Vaccine update + safety update

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Coordination across the COVID-19 outbreak response is critical to ensure joined-up activity and clear messaging

The vaccination program is one part of an integrated response from the Department

Leadership & Coordination

Vaccination

Access & Delivery

Safety & Quality

Public Trust & Confidence

Prevention

Quarantine Program

Border Management

Infection Prevention and Control

Public health advice

COVID-safe major events

Containment

Outbreak control

Surveillance testing

esting network

Testing approaches

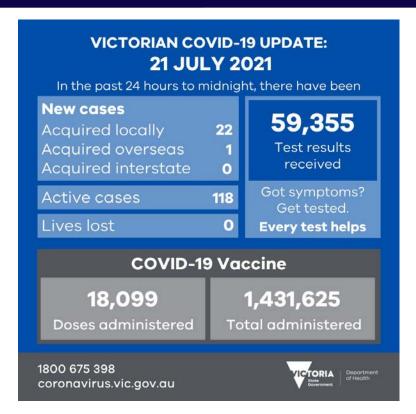
Enablers

People, Leadership & Governance (incl. workforce)
Community engagement and partnerships
Data & Intelligence
Systems and process improvement

Key points of integration and coordination across the Department's COVID-19 response include:

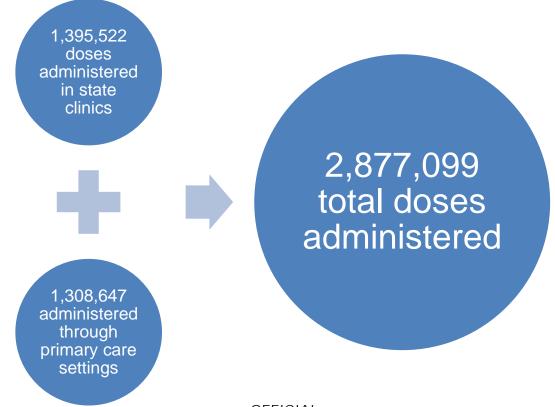
- Workforce: managing the trade-offs of workforce capacity at a system-wide level with multiple pressures on the system across vaccination, testing and health services
- Policy: ensuring a consistent approach to policy making, including coordination through the Premier, Ministers and Cabinet for decision making
- **Communications:** consistent and comprehensive messaging across government and health services to give clarity and certainty to the public
- Contact centre operations: managing the competing pressures on the contact centre with increased demand for vaccinations and broader COVID-19 information on guidelines and regulations

Outbreak update



- There are 118 active cases in Victoria 107 locally acquired and 11 overseas acquired cases.
- Over 19,000 primary close contacts have been identified
- State-wide restrictions extended to at least midnight on 27 July
- Exposure sites are published at: https://www.coronavirus.vic.gov.au/exposure-sites

COVID-19 Vaccine update



Who can access the vaccine?

Phase 1a groups

Phase 1b groups

All people aged 40+ years

Under 60 years

The Pfizer COVID-19 vaccine is preferred

The AstraZeneca COVID-19
vaccine is approved for people
under 60 years where the
benefits of protection
outweigh the risk of adverse
events

People under 60 years who received their first dose of AstraZeneca COVID-19 vaccine without serious adverse events should receive their second dose

All Aboriginal and Torres Strait Islander people aged 16 years and over NDIS
participants
aged 16 years
and over and
carers of NDIS
participants of
any age

60 years and over

People aged 60 years and over will be offered the AstraZeneca COVID-19 vaccine unless they have a specific medical condition identified

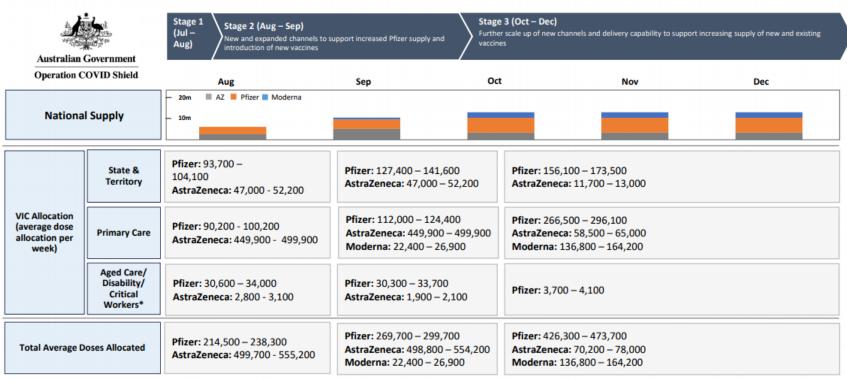
Prioritisation

Priority Pfizer bookings for people yet to receive their first dose of a COVID-19 vaccine for the following groups, regardless of age are still available:

- all health care workers (i.e. eligible under Phase 1A and 1B).
- all hotel quarantine and border workers
- household contacts (aged 16 years and over) of hotel quarantine workers and border workers
- · residential aged and residential disability care workers and residents.
- Eligible people are encouraged to call the Victorian Coronavirus Hotline on 1800 675 398 to book their appointment
- People who have already received a first dose of AstraZeneca should receive a second dose of AstraZeneca.



Allocations by December 2021



^{*}As defined by the Australian Technical Advisory Group on Immunisation.

Vaccine Safety

Objectives

- Describe the vaccine safety system in Victoria
- 2. Understand the incidence of adverse events and common issues to look out for
- 3. Understand current and emerging vaccine safety signals and what actions you should take
- 4. Understand how to work with the VicSIS network

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Vaccine safety services, Victoria

Comprehensive integrated vaccine safety clinical management and safety surveillance

Established national leading spontaneous AEFI surveillance system

Integrated vaccine safety surveillance and clinical support services



Clinical follow-up of reported AEFI

VicSIS adult specialist immunisation services established for COVID response



Multi-faceted data interrogation systems in place & under development

Includes background rates, & monitoring of healthcare datasets (ED, Aged care, GP)



Active (solicited) postvaccination SMS-based survey

SMS sent post vaccination (day 3, 8 & 42) asks if the person experienced an AEFI



Alert Advisory Group (AAG)

Systematic escalation pathway for serious AEFI, signal events or issues that may bring risk to the COVID vaccination program



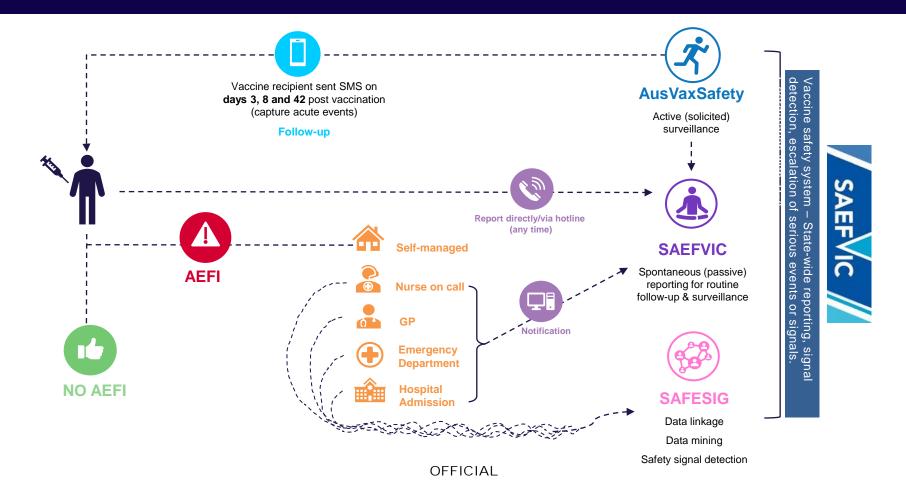
Spontaneous AEFI surveillance

Specialist Clinical Immunisation services Integrated safety signal detection

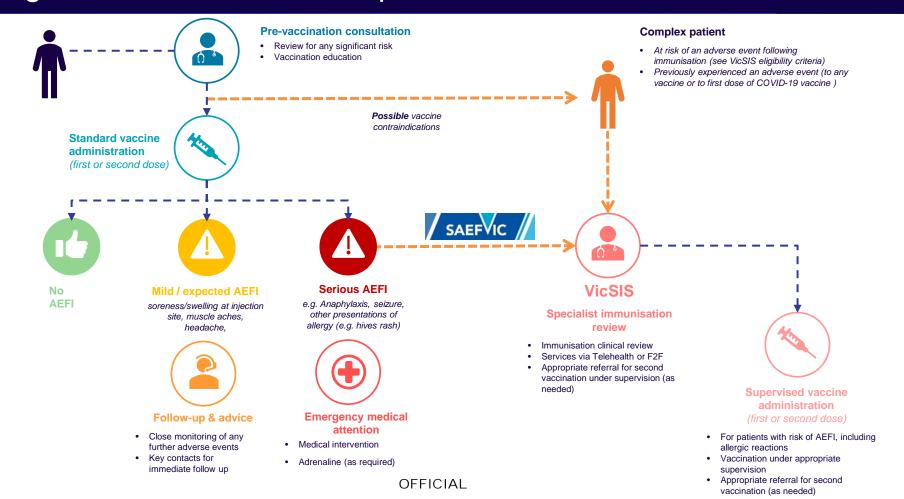
Post-vaccination active surveillance

Serious AEFI
Urgent escalation

Integrated AEFI reporting/surveillance & signal detection

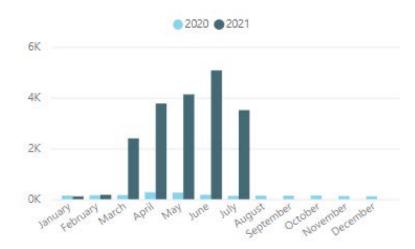


Integrated clinical care and specialist immunization services

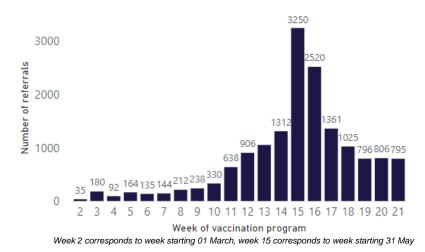


AEFI reporting & VicSIS referral volume

 High AEFI reporting and VicSIS referral volumes have required mitigation strategies



SAEFVIC "rapid" established for self-reporting of minor/common AEFI



VicSIS referrals are not accepted for vaccine brand preference

Reporting to SAEFVIC

Priority is always to manage the clinical needs

All medically attended AEFI should be reported so we can monitor the safety of the vaccines

• Medically attended = visit to general practitioner, emergency department, or hospital admission



SAEFVIC is Victoria's Vaccine Safety Service.

- Accepts AEFI reports from HCW & vaccinees
- Provides specialist care to patients following AEFI

Reporting serious and significant AEFI

- Report directly to SAEFVIC online
- Open to reports from GPs, nurses, and the public
- The vaccinee may receive follow up clinical advice
- saefvic.online/aefi_reporter

Reporting minor/common/expected AEFI

- Patients can self-report using the SAEFVIC rapid report.
 These reports are not clinically reviewed, but feed into overall surveillance
- saefvic.online/report

Vaccine safety data

SAEFVIC is Victoria's Immunisation Safety Service

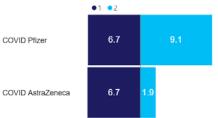
An AEFI is any untoward medical occurrence that happens following administration of a vaccine. It can be coincidentally associated with immunisation, without necessarily being caused by the vaccine

Total AEFI reported **17,784**

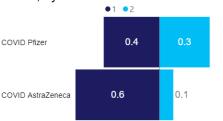
Rate per 1000 doses

% Medically attended AEFI **0.4%**

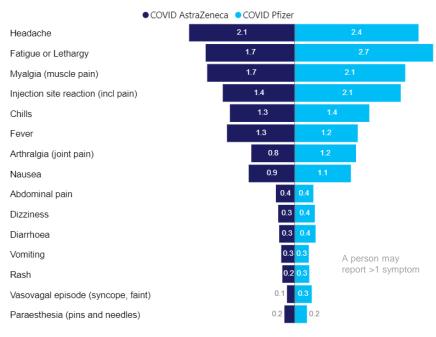
AEFI reports per 1000 doses, by vaccine brand and dose



Serious AEFI reports per 1000 doses, by vaccine brand and dose



Top 15 most frequently reported adverse events, per 1000 doses



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Key vaccine safety signals

Safety signals that are flagged nationally or internationally are monitored through SAEFVIC and TGA in Australia through a transparent reporting process.

Current safety signals being monitored include:

- ➤ Thrombosis with Thrombocytopenia (TTS)
- ➤ Idiopathic thrombocytopenic purpura (ITP)
- ➤ Guillain-Barre syndrome (GBS)
- Myocarditis and pericarditis
- ➤ Capillary leak syndrome

TTS update

In April 2021, COVID-19 vaccine AstraZeneca was found to be linked with a rare condition involving blood clotting and low platelet levels, called thrombosis with thrombocytopenia syndrome (TTS).

Pfizer (Comirnaty) is not currently associated with a risk of TTS.

Current policy advice based on ATAGI recommendations:

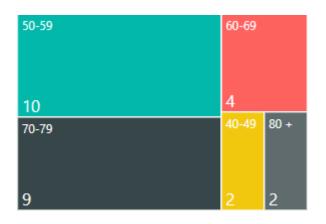
- People aged 60 and over are recommended to receive the AstraZeneca vaccine
- Pfizer is preferred for individuals under 60 years of age
- People aged 18-59 can choose to receive the AstraZeneca vaccine following a process of informed consent
 - o ATAGI statement on use of COVID-19 vaccines in an outbreak setting | Australian Government Department of Health
 - COVID-19 vaccination Weighing up the potential benefits against risk of harm from COVID-19 Vaccine AstraZeneca | Australian Government Department of Health
- People should receive second dose of same vaccine brand (mixed dosing not currently recommended)
- While no risk factors have been identified for TTS, Pfizer preferentially recommended for patients with previous history of CVST, HIT, idiopathic splanchnic vein thrombosis or antiphospholipid syndrome with thrombosis. Capillary leak syndrome recently added to this list

TTS update

TTS national update

- Total number of cases: 83 out of 5.4 million doses to date
- Rate in under 60s: 2.6 cases per 100,000 doses of AstraZeneca
- Rate in over 60s: 1.7 cases per 100,000 doses of AstraZeneca
- Majority of cases have occurred after first doses of AZ
- Two Tiers for classification based on CDC working case definition
 - Tier 1 = clots in unusual location and low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
 - Tier 2 = clots found in common locations and a low platelet count and anti-PF4 antibodies
- TGA COVID-19 Vaccine Safety Report | 15 July 2021
- CDC Presentation

Victoria TTS cases 30



The role of primary care in TTS

- People encouraged to seek immediate medical attention after vaccination if they develop:
 - o Severe or persistent headache or blurred vision
 - Shortness of breath, chest pain, leg swelling or persistent abdominal pain
 - Unusual skin bruising and/or pinpoint round spots beyond the site of vaccination
- Most common time period for onset of TTS symptoms is 4-42 days after vaccination
- Primary care guidance for identification and initial management for suspected TTS cases was recently released:
 - Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine

Refer to ED if:

- Acutely unwell e.g. acute neurological deficit, severe abdominal pain, severe bleeding or any other concerning symptoms or signs
- o Have thrombocytopenia (platelets < 150 x 10^9 /L) or D-Dimer ≥ 5 x upper limit of normal
- Blood tests cannot be performed and reviewed within 6 hours
- Repeat initial investigations in 24-48 hours in patients whose results are reassuring but who have persistent symptoms. This includes patients who have been discharged from ED with reassuring results.

Ref: https://www.health.gov.au/sites/default/files/documents/2021/07/covid-19-vaccination-primary-care-approach-to-thrombosis-with-thrombocytopenia-syndrome-after-covid-19-astrazeneca-vaccine.pdf

TTS Primary Care Guidance

Table 1: TTS symptoms and signs

Cerebral venous sinus thrombosis (CVST)	Unusual headache that starts or persists at least 48 hours after vaccination, and which is severe or does not improve following simple analgesia. Headache is a common adverse event immediately following COVID-19 Vaccine AstraZeneca, and usually subsides within 48 hours. Signs or symptoms of raised intracranial pressure (e.g. headache worse when supine or associated with nausea and vomiting) Neurological deficit (e.g. blurred vision, dysarthria, altered mental status or seizures)
Abdominal (splanchnic)	Variable presentation and can be asymptomatic. ²
circulation thrombosis	 Abdominal pain is the most common symptom, accompanying symptoms may include gastrointestinal bleeding, nausea, vomiting, anorexia, diarrhoea or constipation, or fever.
DVT	Lower limb pain, redness or swelling
PE	Sudden onset chest pain, shortness of breath
Arterial ischaemia	 Limb coldness or pallor, signs/symptoms of myocardial ischaemia or stroke
Thrombocytopenia	Petechiae, purpura, acute onset bleeding (e.g. nose, gums).

Table 2: Interpretation and recommendations based on investigation results for patients with symptoms and signs of suspected TTS

Findings	Interpretation	Management				
Platelets < 150 x 10 ⁹ /L D-dimer ≥ 5 x ULN	TTS is likely	Refer to ED for further investigation and urgent haematology advice Refer to ED for further investigation and urgent haematology advice Refer to ED for further investigation and urgent haematology advice				
Platelets > 150 x 10 ⁹ /L D-dimer ≥ 5 x ULN	TTS is possible					
Platelets < 150 x 10 ⁹ /L D-dimer raised but < 5 x ULN	TTS is possible					
Platelets > 150 x 10 ⁹ /L	TTS is unlikely	Consider other causes				
D-dimer raised but < 5 x ULN		Should repeat FBC and D-dimer if persistent symptoms*				
Platelets < 150 x 10 ⁹ /L	TTS is unlikely	Consider other causes including ITP				
D-dimer normal		Counsel patient to return if any new				
No evidence of thrombosis		symptoms				
		Consider repeating FBC and D-dimer if persistent symptoms*				

Safety Update – other safety signals

ITP

- The TGA is evaluating reports of suspected ITP following vaccination and will report further information when it is known.
- To 11 July 2021, the TGA has received 31 reports of suspected ITP.
- TGA concluded a fatal case of ITP in 61yo woman (WA) who had received AZ was likely related to immunisation.
- Vaccinees should be encouraged to seek medical attention if they experience signs and symptoms of ITP e.g. unusual skin bruising, unusual bleeding, petechiae.

GBS

- The TGA has been closely monitoring reports of GBS since the beginning of the COVID-19 vaccine rollout as <u>it has been associated with other types immunisations such as influenza vaccines</u>
- To 11 July 2021, the TGA has received 52 reports of suspected GBS in people who have received the AstraZeneca vaccine. A possible link between GBS and the AstraZeneca vaccine remains under investigation by the TGA and involves looking more closely at whether these suspected cases meet the clinical criteria for GBS.
- A causal link between GBS and AZ has not been confirmed in Australia or overseas
- People are encouraged to seek medical attention if they experience symptoms that could suggest GBS. This includes weakness and paralysis in the hands or feet that can progress to the chest and face over a few days or weeks.

Safety Update – other safety signals

Myocarditis and pericarditis

<u>US Advisory Committee on Immunisation Practices</u> (ACIP) have concluded that myocarditis and pericarditis are likely linked to vaccination, however that the benefits of vaccination outweigh the risks.

- TGA has received 50 cases of suspected myocarditis or pericarditis (to 11 July).
- Appears to affect predominantly males, 18-30 years old and be associated with mRNA vaccines
- Symptoms generally occur within 7 days post vaccination and more commonly after Pfizer Dose 2.
- Myocarditis and pericarditis are much more common with COVID-19 infection and the risks to the heart can be more severe in this context.
- TGA are working with Pfizer to add warning statement to Product Information
- People are encouraged to seek medical attention if they are experiencing symptoms which could be consistent with myocarditis or pericarditis e.g. chest pain, shortness of breath or palpitations.

Safety Update – other safety signals

Capillary leak syndrome

Capillary leak syndrome is an extremely rare but severe relapsing-remitting condition where fluid from small blood vessels (capillaries) leaks into surrounding tissues

On July 15, The <u>TGA weekly report</u> included additional information on capillary leak syndrome.

- Internationally 8 cases of capillary leak syndrome following vaccination with AstraZeneca have been reported with two of these cases having a prior history of capillary leak syndrome. It is not well understood what triggers a relapse.
- Australia has reported 1 probable case (WA) who sadly died (reported to TGA) of multi-organ failure with signs of capillary leakage. The Vaccine Safety Investigation Group (VSIG) was unable to establish a causal link as other causes could not be ruled out
- As a precautionary measure, the sponsor of the AstraZeneca vaccine has included a warning in the Product Information about capillary leak syndrome and specifically advised that the vaccine should not be used in people who have a history of this condition.

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

Vaccination in pregnancy

- ATAGI and RANCOG released a joint statement on 9 June 2021 recommending that pregnant women be vaccinated with Pfizer vaccine.
- This is due to:
 - Pregnant women being at higher risk of severe illness from COVID-19, and their babies have a higher risk of being born prematurely or being admitted to the Neonatal Intensive Care Unit
 - US study of over 35,000 pregnant women showing side effects were similar in pregnant women compared to non-pregnant women who received the Pfizer vaccine. This research is yet to be carried out for the COVID-19 Vaccine AstraZeneca
- Pregnant women should be routinely offered Pfizer at any stage of pregnancy
- Women who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination
- COVID-19 vaccination may provide indirect protection to babies by transferring antibodies through placenta or breastmilk
- Pregnant women currently not a priority group eligible for vaccination
- ATAGI advise that women who received their first dose of AstraZeneca and are pregnant can receive either dose two of AstraZeneca or Pfizer, although the latter is preferred.

Joint statement between RANZCOG and ATAGI about COVID-19 vaccination for pregnant women | 09 June 2021 COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy (health.gov.au)

Vaccine intervals

COVID-19 vaccines

Pfizer

- At least 21 days between doses
- Minimum accepted interval = 19 days
- Complete course within 6 weeks
- If second dose >6 weeks apart, no third dose required

AstraZeneca

- Non-outbreak setting
 - Minimum accepted interval = 4 weeks
 - Recommended interval is 12 weeks
 - If second dose > 12 weeks, no third dose or reporting required
 - If second dose < 4 weeks, must be reported to SAEFVIC as administration error
- Outbreak setting
 - Recent ATAGI update to AZ intervals in outbreak setting
 - interval of between 4 to 8 weeks is reasonable

COVID-19 and Influenza Vaccines

The Australian Technical Advisory Group on Immunisation has issued updated advice on the relative timing of administering influenza vaccines and COVID-19 vaccines in 2021.

The preferred minimum interval between a dose of influenza vaccine and a dose of either Pfizer/BioNTech (Comirnaty) vaccine or Oxford/AstraZeneca vaccine is now <u>7 days</u> (previously 14 days).

In some situations, such as an outbreak, a shorter interval (including co-administration) is acceptable.

Victorian COVID-19 Vaccination Guidelines

Victorian Specialist Immunisation Services (VicSIS)

Vaccine safety in Victoria is managed under a Department of Health (DH) contract by SAEFVIC, a vaccine safety team based at the Murdoch Children's Research Institute (MCRI), Parkville.

VicSIS was established to provide adult specialist immunisation services to support the COVID-19 vaccination program in Victoria.

VicSIS is made up of eight specialist immunisation clinics

Consultations occur via **telehealth** or **face to face** and are either:

- <u>Pre-vaccination:</u> persons at-risk of adverse events following immunisation (AEFI), for example a history of anaphylaxis, or those who fall into special risk groups.
- <u>Post-vaccination</u>: persons who have experienced an AEFI after a dose of a COVID-19 vaccine and require clinical review prior to second dose or ongoing follow-up

VicSIS also has **two allergy-specific services** which offer expert opinion, skin prick testing, challenges and supervised vaccination as required and are coordinated by expert Allergist and Immunologists.

3360 total consults have been completed across the eight VicSIS clinics with the **majority recommended for routine vaccination**.







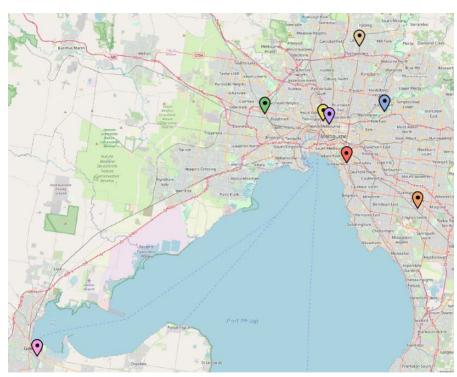
Victorian Specialist Immunisation Services (VicSIS) Clinics

VicSIS Clinics

There are 8 VicSIS clinics, with two dedicated allergy services and one regional site.

- Alfred Health
- Austin Health allergy services
- Monash Health allergy services
- Western Health
- 🕈 Barwon Health regional lead
- Northern Health
- Royal Melbourne Hospital
- Peter MacCallum Cancer Center
- (Royal Children's Hospital) established immunisation clinic with increased capacity for the future rollout of COVID-19 vaccination for children and adolescents

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Locations of current VicSIS clinics across metropolitan Melbourne and Geelong



Clinician Referral Guide to the Victorian Specialist Immunisation Services (VicSIS)

The purpose of this document is to provide clinicians and vaccine providers with additional information for when it is appropriate to refer patients into VicSIS vs when patients can receive their vaccines in clinic.

TORIA

7 July 2021

Does the patient meet the following criteria? Previous cerebral venous sinus thrombosis (CVST), heparin-induced thrombocytopaenia (HIT), idiopathic splanchnic (mesenteric, portal Referral to Victorian and splenic) venous thrombosis, anti-phospholipid syndrome with thrombosis or thrombosis with thrombocytopenia syndrome (TTS). Anaphylaxis or generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered Yes Specialist A history of PEG or polysorbate related reactions and/or a history of multiple allergic reactions to other medications containing PEG or Immunisation polysorbate. Services (VicSIS) Immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. hives) to a previous dose of a COVID-19 vaccine. No Does the patient meet the following If the patient meets the following criteria: Does the patient meet the Does the patient criteria? following criteria? History of allergy, including anaphylaxis to food, venom, or latex meet the following criteria? Significantly Allergic conditions including asthma, atopic dermatitis (eczema), or allergic rhinitis (hay - A mast cell activation immunocompromised (e.g. on Previous history disorder with raised chemotherapy, DMARDs, post History of venous thromboembolism in typical sites (DVT or pulmonary embolism) of anaphylaxis mast cell tryptase bone marrow transplant) Predisposition to form blood clots (e.g. Factor V Leiden) or other non-immune thrombophilic needing treatment and to other On anticoagulants with INR>3 disorders vaccines or has been unable to Previous multiple Family history of clots or clotting conditions multiple drugs tolerate previous sclerosis/Guillain-Barré Receiving anticoagulant medications injections (e.g. flu syndrome (GBS) History of ischaemic heart disease or cerebrovascular accident vaccine) Current or past history of thrombocytopenia* Or GP not comfortable to proceed Please see recent ATAGI and THANZ statement on TTS and the COVID-19 vaccine AstraZeneca Yes Yes Yes No No Yes Proceed to routine vaccination at GP clinic Referral to Proceed to vaccinate at GP or vaccine hub. VicSIS clinic or vaccine hub with 30-Refer to the MVEC resources and The *if platelets <20, reduce risk of haematoma at injection minute observation period. Australian Immunisation Handbook or site with pressure/cool compress usual treating specialist

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How to refer to VicSIS

Referral to VicSIS Clinics:

- Referral criteria can be found on the front of the VicSIS referral form (pictured).
- All referrals are to be made using the live version of the referral form available on the VicSIS page on the MVEC website
- Referrals must be made by a Medical Practitioner to the patient's closest geographical location
- Referrals should be made to only <u>one</u> VicSIS site
- VicSIS is experiencing a high volume of referrals at this time and there
 may be significant delays in triaging referrals of up to 4-6 weeks. Please
 communicate this to your patients to help manage expectations
- Referrals without clear rationale for a VicSIS referral and/or insufficient background medical history <u>will not</u> be triaged until more information is provided



Victorian Specialist Immunisation Services (VicSIS) Clinic Referral Form

Please note: VicSIS clinics strictly do not accept any requests for the Pfizer vaccine.

The key purpose of the Victorian Specialist Immunisation Services (VicSIS) is to oversee and provide comprehensive specialist review and advice for those identified as at-risk of adverse events following immunisation (AEFI)* or those who experienced an AEFI following a COVID-19 vaccine.

All COVID-19 vaccines approved in Australia are safe and most people should be able to be vaccinated without needing a referral to a specialist immunisation service, regardless of underlying comorbidities and this should be discussed with their treating GP and subspecialist as required.

Which patients are eligible for referral to a VicSIS clinic?

Patients who experience a significant AEFI following a dose of a COVID-19 vaccine should be referred to a VicSIS clinic for further assessment. A report of this AEFI should also be made to SAEFVIC via their online reporting form, which can be found here: https://www.safevac.org.au/hlome/info/VIC Individuals with a history of any of the following should be referred to VicSIS as they may be at higher risk of an

- Previous cerebral venous sinus thrombosis (CVST), heparin-induced thrombocytopaenia (HIT), idiopathic splanchnic (mesenteric, portal and splenic) venous thrombosis, anti-phospholipid syndrome with thrombosis or thrombosis with thrombosis or thrombosis or thrombosis with thrombosis.
- Immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. hives) to a
 previous dose of a COVID-19 vaccine.
- · Previous capillary leak syndrome
- Anaphylaxis or generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered (e.g. PEG (e.g. Movicol) in the Pfizer/BioNTech vaccine).
- A history of PEG or polysorbate related reactions and/or a history of multiple allergic reactions to other
 medications containing PEG or polysorbate. (Please check the ingredients of the patient's
 current/previously tolerated medications as they may contain PEG/polysorbate).
- A systemic mast cell activation condition with a raised tryptase who have been unable to tolerate previous inframuscular injections due to recurrent anaphylaxis. People with a systemic mast cell activation condition, with a raised tryptase that have tolerated previous intramuscular injections (i.e. influenza vaccine) without any adverse reactions, do not require a VicSIS referral - vaccination can be administered safely at a routine vaccination centre with a 30 minute observation period.

Patient with other types of allergy (i.e. to other vaccines or medications not containing PEG or polysorbate 80, food, latex or venom allergies) do not require a VicSIS referral - vaccination can be administered safely at a routine vaccination centre. More information on allergy can be found at the Melbourne Vaccine Education Centre (MVEC) COVID-19, vaccine EAQs.

Please refer to the 'Clinician referral guide to the Victorian Specialist Immunisation Services (VicSIS)' and 'COVID-19 vaccine brand guidance' which can be found at: https://mysc.mcri.edu.eu/references/the-vicsis-victorian-specialist-immunisation-services-network/

How to refer to a specialist immunisation service

- All referrals to VicSIS must be sent via email <u>using the referral form attached</u> with all fields completed.
 All referrals must be made by a Medical Practitioner.
- All referrals from regional Victoria should be sent to the regional VicSIS clinic in Geelong (Barwon Health), who will conduct telehealth appointments and refer on for in person appointments as required. Metropolitan Melbourne referrals should be made to the client's closest geographical location or VicSIS site where they receive their regular medical care.
- Referrals should be made to only one VicSIS site. Referrals without clear rationale for a VicSIS referral
 and/or insufficient background medical history will not be triaged until more information is provided.

'An Adverse Event Following Immunisation (AEFI) is any untoward medical occurrence that occurs following administration of a vaccine. An AEFI can be coincidentally associated with the timing of immunisation without necessarily being caused by the vaccine or immunisation process.



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Referrals to VicSIS

- Priority is given to those who have experienced an adverse event following immunisation (AEFI), and a report to SAEFVIC should be made as usual.
- Submitting referrals to VicSIS for patients that do not meet the criteria may delay patients who are able to be vaccinated safely in the community from doing so. It also causes delays for other patients who require VicSIS support
- VicSIS does **not** accept referrals for COVID-19 vaccine brand preference

Vic	SIS Clinic Refer	ral Form		Date of Referral: DD / MM / YYYY						
Pati	ient Details									
Name:				Date of Birth: DD / MM / YYYY						
Address:				Email:						
Medicare: Ref:				Phone Number:						
		ll only be accepted from medical pro no-reply email addresses ar with in								
Practitioner Name:				Phone:						
Practice Address:				Practice email:						
Practitioner signature:				Provider Number:						
Rea.	son for referral (please	tick one): Please refer to Clinicia	n Referral	Guide to Vi	SIS to ensure	referral meets criteria				
	Pre-vaccination:									
	☐ Previous HIT, CVST, idiopathic splanchnic venous thrombosis or anti-phospholipid syndrome with thrombosis, thrombosis with thrombocytopenia (TTS) and capillary leak syndrome									
Previous adverse event following immunisation (AEFI)				Systemic mast cell disorder with raised tryptase and inability to tolerate IM injections						
	Other (please indicate):									
Post-vaccination: SAEFVIC report made?				□ No □ Yes, ref. no						
	Dose 1 AstraZeneca		☐ Pfi	Pfizer Vaccination date: DD / MI		n date: DD / MM / YYYY				
Dose 2 AstraZeneca		☐ Pfi	Pfizer Vaccination date: DD / MM / Y		n date: DD / MM / YYYY					
	se provide further details stigations, specialist corn	including medical history (mai espondence: Please note refe				nary/medications, relevant will not be accepted.				
Whi	ch VicSIS clinic is this refe	rral for (please refer to <u>ONE</u> cli	nic only)							
☐ Alfred Health		☐ Austin Health*	☐ Barwon Health		h	☐ Monash Health*				
Northern Health		Peter MacCallum Cancer Centre		Royal Melbourne		☐ Sunshine Hospital				
Is an interpretor required? No. No. No.				Is national aurage of soforcal?						





Useful Resources

AIR Reporting: Australian Immunisation Register for health professionals - Services Australia (please remember to upload all vaccinations to the AIR)

Reporting AEFI to SAEFVIC:

- SAEFVIC extended report: saefvic.online/aefi_reporter
- SAEFVIC rapid report: <u>saefvic.online/report</u>

MVEC FAQs: https://mvec.mcri.edu.au/references/covid-19-vaccines-faq/

Commonwealth resource: Weighing up the potential benefits against risk of harm from COVID-19 vaccine AstraZeneca: https://www.health.gov.au/resources/publications/covid-19-vaccine-astrazeneca

Current ATAGI vaccination guidelines: https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021

Current Approach to TTS post AZ: https://www.health.gov.au/sites/default/files/documents/2021/07/covid-19-vaccination-primary-care-approach-to-thrombosis-with-thrombocytopenia-syndrome-after-covid-19-astrazeneca-vaccine.pdf

Information for COVID-19 Vaccination Providers: https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/information-for-covid-19-vaccination-providers

Information for COVID-19 Vaccine in an outbreak setting https://www.health.gov.au/news/atagi-statement-on-use-of-covid-19-vaccines-in-an-outbreak-setting

Decision making guide for women who are pregnant, breastfeeding or planning pregnancy: https://www.health.gov.au/resources/publications/covid-19-vaccination-shared-decision-making-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy

VicSIS referral form, Clinicians guide to referral to VicSIS and the COVID-19 vaccine Brand Guidance for Clinicians: https://mvec.mcri.edu.au/references/the-vicsis-victorian-specialist-immunisation-services-network/
OFFICIAL

Thank you for participating tonight

Department of Health and RACGP's next webinar Wednesday 18 August, 6pm- 7pm
Topic – Syphilis increase during COVID-19

