Managing vaccine side effects in primary care

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Overview

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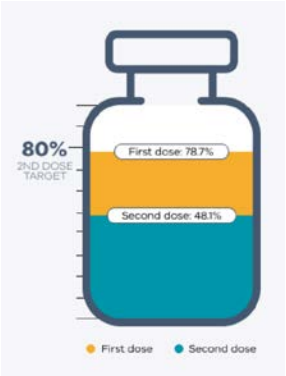
  - AstraZeneca dose 2 safety

COVID-19 Vaccination Program Updates

Vaccination progress

79.5%
First dose

48.8%
Second dose



Commonwealth primary care

3,469,394
Doses administered

- **Moderna and building confidence**
- **When will mRNA availability go live for those >60yrs?**
- **Mixed dosing**
- **Booster update – ATAGI statement**
  - 23 Sept 2021: ATAGI statement about the need for additional doses of COVID-19 vaccines | Australian Government Department of Health

Vaccination Post Infection

In an outbreak setting, people should be vaccinated as soon as possible following resolution of their acute illness and clearance from isolation.

COVID-19 infection prior to commencing vaccination course:

- **No** recommended **minimum interval** between infection and vaccination as long as acute illness resolved
- COVID-19 infection is not a contraindication to any COVID-19 vaccines
- Long COVID is not a contraindication to any COVID-19 vaccines
- **Do not delay** COVID-19 vaccination more than 6 months, as this is when natural immunity wanes.

Vaccination Post Infection

COVID-19 infection between dose 1 and dose 2 of vaccination course:

- Minimal interval for each vaccine needs to be observed **between the first and second dose** (3 weeks Pfizer, 4 weeks Moderna/AZ)
- If at a workplace that mandates vaccines, it is possible to wait for up to a period of 6 months from infection (positive PCR result) before commencing or completing your vaccine course, noting that it **can** be commenced/completed earlier, if they have recovered.

When to delay vaccination after having COVID-19:

1. People with multisystem inflammatory syndrome should delay vaccination until 3 months after symptoms have resolved.
2. People who have received monoclonal antibody therapies or convalescent plasma should delay vaccination until at least 90 days after these have been administered

AIR Medical Exemptions

AIR medical exemption form has been updated to include the 3 COVID-19 vaccines:

https://www.servicesaustralia.gov.au/organisations/health-professionals/forms/im011

COVID-19 disease will be considered an ‘acute major medical condition’ for a temporary exemption (max 6-months).

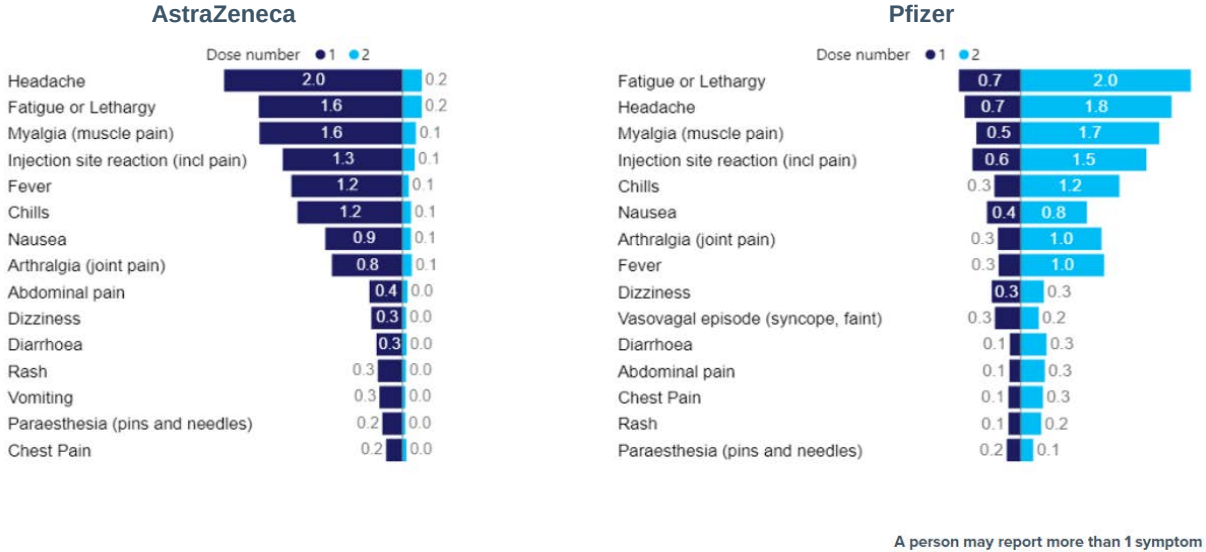
- General practitioners are included in the list of practitioners who can complete an exemption form.

Vaccines side effects

Common side effects

- Pain or swelling at injection site
- Headache
- Arthralgia/myalgia
- Fatigue, chills
- Fever
- Lymphadenopathy

Most frequently reported individual symptoms to SAEFVIC per 1,000 doses administered, by vaccine brand and dose, as of 19 September 2021



Source: Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) & Victorian Department of Health. Safety data for COVID-19 vaccines in Victoria. Melbourne: Melbourne Vaccine Education Centre; 23 September 2021. [https://saefvic.online/vaccinesafety]

Reporting Adverse Events Following Immunisation (AEFI)

Report all **significant** adverse events via

Surveillance of Adverse Events Following Vaccination In the Community (SAEFVIC)

- Includes **video instruction** on how to report an AEFI. Can be done by **provider or patient/parent**.
- **Significant AEFI** should be reported through a SAEFVIC Full Report.
- Patients/parents can also report minor, common and expected AEFI to SAEFVIC through a SAEFVIC Rapid Report (no registration required).
- Persons experiencing significant AEFI may be referred to VicSIS for follow-up of the adverse event and for discussion regarding future vaccinations. Direct **VicSIS referral** can only be **done by a clinician**.

SAEFVIC Rapid Report (no registration required)

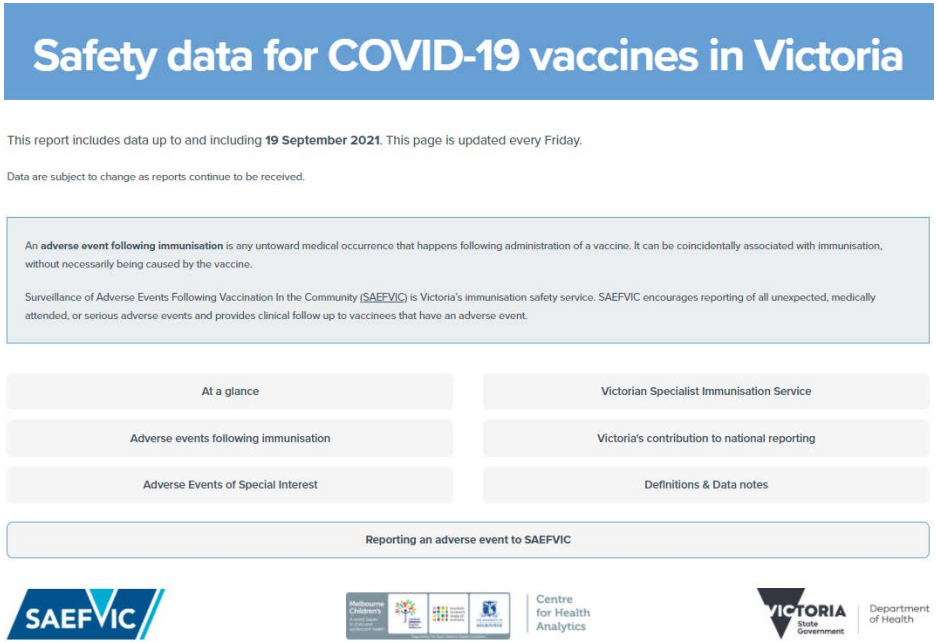
SAEFVIC Full Report (significant AEFI)

Victorian COVID-19 Vaccine Safety Data

Sources of information:

- Safety data for COVID-19 vaccines in Victoria, published each Friday: Safety data for COVID-19 vaccines in Victoria - SAEFVIC

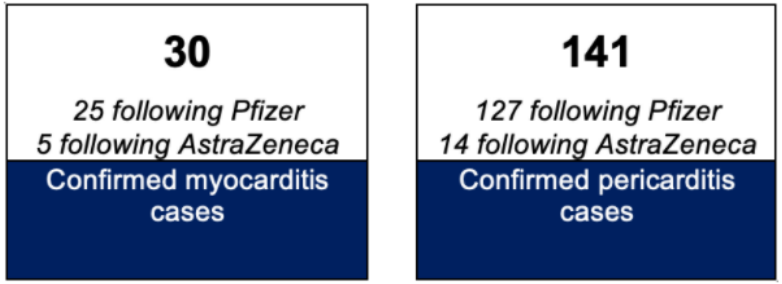
- COVID-19 vaccine weekly safety report (National): COVID-19 vaccine safety monitoring and reporting | Therapeutic Goods Administration (TGA)



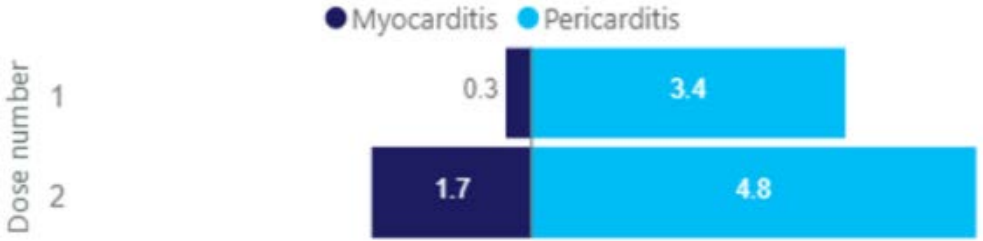
Myocarditis and pericarditis associated with COVID-19 mRNA Vaccination

- Vaccine safety signal associated with COVID-19 mRNA vaccines (Pfizer and Moderna).
  - **Event of special interest – NOT a normal side effect**
- Guidelines for primary care settings:
  - Healthpathways: Myocarditis and Pericarditis after mRNA COVID -19 Vaccines
  - ATAGI: Guidance on Myocarditis and Pericarditis after mRNA COVID -19 Vaccines

Number of myocarditis and pericarditis cases as of 19 September 2021



Rate of myocarditis and pericarditis cases per 100,000 Pfizer doses administered, by dose number, as of 19 September 2021



Source: Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) & Victorian Department of Health. Safety data for COVID-19 vaccines in Victoria. Melbourne: Melbourne Vaccine Education Centre; 23 September 2021. [https://saefvic.online/vaccinesafety]

Primary Care Assessment – Myo/pericarditis post mRNA vaccine

- **History**
  - Chest pain, pressure or discomfort (worse lying down, deep inspiration, relieved on sitting forward)
  - Palpitations
  - Syncope or dizziness
  - Shortness of breath
  - Pain on breathing
  - Recent mRNA vaccine (within 14 days)
    - Most commonly presents day 1-5 post dose

Signs of cardiac tamponade
Tachycardia, tachypnoea, hypotension, JVP distention, hepatomegaly

- **Examination**
  - Vital signs (tachycardia in myocarditis)
  - Pericardial friction rub
  - Pulsus paradoxus
  - Muffled heart sounds
- **Investigations**
  - ECG
  - Troponin, CRP, ESR
  - CXR (avoid in adolescents)
  - COVID-19 test (if patient is febrile)
- **Review within 24hrs**

Ref: Health pathways: Myocarditis and Pericarditis after mRNA COVID-19 vaccines
PREDICT: Guidance for workup of children and adolescents with chest symptoms after mRNA vaccine (predict.org.au)

Primary Care Management – Myo/pericarditis post mRNA vaccine

Investigate in General Practice

- Healthy adult in younger age group
- Clinically well, with minor symptoms
- Normal ECG
- Early (next day) review available

Consult emergency or cardiologist

- Unclear ECG findings
- Significantly raised inflammatory markers but normal troponin

When to send to emergency

- Concerning ECG findings or changes
- Possible life-threatening cause of acute chest pain
- Other circumstances preclude managing in community
- Raised troponin level
- Pericardial effusion on CXR

Ref: Health pathways: Myocarditis and Pericarditis after mRNA COVID-19 vaccines

Primary Care Follow up – Myo/pericarditis post mRNA Vaccine

Normal investigations and ongoing minor symptoms

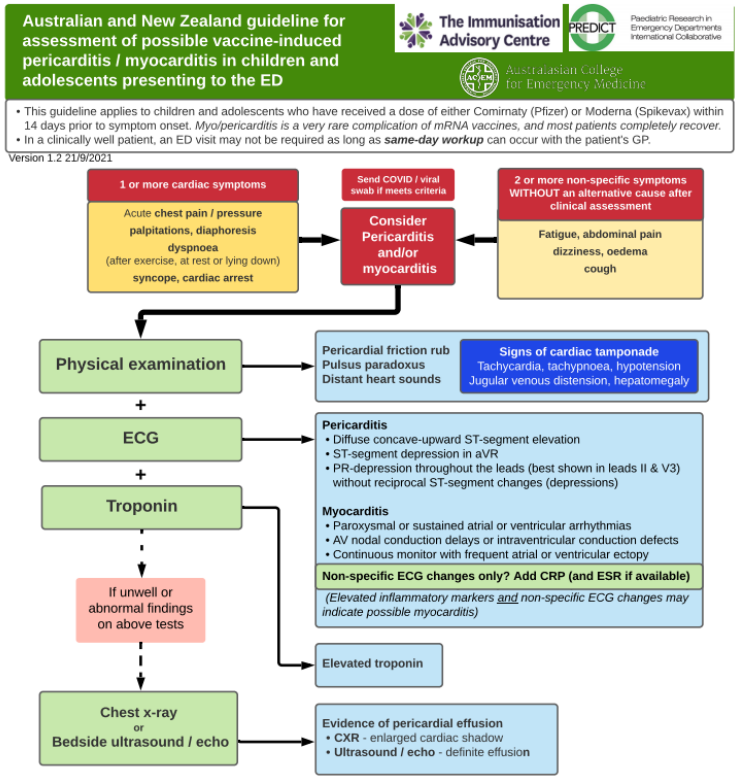
- Reassure
- Treat symptomatically
- Review while symptomatic
- If necessary, repeat ECG
- Advise return to normal activities when symptoms resolve
- *ATAGI advice:*
  - *If investigations (ECG and trop) are normal and clinical suspicion of myo/pericarditis is high, a cardiologist should be consulted.*

Confirmed myocarditis/pericarditis

- Monitor symptoms, and ECG changes
- Consult with cardiologist about return to activities
- Follow-up with Cardiology
  - May require echo +/- other cardiac investigations
- Avoid high intensity exercise until resolution of symptoms, normal ECG and normalisation of cardiac function
- Advise to defer any further mRNA COVID-19 vaccine and refer to VicSIS for further vaccination decisions

Ref: Health pathways: Myocarditis and Pericarditis after mRNA COVID-19 vaccines

PREDICT



(A) Discharge home with GP review:

(Avoid high-intensity exercise / competitive sports until symptoms have resolved)

- ***Normal findings*** (normal examination, normal investigations)
- ***Low-risk pericarditis*** (pain and pericarditis ECG changes, but normal vital signs, no definite effusion). If pericarditis, commence NSAIDS. Consider (case by case) cardiology review / outpatient echo

(B) Early follow-up with repeat assessment (ECG and troponin) in 24 hours

- ***Possible myocarditis*** (non-specific ECG changes, elevated CRP / ESR, normal troponin).

(C) Refer to paediatric cardiology from ED if:

- ***High-risk pericarditis*** (pain + pericarditis ECG changes AND fever OR abnormal vital signs OR definite effusion)
- ***Myocarditis*** (arrhythmia, conduction delays, abnormal vital signs or elevated troponin).

*** If any abnormal findings, report to local vaccine safety authority** (see page 2)

* If presentation relates to **first dose** of mRNA vaccine, ensure expert clinical advice is sought regarding future recommendations for COVID-19 vaccination (see page 2)

[Ref - PREDICT: Guidance for workup of children and adolescents with chest symptoms after mRNA vaccine (predict.org.au)]

Management of Myo/pericarditis following mRNA vaccine

Myocarditis
(raised troponin)

Severe pericarditis with complications
(pericardial effusion on CXR)

→ Should be managed in hospital

Simple pericarditis

→ Can be managed in community

COVID-19 mRNA Vaccine Resources

Pfizer and Moderna:

- Approved for use in those 12 years and older
  - ATAGI Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
  - Melbourne Vaccine Education Centre (MVEC) FAQs: myocarditis/pericarditis following mRNA vaccines - (mcri.edu.au)
  - MVEC animation: Myocarditis, pericarditis and COVID-19 vaccines - (mcri.edu.au)
  - COVID-19 vaccination – ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021 | Australian Government Department of Health
  - PREDICT: Guidance for workup of children and adolescents with chest symptoms after mRNA vaccine (predict.org.au)
  - Health pathways: Myocarditis and Pericarditis after mRNA COVID-19 vaccines
  - Victorian COVID-19 Vaccination Guidelines | Coronavirus Victoria

AstraZeneca Safety Overview

- Safety signals
- TTS – primary care approach
- AstraZeneca dose 2 safety

Safety Update – other safety signals

Immune (Idiopathic) thrombocytopenia

- ITP has been reported following AZ. To 12 September 2021, the TGA has received 71 reports of suspected ITP. Only one case has been causally linked.
- Vaccinees should be encouraged to seek medical attention if they experience signs and symptoms of ITP e.g. unusual skin bruising, unusual bleeding, petechiae.
- Those who develop ITP within 42 days of receiving AZ should consult with a haematologist for Dose 2 advice.

Guillain-Barre Syndrome (GBS)

- To 12 September 2021, the TGA has received 115 reports mentioning GBS occurring after vaccination with AstraZeneca.
- A clear link between GBS and AZ has not been established in Australia or overseas, however as precautionary measure a warning statement about GBS has been added to PI in response to rare cases post vaccination.
- 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.

Capillary Leak Syndrome

- Has been reported rarely after AZ. AZ contraindicated in those with past history of capillary leak syndrome.

Ref: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-16-09-2021
https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021

Primary Care Assessment - TTS post AstraZeneca Vaccine

Most common time period for onset of TTS symptoms is 4-42 days after vaccination

Possible presentations of TTS include;

- Cerebral venous sinus thrombosis (CVST)
- Thrombosis in the splanchnic (abdominal) circulation
- Pulmonary emboli (PE)
- Deep vein thrombosis (DVT)
- Arterial thrombosis

Primary care guidance for identification and initial management for suspected TTS cases released by ATAGI:

- In Australia, TTS has presented more commonly as DVT and PE than CVST or splanchnic thrombosis.
- Patients may less commonly present initially with signs/symptoms of thrombocytopenia

Table 1: TTS symptoms and signs

Cerebral venous sinus thrombosis (CVST)	• Headache is a common adverse event following COVID-19 Vaccine AstraZeneca, and usually subsides within 48 hours. • Headaches related to a CVST diagnosis have been described as starting any time following COVID-19 Vaccine AstraZeneca, and may initially respond to simple analgesia (e.g. paracetamol or ibuprofen). What makes them different to the common, expected headache is that they are persistent beyond 48 hours or appear later than 48 hours after vaccination, and they may progress to have some unusual features, such as: ○ 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) circulation thrombosis	• Variable presentation and can be asymptomatic.[2] • 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).

Ref- ATAGI - Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine https://melbourne.healthpathways.org.au/

Primary Care Management - TTS post AstraZeneca Vaccine

investigate in general practice

- **Patient is clinically stable with mild symptoms**
- **Urgent pathology results are available within 6hrs**
  - FBE and D-dimer is essential
  - Mark as urgent and call pathology service early to ensure priority
- **Individual circumstances are favourable:**
  - Can contact patient easily
  - Patient is not alone
  - Distance to emergency department if escalation required
  - Time of day

send to emergency

- **Acutely unwell**
  - Acute neurological deficit
  - Severe abdominal pain
  - Severe bleeding
  - Any other concerning signs or symptoms
- **D-dimer ≥ 5 x upper limit of normal**
- **Thrombocytopenia - platelet count <150 x10^9 /L**
- **Blood test cannot be performed & reviewed within 6hrs**
- **Differential diagnosis requiring further investigation and management that is not available in primary care.**

Ref- ATAGI - Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine https://melbourne.healthpathways.org.au/

Investigations and Referrals - TTS post AstraZeneca Vaccine

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

- 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
- If D-dimer is raised but < 5 times the upper limit of normal and unsure of cause or management, seek haematology advice, arrange regular clinical review and repeat FBE and D-Dimer within 24hours

Ref: ATAGI - Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine
https://melbourne.healthpathways.org.au/
Victorian Specialist Immunisation Services (VicSIS) - The Melbourne Vaccine Education Centre (MVEC) (mcri.edu.au)

Advice on AstraZeneca Dose 2

- People 18 years old and above who have received their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events attributable to the first dose and without any new contraindications should receive a second dose of COVID-19 Vaccine AstraZeneca.
- This is supported by data indicating a substantially lower rate of TTS following a second COVID-19 Vaccine AstraZeneca dose in the United Kingdom (UK) (1.9 cases per 1 million).

  If TTS is confirmed, refer to Victorian Specialist Immunisation Services (VicSiS) for subsequent mRNA vaccination.
- mRNA COVID-19 vaccines (Comirnaty or Spikevax) are also the recommended vaccines for pregnant women.
- Pregnant women who have already received a first dose of COVID-19 Vaccine AstraZeneca can receive either an mRNA COVID-19 vaccine or COVID-19 Vaccine AstraZeneca for their second dose, although an mRNA COVID-19 vaccine is preferred

Ref - COVID-19 vaccination – ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021 | Australian Government Department of Health
https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

Resources for Consumers and Providers

- THANZ - https://www.thanz.org.au/documents/item/590
- COVID-19 vaccine weekly safety report | Therapeutic Goods Administration (TGA)
- MJA - Approach to Diagnosis & Management TTS
- ACEM - TTS-Guidelines-R5-2.pdf
- Patient information sheet on AstraZeneca COVID-19 vaccine and thrombosis with thrombocytopenia syndrome (TTS) | Australian Government Department of Health
- Talking to patients about AstraZeneca vaccine | Australian Government Department of Health
- ATAGI - Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine

Thank you for participating tonight

Department of Health and RACGP's next webinar
Wednesday 20 October 6pm- 7pm

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For the latest information www.dhhs.vic.gov.au/coronavirus
Information is available in 50+ community languages at www.dhhs.vic.gov.au/translations