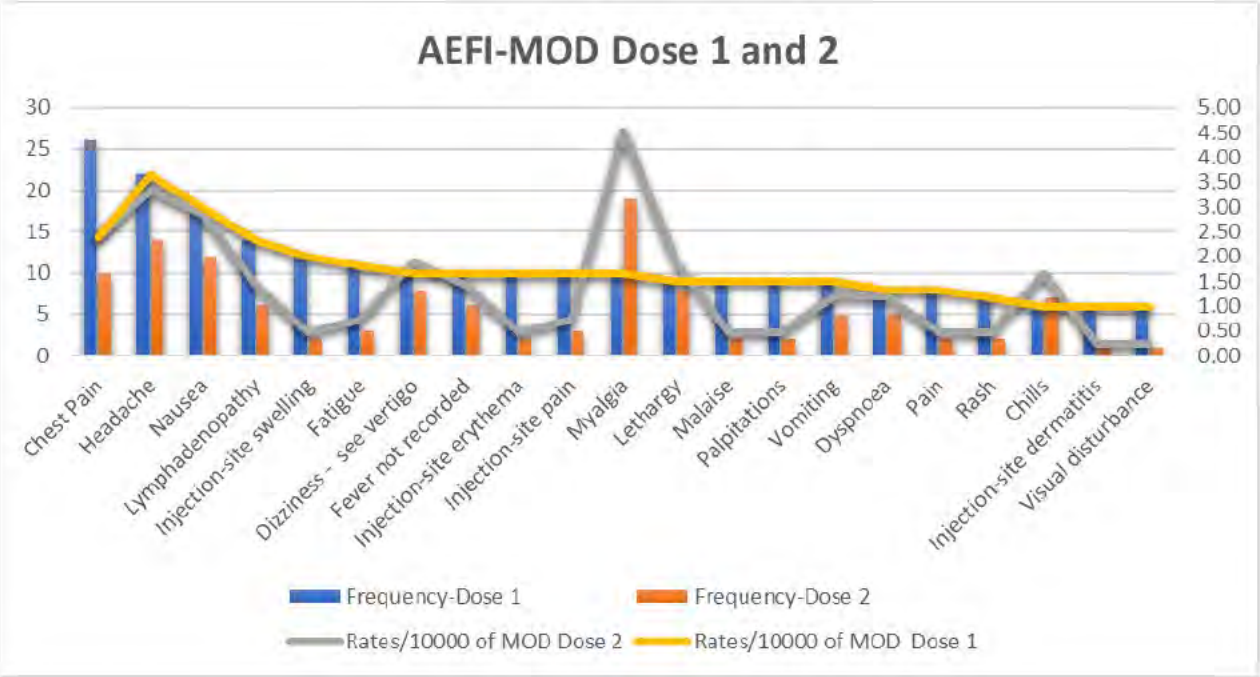


Table 2: Special Interest AEFI Topics as at 07/12/2021 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 40		
Adverse events	1933	Rates/10000 doses of total AZ vacc admin*	14	% of YTD AESI reported**	Rates/10000 doses of total AZ vacc admin***
Abdominal Pain	**108**	1.29	1(1 F: Dose 2)	0.0	0.01
Chest Pain	**84**	1.01	4(2 M: Dose 1, 2 M: Dose 2)	4.7	0.04
Clot	34	0.41	0	0.0	0
Vertigo	**49**	0.59	1(1 F: Dose 2)	2.0	0.01
Visual disturbance	45	0.54	0	0.0	0
Epistaxis	24	0.29	0	0.0	0
Deep vein thrombosis	46	0.55	0	0.0	0
Death	22	0.26	0	0.0	0
Herpes zoster	**29**	0.35	1(1 F: Dose 1)	3.4	0.01
Pulmonary embolism	50	0.60	0	0.0	0
Cerebral vascular accident see Stroke	8	0.10	0	0.0	0
Stroke	12	0.14	0	0.0	0

Thrombocytopenia	9	0.11	0	0.0	0
Bell's Palsy	9	0.11	0	0.0	0
Anaphylaxis	14	0.17	0	0.0	0
Pericarditis	5	0.06	4(2 M: Dose 1, 2 M: Dose 2)	80	0.04
Menstrual Irregularity	8	0.10	0	0.0	0
Guillain Barré syndrome	4	0.05	0	0.0	0
Myocarditis	4	0.05	0	0.0	0
Exacerbation of existing medical condition	41	0.49	0	0.0	0
Thrombosis with thrombocytopenia syndrome TTS	4	0.05	0	0.0	0
Cerebral Venous Sinus Thrombosis	4	0.05	0	0.0	0
Dyskinesia	2	0.02	0	0.0	0
Idiopathic thrombocytopenic purpura	5	0.06	0	0.0	0
Multiple sclerosis	1	0.01	0	0.0	0
Purpura	11	0.13	0	0.0	0
Dysgeusia	19	0.23	0	0.0	0
Thrombophlebitis	11	0.13	0	0.0	0
Lymphadenopathy [a]	25	0.30	2(1 F: Dose 2)	8.0	0.02

a: Dose and gender not available for few patients

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	YTD		Week 40		
Adverse events	2942	Rates/10000 doses of total PZ vacc admin*	129	% of YTD AESI reported**	Rates/10000 doses of total Pfizer vacc admin.***
Chest Pain [a]	510	2.97	39(11 M, 9 F: Dose 1, 6 M, 3 F: Dose 2)	7.6	0.23
Vertigo [a]	63	0.37	2 (1 F: Dose 2)	3.2	0.01
Dizziness – see Vertigo [a]	216	1.26	8(5 F, 2 M: Dose 1)	3.7	0.05

Visual disturbance	**66**	0.38	4(2 F, 1 M: Dose 1, 1 F Dose 2)	6.1	0.02
Death	17	0.10	0	0.0	0.00
Herpes zoster	**38**	0.22	10(4 F: Dose 1, 5 F, 1 M: Dose 2)	26.3	0.06
Pulmonary embolism	**14**	0.08	2(1: Dose 1, 1 F: Dose 2)	14.3	0.01
Bell's Palsy	14	0.08	0	0.0	0.00
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions) [a]	**56**	0.33	3(2 M: Dose 1)	5.4	0.02
Pericarditis [a]	**66**	0.38	3(1 M: Dose 1, 1 F: Dose 2)	4.5	0.02
Myocarditis	**23**	0.13	1(1 M: Dose 2)	4.3	0.01
Myopericarditis	**11**	0.06	2(1 M, 1 F: Dose 2)	18.2	0.01
Menstrual Irregularity [a]	**81**	0.47	6(2 F: Dose 1, 3 F: Dose 2)	7.4	0.03
Exacerbation of existing medical condition	**92**	0.53	1(1 F: Dose 1)	1.1	0.01
Miscarriage	4	0.02	0	0.0	0.00
Tinnitus	**53**	0.31	2(2 F: Dose 1)	3.8	0.01
Lymphadenopathy [a]	**241**	1.40	8(1 M, 1 F: Dose 1, 2 F: Dose 2)	3.3	0.05

a: Dose and gender not available for few patients

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax	**YTD**		**Week 40**		
Adverse events	**198**	**Rates/10000 doses of total Spikevax vacc admin***	**23**	**% of YTD AESI reported****	**Rates/10000 doses of total Spikevax vacc admin*****
Bell's Palsy	1	0.10	0	0	0.00
Chest Pain [a]	**37**	3.61	5(1 F, 2 M: Dose 1,1 F: Dose 2)	13.5	0.48

Death	0	0.00	0	0	0.00
Lymphadenopathy	**20**	1.95	7(1 F, 4 M: Dose 1, 2 M: Dose 2)	35.0	0.68
Pericarditis	**5**	0.49	2(1 M: Dose 1, 1 M: Dose 2)	40.0	0.19
Herpes zoster [a]	**1**	0.10	1(1: Dose 1)	100.0	0.10
Myocarditis	0	0.00	0	0	0.00
Myopericarditis	0	0.00	0	0	0.00
Menstrual Irregularity	4	0.39	0	0	0.00
Anaphylaxis	1	0.10	0	0	0.00
Miscarriage	1	0.10	0	0	0.00

a: Dose and gender not available for few patients

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 3: TGA reported TTS Summary as at 07/12/2021 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 4: Events received following Moderna Spikevax vaccine:

Event ID #	**TGA AEFI/A ESI Cat**	**Age and Gender**	**Incident details**	**Recommendation for client from Committee**	**Vaccination Program Implications**
			Diagnosis: **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review	No Change Change/Review rationale:

			Imaging & Findings: **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP suggesting Specialist review No Letter required	

Table 5: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	33[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 22/11/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] RP [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	No Letter required	No Change Change/Review rationale:
[redacted]	[redacted]	28[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 19/11 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** none **Medical History:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	38[redacted]	**Diagnosis: Anaphylaxis** **Date and time vaccinated**: 02/12/2021 @ 1133hrs **Dose number: 1** **Details**: [redacted] **Laboratory Results:** [redacted] [redacted]s **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	23[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 03/12/2021 @ 13.17hrs **Dose number: 2** **Details**: [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 6: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	55 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 9/6/2021 **Dose number:** 1 **Details**: [redacted] **Laboratory Results:** [redacted]	[redacted]	No Change Change/Review rationale:

			Imaging & Findings: [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	68 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated**: 6/8/2021 **Dose number:** 1 **Details**: [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History**: [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 2 December 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-02-12-2021

Summary

- Vaccination against COVID-19 is the most effective way to reduce deaths and severe illness from infection. The protective benefits of vaccination continue to far outweigh the potential risks.
- Like all medicines, COVID-19 vaccines may cause some side effects. The most frequently reported include injection-site reactions (such as a sore arm) and more general symptoms, like headache, muscle pain, fever and chills. This reflects what was seen in the clinical trials.
- We are carefully monitoring and reviewing reports of:
    - myocarditis and pericarditis following mRNA vaccines, particularly in younger age groups
    - thrombosis with thrombocytopenia syndrome (TTS) following Vaxzevria (AstraZeneca)
    - Guillain-Barre Syndrome (GBS) following Vaxzevria (AstraZeneca)
    - Immune thrombocytopenia (ITP) following Vaxzevria (AstraZeneca)
- Myocarditis is a known but very rare side effect of Comirnaty (Pfizer) and Spikevax (Moderna). It is usually temporary, with most people getting better within a few days. Myocarditis is reported in 1–2 in every 100,000 people who receive Comirnaty (Pfizer), although it is more common in young men and teenage boys after the second dose (6–11 cases per 100,000 doses).
    - To 28 November 2021, the TGA has received 354 reports which have been assessed as likely to be myocarditis from about 24.4 million doses of Comirnaty (Pfizer).
- Thrombosis with thrombocytopenia syndrome (or TTS) is a very rare but serious side effect of Vaxzevria (AstraZeneca). Our analysis shows it is reported in about 2 in every 100,000 vaccinated people following the first dose. The risk of TTS is much lower after the second dose (0.3 in every 100,000 vaccinated people).
    - Two new cases of TTS were reported this week, taking the total to 166 cases from about 13.5 million doses of Vaxzevria (AstraZeneca).

Total adverse event reports to 28 November 2021

2.2	85,714	39,106,606
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

41,598	41,762	2,013
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax

To 28 November 2021, the total number of adverse event reports received where the brand of the COVID-19 vaccine was not specified was 430.

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)

- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE
Revised 22 July 2021

Table 1:Adverse reactions from COMIRNATY clinical trials

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[a]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[b]; Injection site swelling	Injection site redness	Asthenia Malaise		

[a] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.
[b] A higher frequency of pyrexia was observed after the second dose.

The safety profile in 545 subjects receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Post-marketing experience

Although the events listed in Table 2 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 2:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[73]

	12 – 15 years of age		16–55 years of age		>55 years of age	
			Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	71%	66%
Fever	10%	20%	4%	16%	1%	11%
Fatigue	60%	66%	47%	59%	23%	51%
Headache	55%	65%	42%	52%	25%	39%
Chills	28%	42%	14%	35%	6%	23%
Muscle pain	24%	32%	21%	37%	14%	28%
Joint pain	10%	16%	11%	22%	9%	19%
Required paracetamol	37%	51%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection – Revised 20 August 2021

Table 1 **Adverse Drug Reactions (ADR) interim analysis – pooled data set (safety analysis set[a])**

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 069)	Control[c] (N= 9, 902)
Nervous system disorders	Headache	Very common (52.6%)	Very common (39.0%)
Gastrointestinal disorders	Nausea	Very common (21.9%)	Very common (13.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (44.0%)	Very common (21.6%)
	Joint pain (Arthralgia)	Very common (26.4%)	Very common (12.4%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.7%)	Very common (39.5%)
	Injection site pain	Very common (54.2%)	Very common (36.7%)
	Injection site warmth	Very common (17.7%)	Very common (14.5%)
	Injection site itch (Injection site pruritus)	Very common (12.7%)	Common (7.5%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.1%)	Very common (38.2%)
	Malaise	Very common (44.2%)	Very common (20.2%)
	Feverishness[d] (Pyrexia)	Very common (33.6%)	Very common (10.7%)
	Chills	Very common (31.9%)	Common (8.3%)
	Fever[d] (Pyrexia)	Common (7.9%)	Common (1.2%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C

The following table provides new ADR reported from the primary analysis of the pooled data from the four clinical trials (data lock: 7 December 2020; medium duration of follow-up of 4.5 months).

Table 2 New Adverse Drug Reactions (ADR) from the primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA	Control [c]
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon	Uncommon
Nervous system disorders	Dizziness[d]	Uncommon	Uncommon
	Somnolence[d]	Uncommon	Uncommon
Gastrointestinal disorders	Vomiting	Common	Uncommon
	Diarrhoea[d]	Common	Common
	Abdominal pain[d]	Uncommon	Uncommon
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon	Uncommon
	Pruritus[d]	Uncommon	Uncommon
	Rash[d]	Uncommon	Uncommon
	Urticaria[d]	Uncommon	Uncommon
Musculoskeletal and connective tissue disorders	Pain in extremity[d]	Common	Uncommon
General disorders and administration site conditions	**Systemic**		
	Influenza-like illness[d]	Common	Uncommon

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.

[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses

[c] Control was either meningococcal vaccine or saline solution

[d] Unsolicited adverse reactions

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use).
	Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old.

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

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Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of COVID-19 Vaccine AstraZeneca in phase II/III trial in people aged >18 years[89]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 VACCINE

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class Frequency Adverse reactions	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.
**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.
***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.
**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[59]

	18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	87%	90%	74%	83%
Lymph node swelling at the axilla	12%	16%	6%	9%
Fever	0.9%	17%	0.3%	10%
Fatigue	38%	68%	33%	58%
Headache	35%	63%	25%	46%
Chills	9%	49%	5%	31%
Myalgia	24%	62%	20%	47%
Arthralgia	17%	46%	16%	35%
Nausea/vomiting	9%	21%	5%	12%

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OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 41

Meeting date: 11 January 2022

Report period:

8 December 2021 to 5 January 2022

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 05/01/2022*

Total vaccines:

1st 1,403,987

2nd 1,337,588

Boosters 181,943

Total Doses/episodes: 2,923,518

Vaxzevria:

1st 426,030

2nd 415,442

Boosters 428

Total Doses/episodes: 841,900

Pfizer:

1st 912,836

2nd 866,455

Boosters 161,056

Total Doses/episodes: 1,940,347

Moderna:

1st 65,121

2nd 55,691

Boosters 20,459

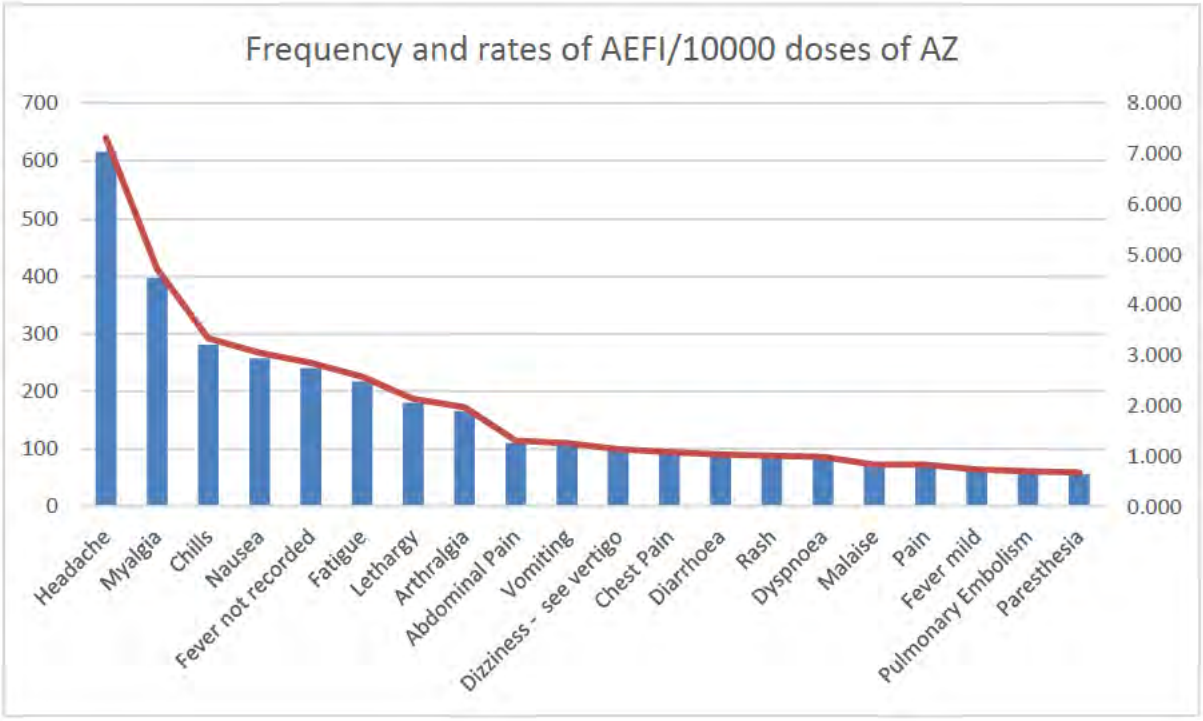
Total Doses/episodes: 141,271

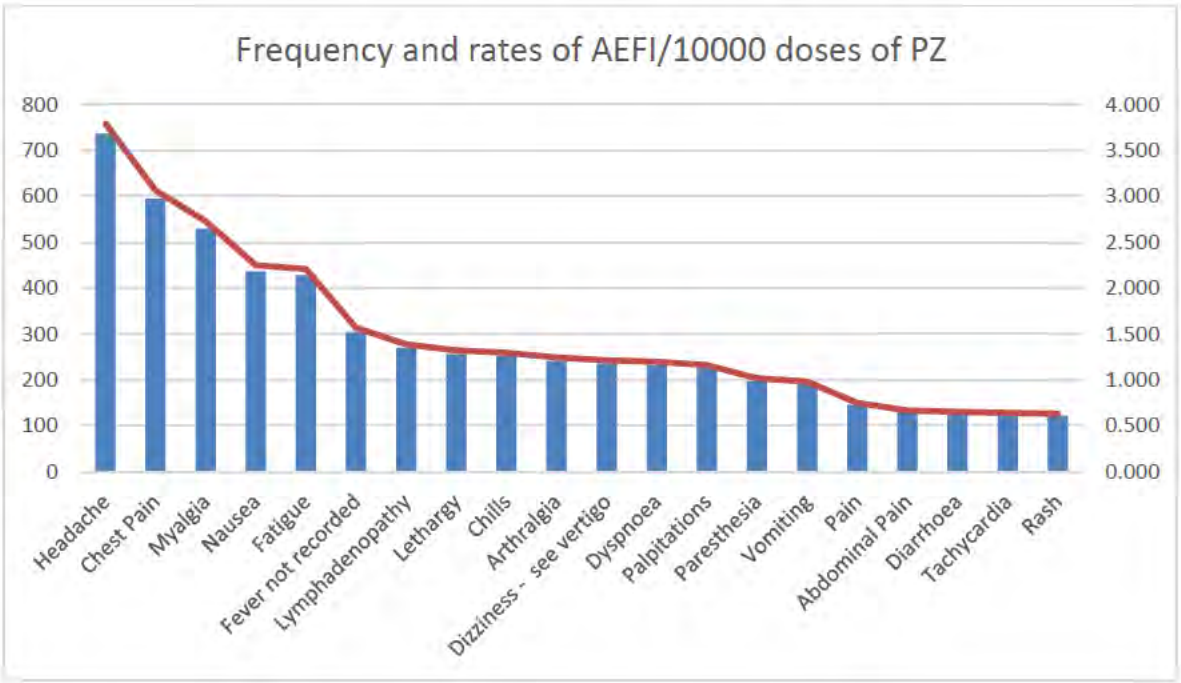
available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 05/01/2022 YTD:

Number of Reports			**5392**
Gender	**Male**		**1551**
	Female		**3827**
Indigenous	**Yes**		**75**
Injection site reactions total number Covid-19 vaccines reports			**1303**
General reactions total number of COVID-19 vaccines reports			**4722**
Vaccine	**Reports**	**Injection site reaction**	**General Reaction**
AstraZeneca	1969	438	1786
Pfizer	3186	772	2738
Moderna	237	93	198

Figure 1: YTD Rates of common AEFI by vaccination




Frequency and rates of AEFI/10000 doses of PZ
800
700
600
500
400
300
200
100
0
4.000
3.500
3.000
2.500
2.000
1.500
1.000
0.500
0.000
Headache
Chest Pain
Myalgia
Nausea
Fatigue
Fever not recorded
Lymphadenopathy
Lethargy
Chills
Arthralgia
Dizziness - see vertigo
Dyspnoea
Palpitations
Paresthesia
Vomiting
Pain
Abdominal Pain
Diarrhoea
Tachycardia
Rash

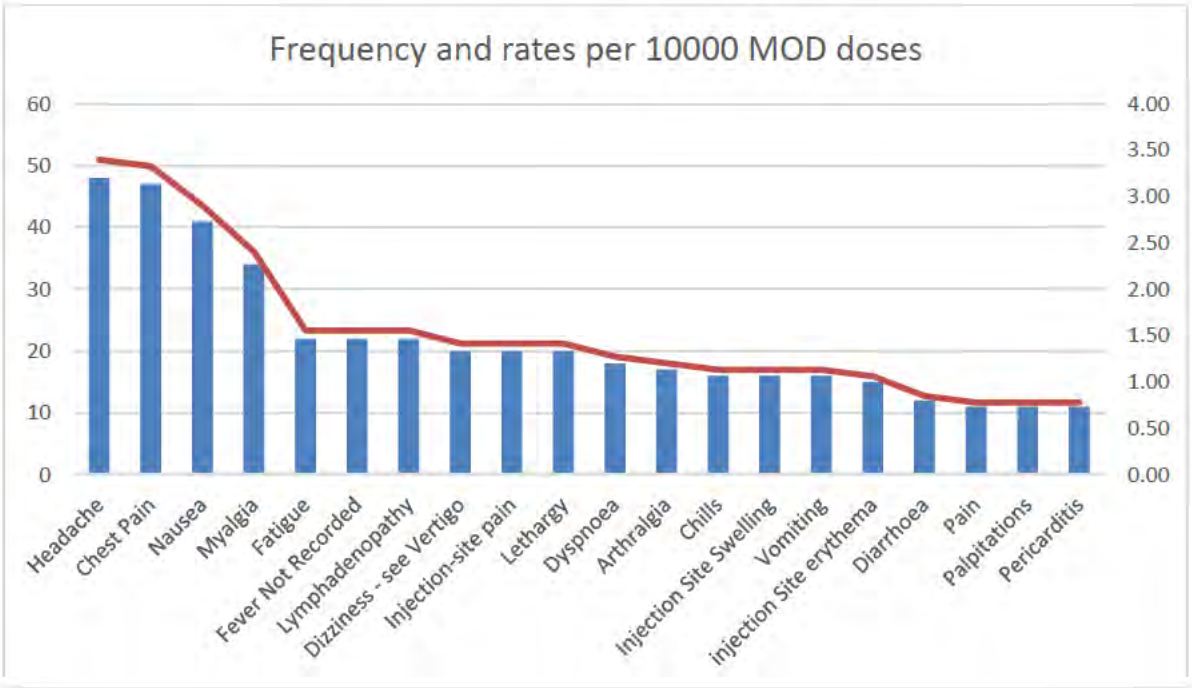

Frequency and rates per 10000 MOD doses
60
50
40
30
20
10
0
4.00
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
Headache
Chest Pain
Nausea
Myalgia
Fatigue
Fever Not Recorded
Lymphadenopathy
Dizziness - see Vertigo
Injection-site pain
Lethargy
Dyspnoea
Arthralgia
Chills
Injection Site Swelling
Vomiting
injection Site erythema
Diarrhoea
Pain
Palpitations
Pericarditis

Table 2: TGA report of Myocarditis and Pericarditis Australia Wide as of 2 January 2022

Table 1. Reports of suspected myocarditis and pericarditis received by the TGA to 2 January 2022

		Comirnaty (Pfizer) (27.3 million doses given)		Spikevax (Moderna) (1.8 million doses given)	
		All cases	Cases in adolescents (12–17 years)	All cases	Cases in adolescents (12–17 years)
Suspected myocarditis cases*		**928**	**175**	**89**	**23**
Likely myocarditis†‡	Level 1	37	7	0	0
	Level 2	309	98	30	13
	Level 3	70	11	10	3
Unlikely myocarditis		201	18	16	2
Insufficient information		311	41	33	5
Suspected pericarditis cases		**1930**	**140**	**155**	**10**
Likely pericarditis£		735	59	52	2

**Cases reporting both myocarditis and pericarditis are included in suspected myocarditis cases.*

‡ Cases classified as level 1 are confirmed to be myocarditis based on strong clinical evidence including the patient's symptoms, and results of tests and imaging indicating a diagnosis of myocarditis. Level 2 cases are probably myocarditis based on a combination of symptoms and routine tests for heart conditions. Level 3 cases are possibly myocarditis based on symptoms and a doctor's report that myocarditis is the most likely diagnosis in the absence of medical tests and investigations. For all cases of suspected myocarditis, where possible, other known causes of the patient's symptoms or test results are ruled out before cases are classified.

†The youngest case classified as 'likely myocarditis' to date was 12 years old.

£ Classification of likely pericarditis is based on the patient's symptoms and test results and the absence of other known causes of pericarditis.

Rates of myocarditis by age and dose are given for Comirnaty (Pfizer) and Spikevax (Moderna) in Table 2. The estimated reporting rates in Australia appear similar to overseas rates. The rates for Spikevax (Moderna) are less certain due to low numbers of cases overall.

Table 2. Rates of likely myocarditis cases following the mRNA vaccines A. Comirnaty (Pfizer)

Age (years)	All doses		Second doses	
	Rate* per 100,000 doses		Rate* per 100,000 doses	
	Male	Female	Male	Female
12-17	7.2	1.5	11.6	2.5
18-29	4.0	1.3	6.2	1.8
30-39	1.6	0.7	1.6	0.5
40-49	0.8	0.6	1.2	0.8
50-59	0.4	0.3	0.1	0.4
60-69	0.2	0.3	0.0	0.3
70+	0	0.1	0	0
All ages*	2.3	0.8	3.3	1.0

B. Spikevax (Moderna)

Age (years)	All doses		Second doses	
	Rate* per 100,000 doses		Rate* per 100,000 doses	
	Male	Female	Male	Female
12-17	9.2	1.4	16.8	1.5
18-29	5.8	0.6	9.6	0.0
30-39	3.2	0.7	4.6	0.0
40-49	1.4	0.8	0.0	0.0
50-59	0.8	1.8	0.0	0.0
60-69	0.0	0.0	0.0	0.0
70+	0.0	0.0	0.0	0.0
All ages*	**4.9**	**1.1**	**6.5**	**0.5**

**The rate includes cases of myocarditis that occurred after vaccination but may not be vaccine related. The number of younger people vaccinated is still relatively low in Australia, so estimated reporting rates are based on limited data.*

Table 3: SA Reports YTD Myocarditis / Pericarditis / Myopericarditis as at 5/1/2022

	Pericarditis	Myocarditis	Myopericarditis	Total
Pfizer	80	31	13	124
Moderna	11	1	0	12
Vaxevria	9	4	0	13
Total	100	36	13	149

Table 4: TGA reported TTS Summary as at 04/01/2022 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 5: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	34 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 3/12/21 **Dose number**: 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] c **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 6: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	13 [redacted]	**Diagnosis:** [redacted]		No Change

[redacted]			**Date and time vaccinated:** [redacted] **Dose number:** [redacted] [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	**No Letter required**	Change/Review rationale:
[redacted]	[redacted]	63 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 2/12/2021 **Dose number:** 1 **Details:** [redacted] **Laboratory Results:** [redacted]	[redacted]	No Change Change/Review rationale:

			Imaging & Findings: [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	38 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated: 12/12/2021** **Dose number: 2** **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	12 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** [redacted] **Dose number:** [redacted] **Details:** [redacted]	[redacted]	No Change Change/Review rationale:

			Laboratory Results: [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	51 [redacted]	**Diagnosis:** Myocarditis **Date and time vaccinated:** 7/12/2021 **Dose number**: 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified: yes** **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:
[redacted]	[redacted]	12 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** [redacted] **Dose number:** [redacted] **Details:** [redacted] **Laboratory Results:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		
[redacted]	[redacted]	27 [redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 30/11/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified**: [redacted] **Classification:** [redacted]	[redacted]	No Change Change/Review rationale:

Table 7: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/AESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	[redacted]	74[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 23/07/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

2. Summary of the TGA COVID-19 vaccine updates:

Last data reported available on TGA website https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

TGA weekly report as at 9 December 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-09-12-2021

TGA weekly report as at 16 December 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-16-12-2021

TGA weekly report as at 23 December 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-23-12-2021

3. Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.

- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

- Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether

expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia
- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome

- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (tozinameran) COVID-19

Revised PI 03/12/2021

Table 1: Adverse reactions from COMIRNATY clinical trials: Individuals 12 years of age and older

System Organ Class	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy[a]		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[b]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[c]; Injection site swelling	Injection site redness	Asthenia Malaise		Facial swelling[d]

[a] A higher frequency of lymphadenopathy (5.2% vs 0.4%) was observed in participants receiving a booster dose (third dose) compared to participants receiving 2 doses.

[b] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

[c] A higher frequency of pyrexia was observed after the second dose.

[d] Facial swelling in vaccine recipients with a history of injection of dermatological fillers

Table 2. Adverse Reactions from COMIRNATY clinical trial: Individuals 5 to <12 Years of Age (06 September 2021 Data Cut-off Date)

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria[a,b]; Pruritus[a,b]; Rash[a,b]			Anaphylaxis[a]
Metabolism and nutrition disorders			Decreased appetite			
Nervous system disorders	Headache					
Gastrointestinal disorders		Diarrhoea;[a] Vomiting[a]	Nausea			
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia	Pain in extremity (arm)[a]			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Injection site swelling; Injection site redness	Pyrexia	Malaise			

a. These adverse reactions were identified in the post-authorisation period. The following events were not reported in participants 5 to <12 Years of Age in Study C4591007 but were reported in individuals ≥16 years of age in Study C4591001: angioedema, lethargy, asthenia, hyperhidrosis, and night sweats.

b. The following events are categorised as hypersensitivity reactions: urticaria, pruritus, and rash

Post-marketing experience Although the events listed in Table 3 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 3:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)
General disorders and administration site conditions	Extensive swelling of vaccinated limb

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[45,82]

	12 – 15 years of age		16 to 25 years of age		16–55 years of age		>55 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	83%	78%	71%	66%
Fever	10%	20%	7%	17%	4%	16%	1%	11%
Fatigue	60%	66%	60%	66%	47%	59%	23%	51%
Headache	55%	65%	54%	61%	42%	52%	25%	39%
Chills	28%	42%	25%	40%	14%	35%	6%	23%
Muscle pain	24%	32%	27%	41%	21%	37%	14%	28%
Joint pain	10%	16%	13%	22%	11%	22%	9%	19%
Required paracetamol	37%	51%	32%	46%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca)
Revised PI 25/11/2021

Table 1 Adverse Drug Reactions (ADR) primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 317)	Control[c] (N= 10, 141)
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon (0.3%)	Uncommon (0.3%)
Nervous system disorders	Headache	Very common (52.7%)	Very common (39.8%)
	Dizziness[d]	Uncommon (0.7%)	Uncommon (0.7%)
	Somnolence[d]	Uncommon (0.5%)	Uncommon (0.3%)
Gastrointestinal disorders	Nausea	Very common (22.2%)	Very common (13.4%)
	Vomiting	Common (1.8%)	Uncommon (0.9%)
	Diarrhoea[d]	Common (1.6%)	Common (1.5%)
	Abdominal pain[d]	Uncommon (0.6%)	Uncommon (0.4%)
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon (0.4%)	Uncommon (0.2%)
	Pruritus[d]	Uncommon (0.3%)	Uncommon (0.3%)
	Rash[d]	Uncommon (0.2%)	Uncommon (0.3%)
	Urticaria[d]	Uncommon (0.1%)	Uncommon (0.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (43.9%)	Very common (22.3%)
	Joint pain (Arthralgia)	Very common (26.6%)	Very common (13.0%)
	Pain in extremity[d]	Common (1.3%)	Uncommon (0.8%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.8%)	Very common (40.1%)
	Injection site pain	Very common (54.3%)	Very common (37.5%)
	Injection site warmth	Very common (17.9%)	Very common (15.2%)
	Injection site itch (Injection site pruritus)	Very common (13.1%)	Common (7.8%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.0%)	Very common (38.6%)
	Malaise	Very common (44.4%)	Very common (21.0%)
	Feverishness[e] (Pyrexia)	Very common (33.5%)	Very common (11.0%)
	Chills	Very common (32.2%)	Common (8.4%)
	Fever[e] (Pyrexia)	Common (7.6%)	Common (1.5%)
	Influenza-like illness[d]	Common (1.1%)	Uncommon (0.7%)

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use). Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old. Immune thrombocytopenia (frequency not known).
Nervous system disorders	Guillain-Barré syndrome (GBS) (frequency very rare).

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of Vaxzevria in phase II/III trial in people aged >18 years[99]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

A 3rd dose of Vaxzevria after two previous doses of Vaxzevria was well tolerated and associated with lower adverse event rates than after the primary vaccine doses.[100]

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 Vaccine

Revised PI – 09/12/2021

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.

**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.

***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.

**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[46,67]

	12 – 17 years of age		18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	93%	92%	87%	90%	74%	83%
Lymph node swelling at the axilla	23%	21%	12%	16%	6%	9%
Fever	2.5%	12%	0.9%	17%	0.3%	10%
Fatigue	48%	68%	38%	68%	33%	58%
Headache	45%	70%	35%	63%	25%	46%
Chills	18%	43%	9%	49%	5%	31%
Myalgia	27%	47%	24%	62%	20%	47%
Arthralgia	15%	29%	17%	46%	16%	35%
Nausea/vomiting	10%	18%	9%	21%	5%	12%

In a clinical trial using Spikevax as a booster dose (using a half-dose of 50mcg), adverse events were generally mild to moderate and similar to rates seen following the primary 2-dose series in phase 2 and 3 trials.[85]

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OFFICIAL: Sensitive/Medical

COVID-19 Vaccination Program

Vaccine Safety Surveillance Committee

Report 42

Meeting date: 18 January 2022

Report period:

5 January 2022 to 11 January 2022

Government of South Australia

SA Health

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Appendices

1. COVID-19 Vaccine Program Adverse Event Following Immunisation

Background

The South Australian COVID-19 vaccination program commenced on 22 February 2021.

As part of the safety monitoring for this program, a vaccine safety surveillance system for the South Australian COVID-19 Vaccination Program actively collects reports on Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI).

An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine. Appendices 1 to 4 of this report provide further details on (1) a list of Serious AEFI and AESI as highlighted by the TGA within the context of the COVID-19 vaccination program, (2) frequency of AEFI associated with the Pfizer vaccine, (3) frequency of AEFI associated with the Vaxzevria (Astra Zeneca) vaccine and (4) frequency of AEFI associated with the Moderna Spikevax vaccine (within the MedDra System Organ Class hierarchy).

AEFI/AESI reports are received online via the South Australian Vaccine Safety Surveillance System (SAVSSS), by phone or infrequently via the DHW Safety Learning System (SLS). Each report received through SAVSSS is automatically uploaded to the TGA with any additional reports received through other mechanisms that meet the criteria for categorisation as a Serious AEFI or AESI also reported to the TGA by the Vaccine Safety Surveillance Team (VSST). Reports that meet the definition of a Serious AEFI or are an identified AESI requiring further analysis i.e. Category 1 AESI (as defined in the Vaccine Safety Surveillance – Incident Management and Escalation Matrix) are analysed by the COVID-19 Vaccination Program Vaccine Surveillance Safety Team and reported to the COVID-19 Vaccine Safety Surveillance Committee (VSSC) for review immediately if/as required, otherwise they are reviewed on a weekly basis by the VSSC.

Case Definitions

The Brighton Collaboration provides Case Definitions for Category 1 AESI, as follows;

- Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation/VAED

These Case Definitions inform analysis and classification of reports by the VSST. No Brighton Collaboration Case Definition is currently available for 'Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)'.

Summary of Vaccination Activity

Vaccination recorded to the Australian Immunisation Register as at 11/01/2022*

Total vaccines:

1st 1,419,178

2nd 1,350,669

Boosters 278,534

Total Doses/episodes: 3,048,381

Vaxzevria:

1st 427,008

2nd 416,711

Boosters 614

Total Doses/episodes: 844,333

Pfizer:

1st 921,637

2nd 876,191

Boosters 241,537

Total Doses/episodes: 2,039,365

Pfizer Kids:

1st 4,581

2nd 1

Moderna:

1st 65,952

2nd 57,766

Boosters 36,383

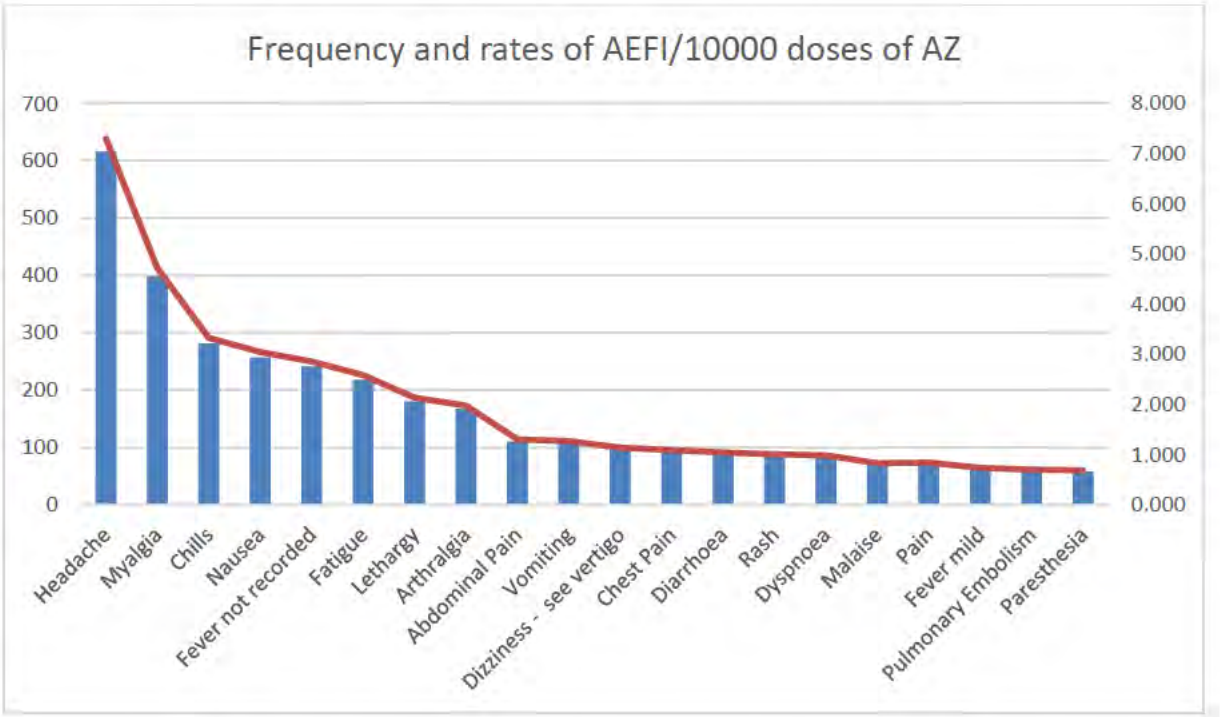
Total Doses/episodes: 160,101

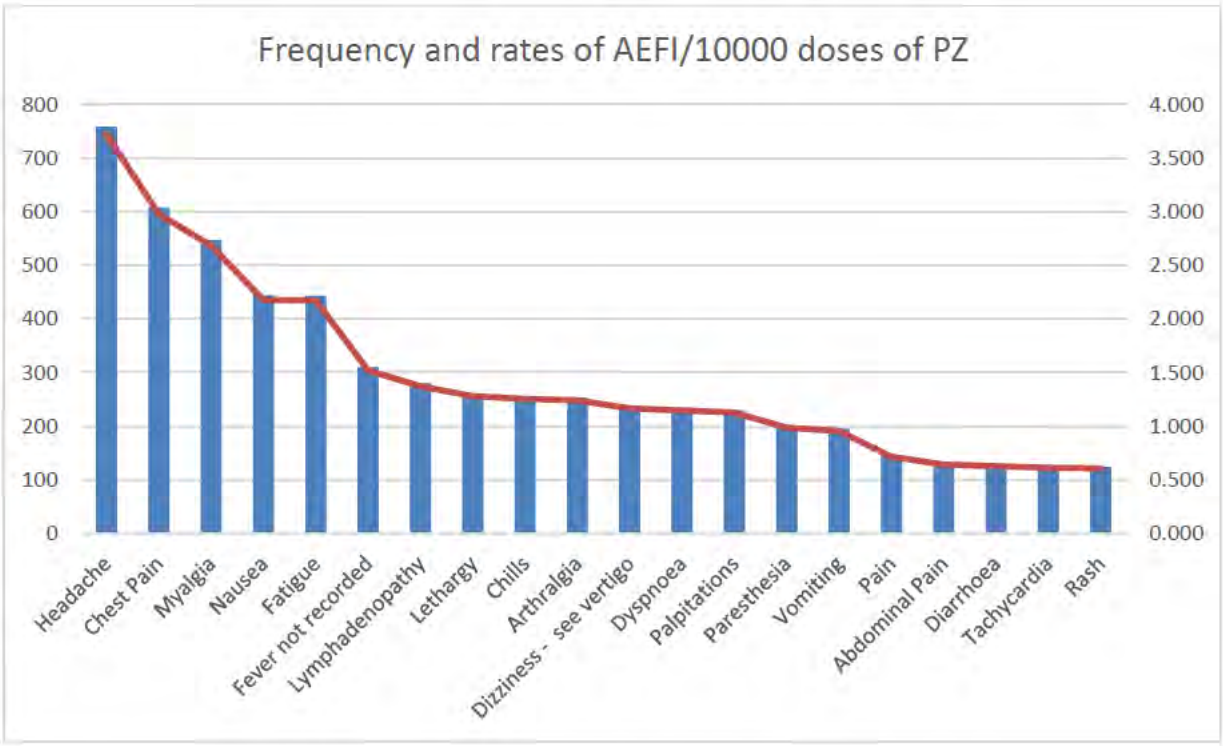
available data from Australian Immunisation Register report

Table 1: Summary of all COVID-19 vaccine AEFI reports received into SAVSSS as at 11/01/2022 YTD:

Number of Reports			**5,489**
Gender	**Male**		**1,581**
	Female		**3,894**
Indigenous	**Yes**		**76**
Injection site reactions total number Covid-19 vaccines reports			
General reactions total number of COVID-19 vaccines reports			
Vaccine	**Reports**	**Injection site reaction**	**General Reaction**
AstraZeneca	1,975	441	1,792
Pfizer	3,258	797	2,805
Moderna	256	101	216

Figure 1: YTD Rates of common AEFI by vaccination




Frequency and rates of AEFI/10000 doses of PZ
800
700
600
500
400
300
200
100
0
4.000
3.500
3.000
2.500
2.000
1.500
1.000
0.500
0.000
Headache
Chest Pain
Myalgia
Nausea
Fatigue
Fever not recorded
Lymphadenopathy
Lethargy
Chills
Arthralgia
Dizziness - see vertigo
Dyspnoea
Palpitations
Paresthesia
Vomiting
Pain
Abdominal Pain
Diarrhoea
Tachycardia
Rash

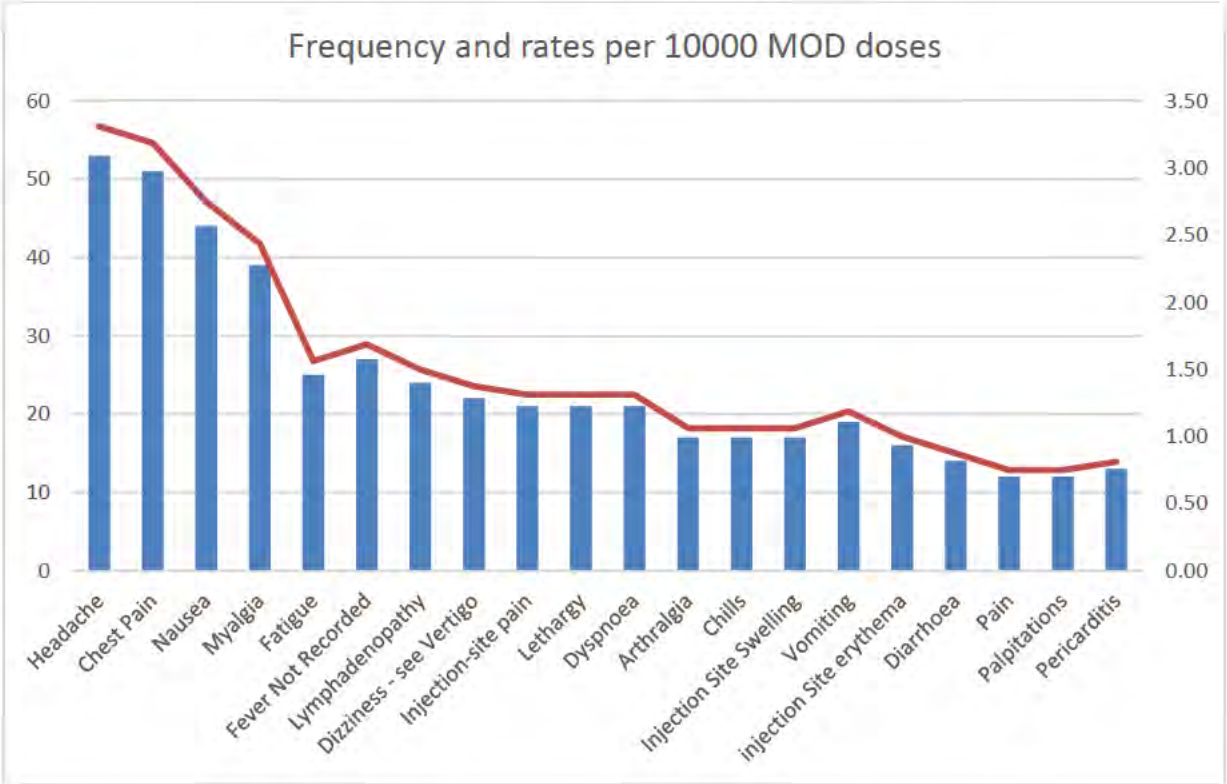

Frequency and rates per 10000 MOD doses
60
50
40
30
20
10
0
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
Headache
Chest Pain
Nausea
Myalgia
Fatigue
Fever Not Recorded
Lymphadenopathy
Dizziness - see Vertigo
Injection-site pain
Lethargy
Dyspnoea
Arthralgia
Chills
Injection Site Swelling
Vomiting
injection Site erythema
Diarrhoea
Pain
Palpitations
Pericarditis

Table 2: Special Interest AEFI Topics as at 11/01/2022 YTD:

Vaxzevria (Astra Zeneca)	YTD		Week 42		
Adverse events	**1975**	**Rates/10000 doses of total AZ vacc admin***	**7**	**% of YTD AESI reported****	**Rates/10000 doses of total AZ vacc admin*****
Abdominal Pain	**110**	1.303	0	0.00	0.0000
Chest Pain	**92**	1.090	1	1.09	0.0118
Clot	34	0.403	0	0.00	0.0000
Vertigo	**49**	0.580	0	0.00	0.0000
Visual disturbance	45	0.533	0	0.00	0.0000
Epistaxis	25	0.296	0	0.00	0.0000
Deep vein thrombosis	47	0.557	0	0.00	0.0000
Death	23	0.272	0	0.00	0.0000
Herpes zoster	**29**	0.343	0	0.00	0.0000
Pulmonary embolism	59	0.699	0	0.00	0.0000
Cerebral vascular accident see Stroke	8	0.095	0	0.00	0.0000
Stroke	12	0.142	0	0.00	0.0000
Thrombocytopenia	9	0.107	0	0.00	0.0000
Bell's Palsy	9	0.107	0	0.00	0.0000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions	13	0.154	0	0.00	0.0000
Pericarditis	**9**	0.107	0	0.00	0.0000
Menstrual Irregularity	8	0.095	0	0.00	0.0000
Guillain Barré syndrome	6	0.071	0	0.00	0.0000
Myocarditis	4	0.047	0	0.00	0.0000
Exacerbation of existing medical condition	41	0.486	0	0.00	0.0000
Thrombosis with thrombocytopenia syndrome TTS	4	0.047	0	0.00	0.0000
Cerebral Venous Sinus Thrombosis	4	0.047	0	0.00	0.0000
Dyskinesia	2	0.024	0	0.00	0.0000

Idiopathic thrombocytopenic purpura	5	0.059	0	0.00	0.0000
Multiple sclerosis	1	0.012	0	0.00	0.0000
Purpura	11	0.130	0	0.00	0.0000
Dysgeusia	19	0.225	0	0.00	0.0000
Thrombophlebitis	16	0.189	0	0.00	0.0000
Lymphadenopathy [a]	25	0.296	0	0.00	0.0000

a: Dose and gender not available for few patients

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Pfizer	YTD		Week 42		
Adverse events	3258	Rates/10000 doses of total PZ vacc admin*	74	% of YTD AESI reported**	Rates/10000 doses of total Pfizer vacc admin.***
Chest Pain [a]	607	2.976	14	2.31	0.069
Vertigo [a]	69	0.338	0	0.00	0.000
Dizziness – see Vertigo [a]	238	1.167	3	1.26	0.015
Visual disturbance	70	0.343	1	1.43	0.005
Death	18	0.088	0	0.00	0.000
Herpes zoster	39	0.191	1	2.56	0.005
Pulmonary embolism	16	0.078	1	6.25	0.005
Bell's Palsy	15	0.074	0	0.00	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions) [a]	56	0.275	0	0.00	0.000
Pericarditis [a]	81	0.397	2	2.47	0.010
Myocarditis	31	0.152	0	0.00	0.000
Myopericarditis	13	0.064	0	0.00	0.000
Menstrual Irregularity [a]	95	0.466	7	7.37	0.034
Exacerbation of existing medical condition	102	0.500	1	0.98	0.005
Miscarriage	4	0.020	0	0.00	0.000
Tinnitus	57	0.279	1	1.75	0.005

Lymphadenopathy [a]	**280**	1.373	10	3.57	0.049

a: Dose and gender not available for few patients

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Moderna Spikevax	**YTD**		**Week 42**		
Adverse events	**256**	**Rates/10000 doses of total Spikevax vacc admin***	**18**	**% of YTD AESI reported****	**Rates/10000 doses of total Spikevax vacc admin*****
Bell's Palsy	**1**	0.062	0	0.000	0.000
Chest Pain [a]	**51**	3.185	4	7.843	0.250
Death	**0**	0.000	0	0.000	0.000
Lymphadenopathy	**24**	1.499	2	8.333	0.125
Pericarditis	**13**	0.812	2	15.385	0.125
Herpes zoster [a]	**2**	0.125	0	0.000	0.000
Myocarditis	**1**	0.062	0	0.000	0.000
Myopericarditis	**0**	0.000	0	0.000	0.000
Menstrual Irregularity	**7**	0.437	0	0.000	0.000
Anaphylaxis (including anaphylactoid reactions, acute hypersensitivity, allergic reactions, Hypersensitivity reactions)	**1**	0.062	0	0.000	0.000
Miscarriage	**1**	0.062	0	0.000	0.000

a: Dose and gender not available for few patients

* Number of Special Interest symptoms reported against all vaccinations administered YTD

** Number of Special Interest symptoms reported that week against total number of Special Interest symptom reported YTD

***Number of Special Interest symptoms reported that week against all vaccinations administered YTD

Table 4: TGA reported TTS Summary as at 11/01/2022 YTD:

Confirmed	Probable	Possible	Haem (TGA) Review	Unlikely	Dismissed	Total
4	3	6	0	6	3	22

Table 5: Events received following Moderna Spikevax vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Diagnosis: **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

Table 6: Events received following Pfizer's Comirnaty vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
[redacted]	Cat 3	20[redacted]	**Diagnosis:** [redacted] **Date and time vaccinated:** 11/12/2021 **Dose number:** 2 **Details:** [redacted] **Laboratory Results:** [redacted]	[redacted]	No Change Change/Review rationale:

			[redacted] **Imaging & Findings:** [redacted] **Treatment:** [redacted] **Medical History:** [redacted] **GP contacted/notified:** [redacted] **Classification:** [redacted]		

Table 7: Events received following Vaxzevria (AstraZeneca) COVID-19 Vaccine:

Event ID #	TGA AEFI/A ESI Cat	Age and Gender	Incident details	Recommendation for client from Committee	Vaccination Program Implications
			Diagnosis: **Date and time vaccinated:** **Dose number:** **Details:** **Laboratory Results:** **Imaging & Findings:** **Treatment:** **Medical History:** **GP contacted/notified:** **Classification:**	Uncommon – refer back to GP for review Uncommon – refer back to GP suggesting SACISC Review Uncommon – refer back to GP suggesting Specialist review No Letter required	No Change Change/Review rationale:

2. Summary of the TGA COVID-19 vaccine updates:

TGA weekly report as at 6 January 2022: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-06-01-2022

Program Errors Summary COVID-19 Vaccination Program

Background

Immunisation errors (Program Errors) are an unwanted, but expected, outcome of any vaccination program. They may result from errors in vaccine preparation, handling, storage or administration.

Program Errors can result in a cluster of events, defined by WHO as two or more cases of the same adverse event related in time, place or vaccine administered. These clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated. Program Errors can also affect many vials and many people, for example, incorrect preparation of multidose vials can affect many people.

They are preventable.

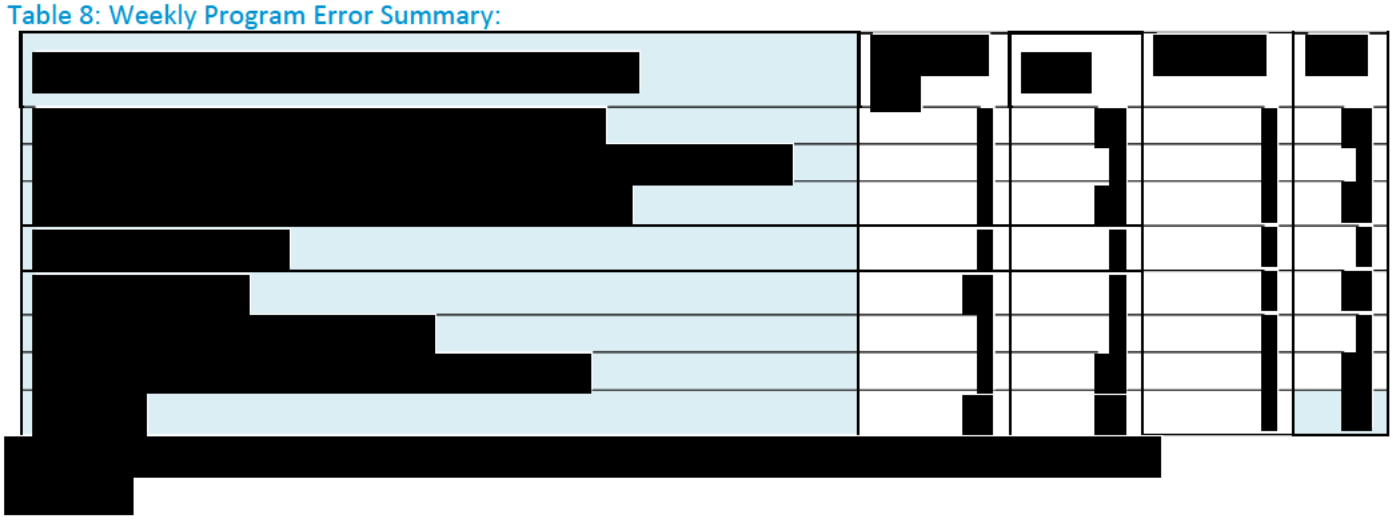
Systems and Processes for Monitoring Program Errors

The COVID Clinical Advisory Service (CAS) functions as a central point for receipt of reports of COVID 19 vaccine program errors.

As per the 'Incident Escalation and Communication Process Flow – Clinical' endorsed through the Vaccine Strategy Group (VSG) on 19 May 2021 (see Appendix 1);

- Non-critical errors undergo weekly analysis by the CAS, with medical oversight, with documented feedback and recommendations to the provider and/or patients as required. A weekly summary of non-critical errors will be provided to the Clinical Advisory Group (CAG) as part of the Vaccine Safety Surveillance Report, with updates provided to the Vaccine Strategy Group as/if required by CAG.
- Critical Program errors (as defined in the 'VSS - Incident Management and Escalation' Framework) are escalated to CAG, Strategy & Intergovernmental Relations (S&IGR), VSG, the Commonwealth Vaccines Operation Centre and SA Health Media and Communications team, with documented feedback and recommendations to the provider, patients and/or public as required.

Table 8: Weekly Program Error Summary:



Critical Errors

Nil new reports

Non-Critical Errors

Nil new reports

- Appendix 1: TGA listed AEFI and adverse events of special interest (AESI) for the Pfizer vaccine and AstraZeneca vaccines

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation, whether expected or unexpected, and whether triggered by the vaccine or only coincidentally occurring after receipt of a vaccine.[1]

Adverse event case definitions:

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1,000 to < 1/100)
- Rare (≥ 1/10,000 to < 1/1,000)
- Very rare (< 1/10,000)

Therapeutic Goods Administration (TGA) definition of serious Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI):

Serious adverse event following immunisation (AEFI):

Any AEFI that is serious as defined by the WHO Global manual on surveillance of adverse events following immunization:

- results in death – requires rapid escalation.
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect, or
- requires intervention to prevent one of the outcomes above.

Adverse Events of Special Interest (AESI) – COVID-19 vaccines:

Category 1: AESI related to COVID-19 vaccination in general

- Generalised convulsion
- Guillain-Barre Syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Vasculitides (incl. single organ cutaneous vasculitis, Kawasaki Disease)
- Encephalitis/encephalomyelitis/myelitis (*include transverse myelitis?)
- Idiopathic peripheral facial nerve palsy (see also Category 2 below)
- Thrombocytopenia

- Enhanced disease following immunisation/VAED (also considered a Category 2 & 3 AESI)

Category 2: AESI relevant to specific vaccine platforms for potential COVID-19 vaccines

- Nil for the registered COVID-19 vaccines in Australia at this point in time

Category 3: AESI related to COVID-19 disease

- Enhanced disease following immunisation/VAED (also considered a Category 1 & 2 AESI)
- Multisystem inflammatory syndrome
- Acute respiratory distress syndrome (ARDS)/vaccine-associated (VA)-ARDS
- Acute cardiac injury (includes myocarditis, pericarditis, arrhythmias, heart failure, infarction)
- Coagulation disorder
- (includes coagulopathy, thrombosis, thromboembolism, internal/external bleed, stroke, disseminated intravascular coagulation)
- Acute kidney injury
- Acute liver injury

Category 3: AESI related to COVID-19 disease

- Anosmia, ageusia
- Chilblain-like lesions
- Single organ cutaneous vasculitis
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Category 4: AESI related to TGA clinical evaluation

- Pregnancy and birth outcomes

Appendix 2: TGA published definitions AEFI Pfizer– Comirnaty (BNT162b2[mRNA]) COVID-19 Vaccine#

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (tozinameran) COVID-19

Revised PI 03/12/2021

Table 1: Adverse reactions from COMIRNATY clinical trials: Individuals 12 years of age and older

System Organ Class	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy[a]		
Psychiatric disorders			Insomnia		
Metabolism and nutrition disorders			Decreased appetite		
Nervous system disorders	Headache		Lethargy	Acute peripheral facial paralysis[b]	
Gastrointestinal disorders		Nausea			
Skin and subcutaneous disorders			Hyperhidrosis Night sweats		
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[c]; Injection site swelling	Injection site redness	Asthenia Malaise		Facial swelling[d]

[a] A higher frequency of lymphadenopathy (5.2% vs 0.4%) was observed in participants receiving a booster dose (third dose) compared to participants receiving 2 doses.

[b] Through the clinical trial safety follow-up period to 14 November 2020, acute peripheral facial paralysis (or palsy) was reported by four participants in the COMIRNATY group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

[c] A higher frequency of pyrexia was observed after the second dose.

[d] Facial swelling in vaccine recipients with a history of injection of dermatological fillers

Table 2. Adverse Reactions from COMIRNATY clinical trial: Individuals 5 to <12 Years of Age (06 September 2021 Data Cut-off Date)

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria[a,b]; Pruritus[a,b]; Rash[a,b]			Anaphylaxis[a]
Metabolism and nutrition disorders			Decreased appetite			
Nervous system disorders	Headache					
Gastrointestinal disorders		Diarrhoea;[a] Vomiting[a]	Nausea			
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia	Pain in extremity (arm)[a]			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Injection site swelling; Injection site redness	Pyrexia	Malaise			

a. These adverse reactions were identified in the post-authorisation period. The following events were not reported in participants 5 to <12 Years of Age in Study C4591007 but were reported in individuals ≥16 years of age in Study C4591001: angioedema, lethargy, asthenia, hyperhidrosis, and night sweats.

b. The following events are categorised as hypersensitivity reactions: urticaria, pruritus, and rash

Post-marketing experience Although the events listed in Table 3 were not observed in the clinical trials, they are considered adverse drug reactions for COMIRNATY as they were reported in the post-marketing experience. As these reactions were derived from spontaneous reports, the frequencies could not be determined and are thus considered as not known.

Table 3:Adverse reactions from COMIRNATY post marketing experience

System Organ Class	Adverse Drug Reaction
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhoea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)
General disorders and administration site conditions	Extensive swelling of vaccinated limb

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty in phase II/III trial[45,82]

	12 – 15 years of age		16 to 25 years of age		16–55 years of age		>55 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	86%	79%	83%	78%	83%	78%	71%	66%
Fever	10%	20%	7%	17%	4%	16%	1%	11%
Fatigue	60%	66%	60%	66%	47%	59%	23%	51%
Headache	55%	65%	54%	61%	42%	52%	25%	39%
Chills	28%	42%	25%	40%	14%	35%	6%	23%
Muscle pain	24%	32%	27%	41%	21%	37%	14%	28%
Joint pain	10%	16%	13%	22%	11%	22%	9%	19%
Required paracetamol	37%	51%	32%	46%	28%	45%	20%	38%

Appendix 3: TGA published AEFI definitions COVID-19 Vaccine AstraZeneca (ChAdOx1-S)*

AUSTRALIAN PRODUCT INFORMATION VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca)
Revised PI 25/11/2021

Table 1 Adverse Drug Reactions (ADR) primary analysis – pooled data set (safety analysis set[a])

MedDRA SOC	Adverse reaction[b]	VAXZEVRIA (N= 10, 317)	Control[c] (N= 10, 141)
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon (0.3%)	Uncommon (0.3%)
Nervous system disorders	Headache	Very common (52.7%)	Very common (39.8%)
	Dizziness[d]	Uncommon (0.7%)	Uncommon (0.7%)
	Somnolence[d]	Uncommon (0.5%)	Uncommon (0.3%)
Gastrointestinal disorders	Nausea	Very common (22.2%)	Very common (13.4%)
	Vomiting	Common (1.8%)	Uncommon (0.9%)
	Diarrhoea[d]	Common (1.6%)	Common (1.5%)
	Abdominal pain[d]	Uncommon (0.6%)	Uncommon (0.4%)
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon (0.4%)	Uncommon (0.2%)
	Pruritus[d]	Uncommon (0.3%)	Uncommon (0.3%)
	Rash[d]	Uncommon (0.2%)	Uncommon (0.3%)
	Urticaria[d]	Uncommon (0.1%)	Uncommon (0.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (43.9%)	Very common (22.3%)
	Joint pain (Arthralgia)	Very common (26.6%)	Very common (13.0%)
	Pain in extremity[d]	Common (1.3%)	Uncommon (0.8%)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.8%)	Very common (40.1%)
	Injection site pain	Very common (54.3%)	Very common (37.5%)
	Injection site warmth	Very common (17.9%)	Very common (15.2%)
	Injection site itch (Injection site pruritus)	Very common (13.1%)	Common (7.8%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.0%)	Very common (38.6%)
	Malaise	Very common (44.4%)	Very common (21.0%)
	Feverishness[e] (Pyrexia)	Very common (33.5%)	Very common (11.0%)
	Chills	Very common (32.2%)	Common (8.4%)
	Fever[e] (Pyrexia)	Common (7.6%)	Common (1.5%)
	Influenza-like illness[d]	Common (1.1%)	Uncommon (0.7%)

Post-marketing experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorisation use of VAXZEVRIA.

Immune system disorders	*Anaphylactic reaction
Skin and subcutaneous tissue disorders	*Angioedema
Vascular disorders	A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see Section 4.4 Special warnings and precautions for use). Capillary leak syndrome (see Section 4.4 Special warnings and precautions for use).
Blood and lymphatic system disorders	Thrombocytopenia (frequency very rare). The majority of reported events occurred in individuals aged 18-59 years old. Immune thrombocytopenia (frequency not known).
Nervous system disorders	Guillain-Barré syndrome (GBS) (frequency very rare).

* The frequency of these adverse reactions is 'not known' (cannot be estimated from available data as the reports come from a population of unknown size).

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Table 3: Frequency of select common adverse events reported within 7 days following at least one dose of Vaxzevria in phase II/III trial in people aged >18 years[99]

	18–55 years		56–69 years		≥70 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	61%	49%	43%	34%	20%	10%
Injection site tenderness	76%	61%	67%	59%	49%	47%
Fatigue	76%	55%	50%	41%	41%	33%
Headache	65%	31%	50%	34%	41%	20%
Muscle pain	53%	35%	37%	24%	18%	18%
Fever	24%	0%	0%	0%	0%	0%

A 3rd dose of Vaxzevria after two previous doses of Vaxzevria was well tolerated and associated with lower adverse event rates than after the primary vaccine doses.[100]

Appendix 4: TGA published AEFI definitions COVID-19 Vaccine Spikevax (Elasomeran)

AUSTRALIAN PRODUCT INFORMATION – SPIKEVAX (ELASOMERAN) COVID-19 Vaccine

Revised PI – 09/12/2021

Table 1: Tabulated list of adverse reactions for SPIKEVAX

MedDRA System Organ Class	Frequency	Adverse reaction
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Not known	Anaphylaxis Hypersensitivity
Nervous system disorders	Very common	Headache
	Rare	Acute peripheral facial paralysis**
Cardiac disorders	Not known	Myocarditis Pericarditis
Gastrointestinal disorders	Very common	Nausea/Vomiting
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills Pyrexia Injection site swelling
	Common	Injection site erythema Injection site urticaria Injection site rash Delayed injection site reaction****
	Uncommon	Injection site pruritus
	Rare	Facial swelling***

*Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site.

**Throughout the safety follow-up period, acute peripheral facial paralysis (or palsy) was reported by three participants in the SPIKEVAX group and one participant in the placebo group. Onset in the vaccine group participants was 22 days, 28 days, and 32 days after Dose 2.

***There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported on Day 1 and Day 3, respectively, relative to day of vaccination.

**** Delayed injection site reactions included pain, erythema and swelling.

The reactogenicity and safety profile in 343 subjects receiving SPIKEVAX, who were seropositive for SARS-CoV-2 at baseline, was comparable to that in subjects seronegative for SARS-CoV-2 at baseline.

Table 2: Frequency of select common adverse events reported within 7 days following each dose of Spikevax in phase III trial[46,67]

	12 – 17 years of age		18-64 years of age		≥65 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	93%	92%	87%	90%	74%	83%
Lymph node swelling at the axilla	23%	21%	12%	16%	6%	9%
Fever	2.5%	12%	0.9%	17%	0.3%	10%
Fatigue	48%	68%	38%	68%	33%	58%
Headache	45%	70%	35%	63%	25%	46%
Chills	18%	43%	9%	49%	5%	31%
Myalgia	27%	47%	24%	62%	20%	47%
Arthralgia	15%	29%	17%	46%	16%	35%
Nausea/vomiting	10%	18%	9%	21%	5%	12%

In a clinical trial using Spikevax as a booster dose (using a half-dose of 50mcg), adverse events were generally mild to moderate and similar to rates seen following the primary 2-dose series in phase 2 and 3 trials.[85]