

ADVERSE EVENT REPORTING- SAEFVIC

The practicalities of reporting in 2021

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Research & Immunisation Nurses

26-04-2021 CVU Mini

Overview

- What SAEFVIC is and what it is not
- SAEFVIC service activity to date – a COVID-19 focus
- AEFI explained
- What to report (what not to report)
- How to report
- Clinical services
- Useful resources for providers and consumers

SAEFVIC - Surveillance of Adverse Events Following Vaccination In the Community

- SAEFVIC is the vaccine safety surveillance service in Victoria for **reporting** any significant Adverse events following immunisation. We are a public health partnership initiative of the Victorian Immunisation Program funded by the Department of Health (DH)
- SAEFVIC confidentially collects, analyses and reports data about significant AEFI as part of monitoring vaccine safety in Victoria. All reports received are forwarded to the Therapeutic Goods Administration (TGA) who closely monitor and assess vaccine safety for signal detection
- Timely reporting to SAEFVIC enables us to quickly detect any potential vaccine or system problems. This helps to ensure Victoria has a safe immunisation program and maintains community confidence.

Contact

- Our operating hours are 9.00am to 5.00pm, Monday to Friday (except public holidays).
- Ways to contact SAEFVIC;
 - Email: saefvic@mcri.edu.au
 - Phone: 1300 882 924 (option 1) – 9.00am to 5.00pm – option to leave a message
 - Online reporting: <https://www.safevac.org.au> (recommended)
- ❖ Due to the high volume of calls and reports, there may be a delay in response

What SAEFVIC is not.....

SAEFVIC is not a service that can respond to a medical emergency or provide acute medical advice over the phone or via email

It is advised, that anyone experiencing a serious adverse event or symptoms that are of concern following an immunisation should seek medical review.

National coronavirus and COVID-19 vaccine helpline

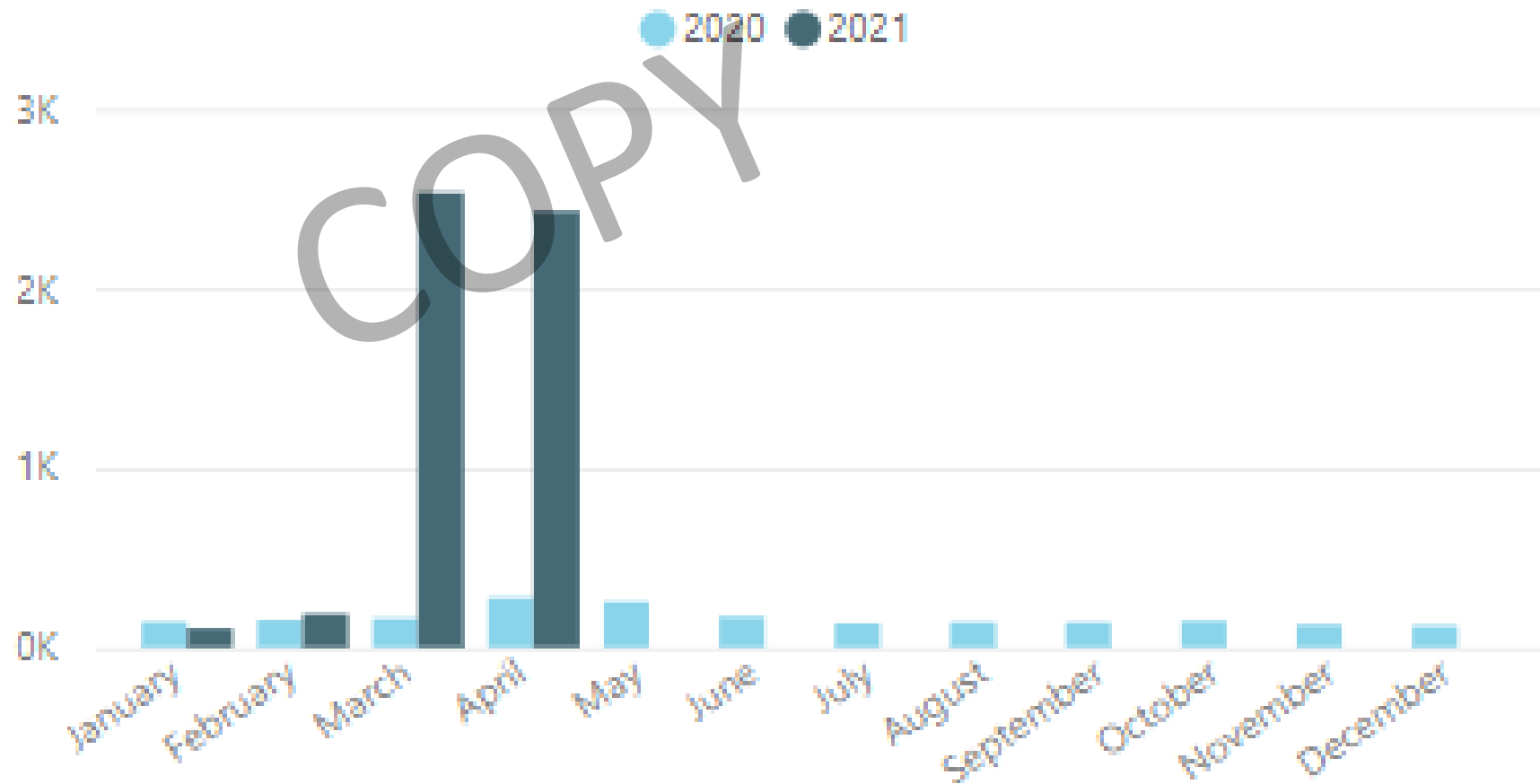
<https://www.health.gov.au/contacts/national-coronavirus-and-covid-19-vaccine-helpline>

Visit the COVID-19 Vaccine Side Effect Checker Tool

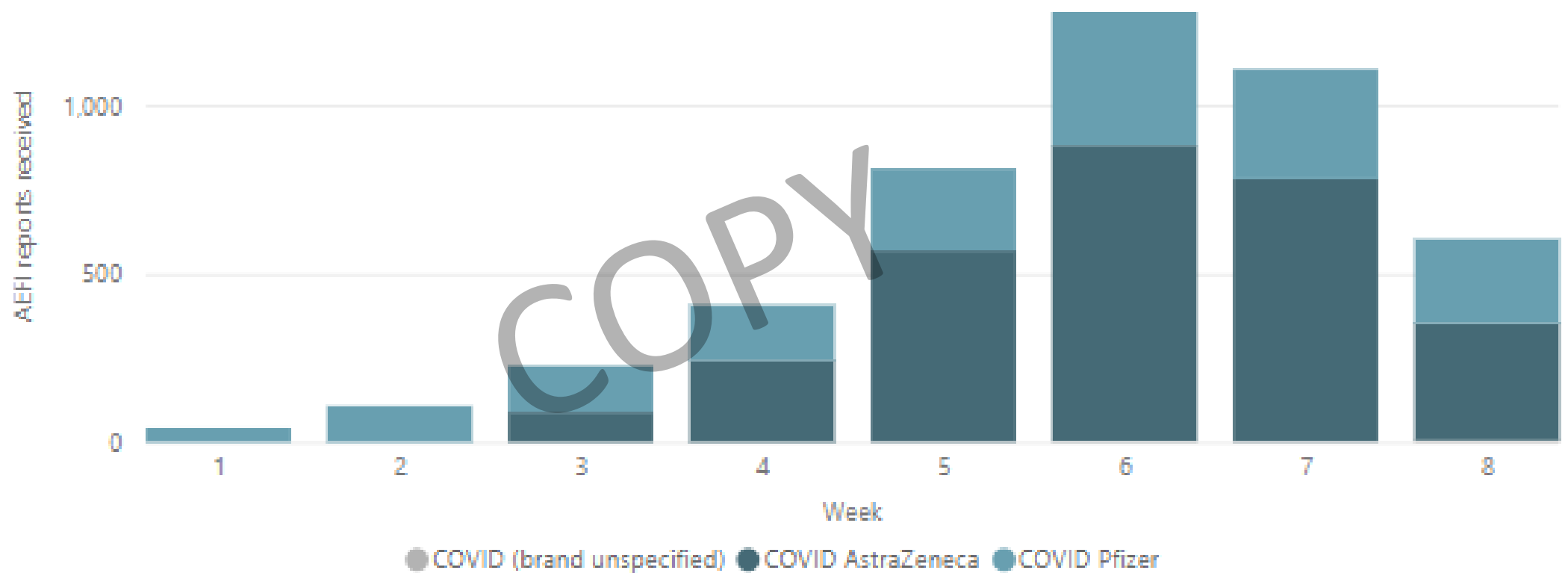
<https://www.healthdirect.gov.au/symptom-checker/tool/basic-details>

SAEFVIC service activity 2021

AEFI reports received (all vaccines) in 2021 (as at 22 April) compared to 2020

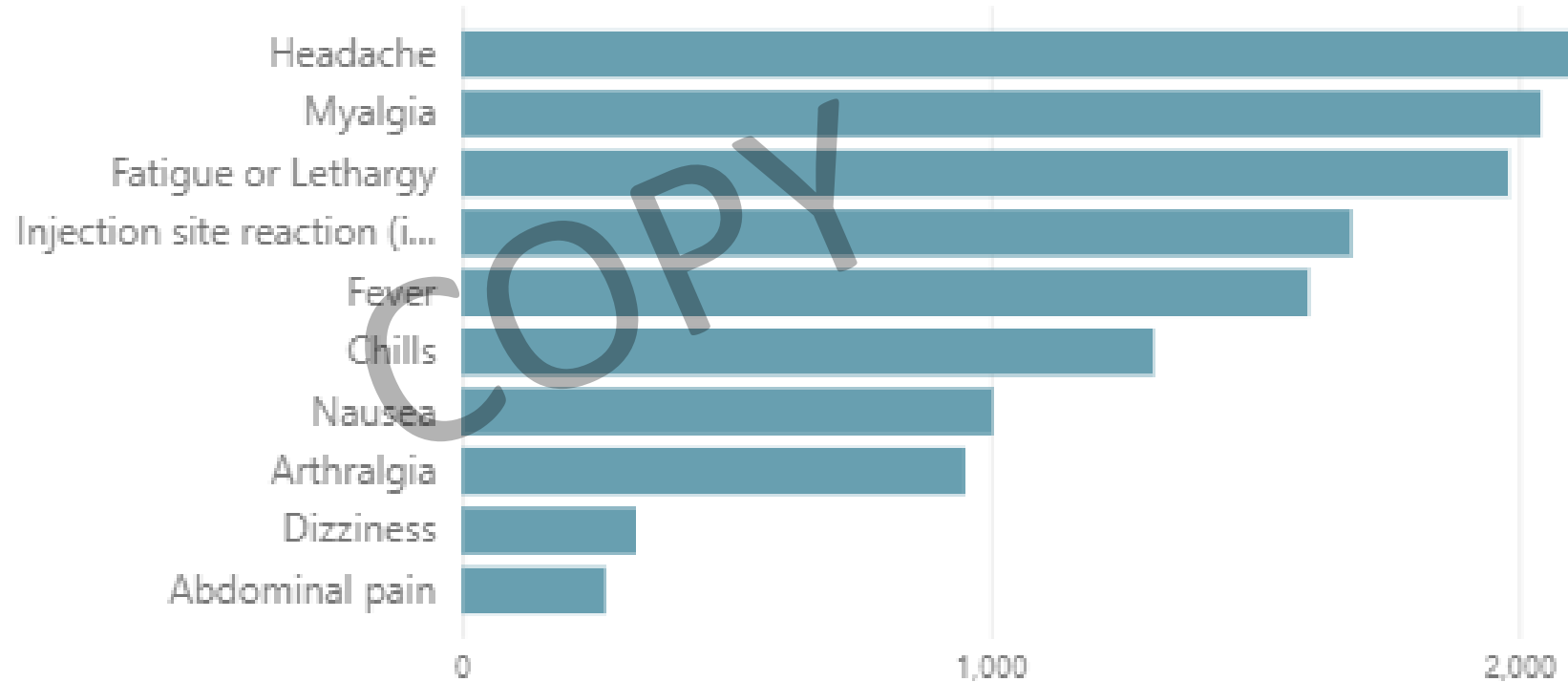


AEFI report received, by COVID brand and week reported



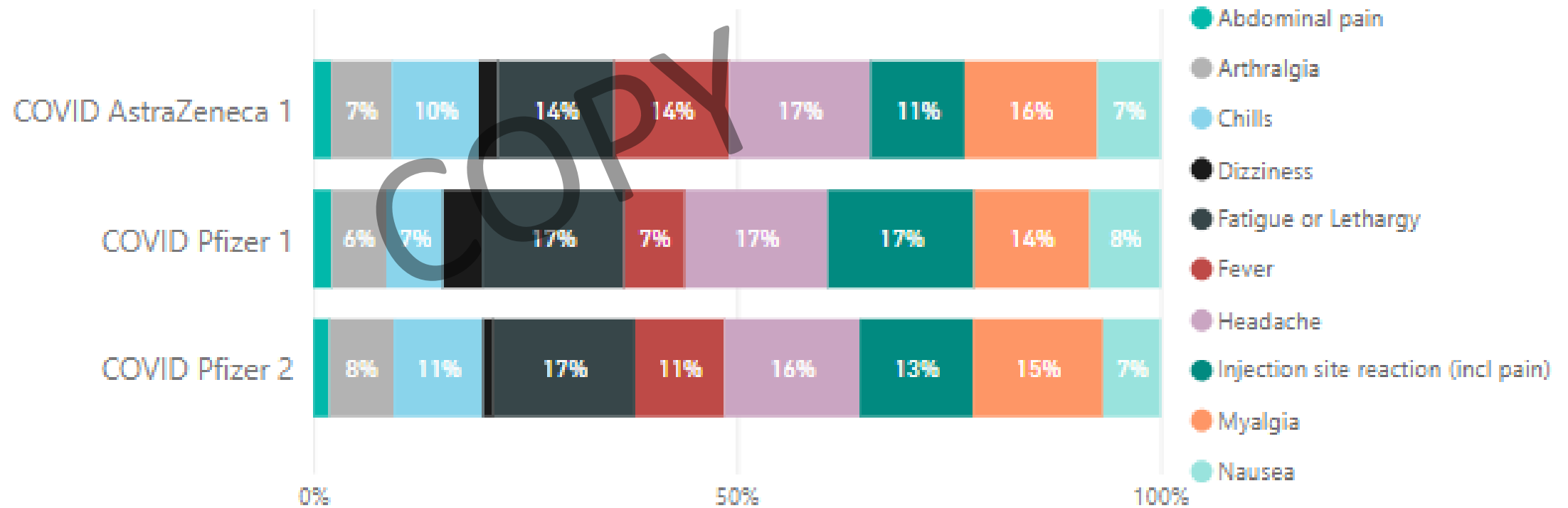
Most frequently described AEFI post Covid19 vaccines

Top most frequently described AEFI symptoms



**Note a person may report >1 AEFI symptom*

Top 10 reported AEFI as % reported by vaccine brand & dose



Should all AEFI's be reported

You do not need to routinely report the commonly expected side effects of COVID-19 vaccines including:

- Pain
- Minor injection site reactions
- Tiredness/Fatigue
- Headache (if <48 hours in duration)
- Nausea
- Fever and chills
- Feeling unwell
- Arthralgia/myalgia
- Pain in limb
- Decreased appetite

What should you report to SAEFVIC?

You **should** report

- Any event felt to be **significant** following COVID-19 immunisation, regardless of whether you think the side effect was related to the vaccine or not
- Any expected reactions that have not gone away after a few days
- Any reaction to a vaccine which requires assessment by a doctor
- Suspected shoulder injury related to vaccine administration (SIRVA)
- Any vaccination administration errors

mvec.mcri.edu.au/references/covid-19-vaccine-adverse-events/

Who can report to SAEFVIC

- Anyone can report an AEFI to SAEFVIC including;
 - The vaccinee/self report
 - Parents/guardians/next of kin/family of a vaccinee
 - Immunisation providers
 - Practice nurses
 - General practitioners
 - Pharmacists
 - Treating medical professionals at a tertiary facility or emergency department

How to report to SAEFVIC

- DHHS and SAEFVIC strongly encourage providers and consumers to report all unexpected or serious adverse events and vaccination errors to us online via <https://www.safevac.org.au/>
- There are new ways of reporting an AEFI following the COVID-19 vaccine rollout including;
- CVMS (COVID Vaccine Management System) – Day 3 and Day 8 active surveillance
- QR code provided to consumers at time of vaccination

Online reporting

SAFEVAC Reporting

Integrated Vaccine Safety

SAFEVAC

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SAFEVAC: Integrated Vaccine Safety

Welcome to SAFEVAC - an Australian database for reporting reporting of Adverse Events Following Immunisation (AEFI) and associated clinical visits. Please note this is the same system previously used by reporters (formerly AEFI-CAN).

Currently AEFI reporting can only be completed via this website if the vaccine was administered in Victoria or Western Australia (reports followed up by SAEFVIC or WAVSS respectively).

The mission of SAFEVAC is to promote confidence in the National Immunisation Program through enhancing national vaccine safety monitoring and rapid signal detection.

To help us achieve this we encourage all immunisation providers and vaccinees **including healthcare workers** to report any unexpected, serious or unusual Adverse events following immunisation (AEFI) to their local surveillance body (see below).

Providers are encouraged to report all vaccine or Drug (program) errors as well.

Details of who you should report to are tabulated below.



State	Reporting Service	Phone	Website
Victoria	SAEFVIC	1300 882 924 (option 1)	SAEFVIC
Western Australia	WAVSS	(08) 6456 0208	WAVSS

Registering

Register

New Users

Email: *

Password: *

Your password must be at least 8 characters long, with no spaces, and contain at least one letter (a-z) and one number (0-9)

Confirm password: *

First Name: *

Surname: *

Type of Reporter: *

Other:

Organisation: *

Address: *

Suburb: *

State: *

Postcode: *

Phone: *

Register

Existing Users

Email: *

Password: *

[Forgotten password?](#)

Login

Adverse event reporting can only be done via this website if the vaccine was administered in Victoria or Western Australia (reports will be followed up as usual by SAEFVIC or WAVSS respectively).

If the vaccine was administered by a provider in ACT, NSW, NT, QLD, SA or TAS you must continue to report using your existing methods.



How to report an AEFI

[Download Reporter Guide](#)

[Report an Adverse Event](#)



Please Note: In response to extra demand relating to Covid19 and associated work place restrictions, there may be some delay in responding to reports.

Thank you for your understanding.

First Time Users

Create your account by clicking on the Register tab on this website. Enter your details which will be used to auto-populate the reporter field. A central email can be registered for clinical practices/councils (eg. nurse@thefamilyclinic.com.au) so all staff can report using the one registration.

All Users

Once registered click on the Login tab and proceed through each page of the report. For more information see the [Reporting Guide](#).

NOTE: If you are not the vaccinee (the person who was immunised) then you will need to gain consent to report **before** you report unless it is impracticable (ie. for serious errors or AEFI where the vaccinee cannot be contacted immediately OR where the vaccinee is incapable of consent for any reason).

What happens once a report is submitted?

All reports submitted are assessed by SAEFVIC and forwarded to the Therapeutic Goods Administration (TGA).

When requested or deemed appropriate, SAEFVIC will provide advice to the immunisation provider and/or reporter. Consent to contact must be obtained if you would like SAEFVIC to follow up with the vaccinee.

Reporter Details

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SAFEVAC

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Reporter Details

Standard AEFI ID: Z2104-000074

Status: Submitted

Submitted: 19/04/2021 2:51 PM by Adele Harris

Last modified: 22/04/2021 4:00 PM by Adele Harris

[Reporter](#) | [Vaccines](#) | [Provider](#) | [Vaccines](#) | [Treatment](#) | [Submission](#) | [Office Use](#) | [Attachments](#)

Reporter Details

First Name: *	Mrs ▾ Adele	Organisation: *	SAEFVIC
Surname: *	Harris	Address: *	MCRI -Flemington Rd
Reporter Type: *	Nurse ▾	Suburb: *	Parkville
Other:		State: *	VIC ▾
Reporter Setting:	-- select -- ▾	Postcode: *	3052
		Phone: *	Landline ▾ (03) 9345 4143
		Email Address:	a.harris@mcri.edu.au

[Save and Next >](#)

Vaccinee Details

Vaccinee Details

Standard AEFI ID: Z2104-000074

Status: Submitted


Submitted: 19/04/2021 2:51 PM by Adele Harris

Last modified: 22/04/2021 4:00 PM by Adele Harris

Reporter Vaccinee Provider Vaccines Treatment Submission Office Use Attachments

Vaccinee Details (Child or Adult)

Same as Reporter Details

First Name: *	Mr <input type="checkbox"/> Bob	Address: *	24 Day St
Surname: *	Hope	Suburb: *	FRANKSTON EAST
Birth Date:	12/06/1984 	State: *	VIC <input type="checkbox"/>
Gender: *	<input checked="" type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Neither <input type="radio"/> Unknown	Postcode: *	3199
Medicare Number:	33345678643	Phone 1: *	Mobile <input type="checkbox"/> 0438 111 222
ATSI Status: *	Unknown <input type="checkbox"/>	Phone 2:	-- select -- <input type="checkbox"/>
Vaccinee Category:*	<input checked="" type="radio"/> Health/aged/disability care worker <input type="radio"/> In residential/aged/disability care <input type="radio"/> None of the above <input type="radio"/> Unknown	Email Address:	<input type="text" value="bob.hope@hotmail.com"/>
		Parent/Guardian Name (if applicable)	
		First Name:	-- <input type="checkbox"/>
		Surname:	<input type="text"/>

Provider Details

Immunisation Provider Details

Standard AEFI ID: Z2104-000074

Submitted: 19/04/2021 2:51 PM by Adele Harris

Status: Submitted

Last modified: 22/04/2021 4:00 PM by Adele Harris

Reporter Vaccinee **Provider** Vaccines Treatment Submission Office Use Attachments

Immunisation Provider Details

Same as Reporter Details

Unknown

Provider Setting:

Vaccine Hub

Other:

First Name: Mrs Adele

Vaccination Venue: RCH

Surname: Harris

Organisation: SAEFVIC

Provider Type: Nurse

Address: MCRI -Flemington Rd

Other:

Suburb: Parkville

Email Address: a.harris@mcri.edu.au

State: VIC

Postcode: 3052

Phone: Landline (03) 9345 4143

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Vaccinee Details

Vaccines Administered

Standard AEFI ID: Z2104-000074
Status: Submitted

Submitted: 19/04/2021 2:51 PM by Adele Harris
Last modified: 22/04/2021 4:00 PM by Adele Harris

Reporter Vaccinee Provider Vaccines Treatment Submission Office Use Attachments

Vaccines Administered Related to AEFI

Vaccination Date: Unknown Antenatal Vaccination
Weeks of Gestation:
Vaccination Time: : :
hour min AM/PM Unknown

Vaccine *	Dose No *	Batch No (if known)	Injection Site
<input type="text" value="COVID Pfizer"/>	<input type="text" value="2"/>	<input type="text" value="3333edg"/>	<input type="text" value="Left Deltoid"/>
<input type="text" value="-- select --"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="-- select --"/>
<input type="text" value="-- select --"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="-- select --"/>
<input type="text" value="-- select --"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="-- select --"/>
<input type="text" value="-- select --"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="-- select --"/>
<input type="text" value="-- select --"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="-- select --"/>

Description of the vaccines (if uncertain or not listed above):

Reaction & Treatment Details

Reaction and Treatment

Standard AEFI ID: Z2104-000074

Status: Submitted

Submitted: 19/04/2021 2:51 PM by Adele Harris

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Reporter Vaccinee Provider Vaccines Treatment Submission Office Use Attachments

Reaction

Time elapsed between the administration of the vaccine and onset of the symptoms: 3 mins 0 hours 0 days 0 weeks Unknown N/A (Drug/program error)

Detailed description of the event including time of AEFI onset as applicable: *

Complained of feeling dizzy then urticarial rash appeared at injection site spreading to arms and torso with associated cough and wheeze. BP 90/40.

Treatment (tick one or more boxes)

Treatment: Known Unknown Paramedic attendance Hospital emergency at: MMC Hospital admission at: # Days: Unknown Other:

None or symptomatic (e.g. paracetamol) only Helpline Nurse assessment GP assessment

Details:

Adrenaline administered and ambulance called. transported to MMC

Outcome

How long did the symptoms last? 0 mins 2 hours 0 days 0 weeks Known Unknown but Ongoing Unknown but Resolved

Detailed description and timing of outcome: * Unknown

Consent

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Submission

Standard AEFI ID: Z2104-000074

Submitted: 19/04/2021 2:51 PM by Adele Harris

Status: Submitted

Last modified: 22/04/2021 4:00 PM by Adele Harris

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Consent

I, the reporter, have obtained the following consent from the vaccinee, parent or guardian to **report** this AEFI and for their local public health unit or specialist immunisation clinic to **contact** them.

Date:



- Full consent was obtained
- Consent to report but **NOT** to contact was obtained
- Consent is **not required*/impracticable**

*only in those jurisdictions where reporting is mandatory

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Clinical services available

- Doctors and nurses reporting significant AEFI may receive advice where required by phone, email or letter to help clinically manage the future care and immunisation needs of these patients
- Specialised immunisation clinics (including allergy services) are available for further discussion including supervised vaccinations if required.
- Specialist paediatric immunisation services are located at RCH, Monash Medical Centre and Sunshine Hospital. Adult immunisation clinics (for non COVID-19 vaccine referrals) are located at Monash Medical Centre & Alfred health.
- Victorian Specialist Immunisation Services (VicSIS's) are available for Covid related AEFI.

<https://mvec.mcri.edu.au/wp-content/uploads/2021/03/VicSIS-referral-guide.pdf>

TAKE HOME MESSAGE

- STOP
 - THINK
 - CONSIDER
- COPY

Before you report to SAEFVIC

USEFUL RESOURCES : MVEC – TGA - DHHS

- <https://mvec.mcri.edu.au/covid-19>
- <https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-07-04-2021>
- <https://www.dhhs.vic.gov.au/coronavirus-covid-19-vaccine-data>
- <https://www.coronavirus.vic.gov.au/vaccine>