COVID-19 vaccination – summary for immunisation providers

13 January 2022

This guide is intended as a summary to assist immunisation providers with the latest information and key guidance relating to the COVID-19 vaccination program. Each section contains links to further detailed information. This guide is a living document and will be updated as new advice becomes available. Any new or updated advice will be listed in the latest advice box and dated.

Contents

Latest advice – as at 13 January 2022

National

Timing of COVID-19 booster vaccination and approval of Spikevax (Moderna) as a booster

- The Australian Technical Advisory Group on Immunisation (ATAGI) recommends COVID-19 booster vaccination for anyone aged 18 years and older who completed their primary course of COVID-19 vaccination 4 or more months ago. This interval has been shortened from 5 months.
- ATAGI also recommends that as soon as practical and when vaccination provider capacity permits, all eligible adults can receive COVID-19 booster vaccination from 3 months following completion of the primary course.
- Either Comirnaty (Pfizer) or Spikevax (Moderna) is recommended for use as a booster vaccine, and both vaccines are considered equally acceptable.
- Immunocompromised people who received a third primary dose are also recommended to have a booster dose ≥ months after their third dose. .

Related resources:

ATAGI statement on the Omicron variant and timing of COVID-19 booster vaccination – 24 December 2021

ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised

ATAGI – Provider guide to COVID-19 vaccination of people with immunocompromise

Myocarditis and pericarditis

The TGA reports that in Australia, the current overall estimated rates (for the entire population) of myocarditis are 1.5 cases per 100,000 doses for Comirnaty (Pfizer) and 2.2 cases per 100,000 doses for Spikevax (Moderna). However, statistical analysis shows that there is more uncertainty around the reporting rate for Spikevax (likely to be between 1.4 and 2.8 cases per 100,000 doses) than for Comirnaty (likely to be between 1.4 and 1.7 cases per 100,000 doses).

People with a history of most chronic cardiovascular conditions can receive the Pfizer or Moderna vaccine without any specific precautions. People with a history of a number of other cardiac conditions can receive the Pfizer or Moderna vaccine but should consult a GP or cardiologist about the best timing of vaccination and whether any additional precautions are recommended. Both these sets of conditions are detailed below:

People with the following conditions can receive Pfizer or Moderna vaccine **without any specific precautions**	People with the following conditions can receive Pfizer or Moderna vaccine but **should consult a GP or cardiologist**
• Prior myocarditis, pericarditis or endocarditis (i.e. >6 months before vaccination) • Coronary artery disease • Myocardial infarction • Stable heart failure • Arrhythmias • Prior history of rheumatic heart disease (RHD) • Kawasaki disease • Most congenital heart diseases • People with implantable cardiac devices • Cardiomyopathy • Congenital heart disease • Cardiac transplant recipients	• Recent (past 6 months) or current inflammatory cardiac illness, for example, myocarditis, pericarditis, endocarditis • Acute rheumatic fever or acute rheumatic heart disease • Acute decompensated heart failure

People who develop myocarditis or pericarditis after receiving their first dose of the Pfizer or Moderna vaccine should defer further doses of an mRNA COVID-19 vaccine and consult their treating doctor.

The TGA details Australian cases of myocarditis and pericarditis associated with mRNA vaccines in the COVID-19 weekly safety report.

Related resources:

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Guidance on myocarditis and pericarditis after mRNA COVID-19 vaccines

Thrombosis with thrombocytopenia syndrome (TTS)

In Australia, the risk of TTS is estimated to be (as at 9 December 2021)

- 2.5 per 100,000 in those aged <60 years
- 2.0 per 100,000 in those aged ≥60 years.

Related resource: **Weighing up the potential benefits against risk of harm from COVID-19 Vaccine AstraZeneca**

Total confirmed and probable TTS cases by age (1st and 2nd doses)

(as at 6 January 2022)

Age, years	Total cases
<30	8
30–39	5
40–49	11
50–59	36
60–69	45
70–79	46
80+	19
All ages	170

Related resource: **TGA COVID-19 vaccine safety weekly report**

Investigation protocols

The most common time period for onset of TTS symptoms is 4–30 days after vaccination.

Investigation protocol in general practice and non-emergency department settings

- Consider TTS in anyone presenting with possible thrombosis or thrombocytopenia, **4–42 days** after having the AstraZeneca vaccine. A full list of symptoms is available here.
- Refer suspected cases immediately to emergency if:
    - they are **acutely unwell** (e.g. neurological deficit, severe abdominal pain, severe bleeding, severe headache that has not responded to analgesia or any other concerning symptoms or sign)
    - have **thrombocytopenia** (platelets < 150 x 109/L) or **D-dimer ≥ 5** x upper limit of normal
    - blood tests cannot be performed and reviewed within 6 hours.
- Initial investigations are:

    - **Full blood count** – looking for thrombocytopenia (platelets < 150x109/L, noting that the platelet count can initially be normal or fall from a higher baseline
    - **D-dimer** – usually raised ≥5 X the upper limit of normal (ULN)
- Typical laboratory findings of TTS are thrombocytopenia (platelets < 150 x 109/L) and very high D-dimer (≥ 5 x ULN).
- Repeat these investigations in 24–48 hours in patients whose results are reassuring but who have persistent symptoms. This includes patients who have been discharged from the emergency department with reassuring results.

Related resource: Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine

Discussing options for AstraZeneca vaccine

The AstraZeneca vaccine is very effective in preventing severe disease and death due to COVID-19 in adults of all ages. A single dose of AstraZeneca vaccine partially reduces transmission by around half.

Three scenarios are detailed in a guide that shows the benefits of vaccination with AstraZeneca vaccine in preventing severe COVID-19 outweigh the potential risks in:

- older adults in the low exposure risk scenario
- all adults in the medium and high exposure risk scenarios.

All individuals aged ≥18 years in Greater Sydney, including adults aged <60 years, should strongly consider getting vaccinated with any available vaccine, including the AstraZeneca vaccine. This is because of the increasing risk of COVID-19 and ongoing constraints of the Pfizer vaccine supplies.

In the context of a COVID-19 outbreak where the supply of Pfizer vaccine is constrained, adults aged <60 years who do not have immediate access to the Pfizer vaccine should re-assess the benefits to them and their contacts from being vaccinated with the AstraZeneca vaccine, versus the rare risk of a serious side effect.

Related resources:

Weighing up the potential benefits against risk of harm from COVID-19 Vaccine AstraZeneca

ATAGI Statement, Response to NSW COVID-19 outbreak 24 July 2021

ATAGI statement on use of COVID-19 vaccines in an outbreak setting (13 July 2021)

Contraindications (updated 20 August 2021)

Contraindications to the AstraZeneca vaccine are:

- anaphylaxis after a previous dose of the same vaccine
- anaphylaxis to any component of the vaccine, including polysorbate 80
- history of capillary leak syndrome
- thrombosis with thrombocytopenia occurring after the first dose
- other serious adverse events attributed to the first dose that has been reported to a state adverse event reporting program and/or TGA and a determination made by a relevant specialist that a repeat dose would be associated with a risk of recurrence of the serious adverse event

Contraindications to the Pfizer vaccine or Moderna vaccine are:

- anaphylaxis after a previous dose of the same vaccine
- anaphylaxis to any component of the vaccine, including polyethylene glycol (PEG)
- myocarditis and/or pericarditis attributed to a previous dose of either of these vaccines
- other serious adverse events attributed to the first dose that has been reported to a state adverse event reporting program and/or TGA and a determination made by a relevant specialist that a repeat dose would be associated with a risk of recurrence of the serious adverse event.

Considerations for dose 2 following a medical contraindication

- If an individual has a medical contraindication following dose one of a COVID-19 vaccine, an alternative brand should be considered for the second dose.
- The recommended interval for administration of a second COVID-19 vaccine dose is 4–12 weeks after the first dose. A longer interval is acceptable if the second dose cannot be administered during this time window.

People should be made aware of the risks and benefits of receiving an alternative vaccine brand for dose two. These people should be aware that there are comparatively less data on the safety and efficacy of mixed vaccine schedules.

Related resources:

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Advice for people with a contraindication to a second dose of COVID-19 vaccine

Anaphylaxis after COVID-19 vaccines

- The observed rate of anaphylaxis after the Pfizer vaccine administration in the United States in early 2021 was 4.7 cases per million doses administered, and the rate of anaphylaxis after the Moderna vaccine administration in the same period was 2.5 cases per million doses.
- 89% of cases occurred within 30 minutes of vaccination.
- The Pfizer vaccine and the Moderna vaccine contain polyethylene glycol (PEG), and it is possible that this component is implicated in anaphylaxis. However, anaphylaxis following PEG is reported to be extremely rare (37 case reports between 1977 and 2016).

Anaphylaxis to polysorbate 80, which is an excipient in the AstraZeneca vaccine and is also included in many other vaccines, is rare. Anaphylaxis to the AstraZeneca vaccine is rare. The rate of reported anaphylaxis after the AstraZeneca vaccine in Australia appears similar to the overall rate for other vaccines.

Related resource: **ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021**

Other medical conditions

Immune thrombocytopenia, Guillain–Barré syndrome (GBS) and capillary leak syndrome have been reported after the AstraZeneca vaccine.

Immune thrombocytopenia (ITP)

- The first dose of the AstraZeneca vaccine has been found to be associated with a small risk of immune thrombocytopenia (ITP).
- People who develop ITP within 42 days of the AstraZeneca vaccine should consult a haematologist regarding whether to proceed with the second dose using the same or an alternate vaccine, and the timing of the second dose.

Guillain–Barré syndrome (GBS)

- GBS has been rarely reported after the AstraZeneca vaccine to the TGA in Australia and in other countries.
- It is not yet known whether the vaccine caused these cases of GBS (i.e. a causal association has not yet been found).
- The TGA and international regulators are investigating these reports.
- GBS was not reported in the clinical trials for the AstraZeneca vaccine.

COVID-19 vaccine safety surveillance

AusVaxSafety (as at 19 December 2021)

AusVaxSafety is conducting comprehensive active safety monitoring of all COVID-19 vaccines being used in Australia. The latest safety surveillance data report on adverse events following dose 1 and dose 2 of both Pfizer and AstraZeneca vaccines for all participants, including Aboriginal and Torres Strait Islander participants.

Almost 5 million participants have responded to surveys with 44% reporting an adverse event following COVID-19 vaccination. Most common adverse events included injection site pain, fatigue, headache and other expected events following immunisations.

Related resource: **AVS COVID-19 vaccine safety surveillance**

Therapeutic Goods Administration

The TGA is closely monitoring suspected adverse events following vaccination with both COVID-19 vaccines in use in Australia. The latest weekly safety report of the TGA provides detailed information about the reported side effects for COVID-19 vaccines, total adverse event reports, reporting rates per 1000 doses by jurisdiction, and most commonly reported vaccine side effects.

The most frequently reported suspected side effects continue to be events that were seen in the clinical trials and are commonly experienced with vaccines generally.

Related resource: **TGA COVID-19 vaccine safety weekly report**

Symptoms of COVID-19

- Fever
- Cough
- Sore throat
- Shortness of breath
- Fatigue
- Aches and pains
- Headaches
- New loss of taste or smell
- Runny nose

The ZOE COVID Symptom Study undertaken in the United Kingdom lists the following top 5 symptoms of COVID-19 of which the Delta strain is predominant:

- headache
- sore throat
- runny nose
- fever
- persistent cough

Related resources:

Identifying the symptoms

National COVID-19 Clinical Evidence Taskforce

ZOE COVID Symptom Study

Variants of concern

The World Health Organization (WHO) is tracking SARS-CoV-2 variants

Related resource: **WHO Variants of concern**

Vaccine information (updated 15 December 2021)

A summary table comparing the COVID-19 vaccines in Australia is available under COVID-19 vaccines: Frequently asked questions on the NCIRS website. In addition, the vaccines ingredients and efficacy are as follows:

	Vaxzevria (COVID-19 Vaccine AstraZeneca) Red cap	**Comirnaty (Pfizer) – 12 years and older Purple cap**	**Comirnaty (Pfizer) – 5-11 years and older Orange cap**	**Spikevax (Moderna) Red cap**
Ingredients (List of excipients)	• Histidine • Histidine hydrochloride monohydrate\ • Sodium chloride • Magnesium chloride hexahydrate • Disodium edetate (EDTA) • Sucrose • Ethanol absolute • Polysorbate 80 • Water for injection	• ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) • 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) • Distearoylphosphatidylcholine (DSPC) • Cholesterol • Potassium chloride • Monobasic potassium phosphate • Sodium chloride • Dibasic sodium phosphate dihydrate7ehydrate • Sucrose • Water for injections	• ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) • 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) • Distearoylphosphatidylcholine (DSPC) • Cholesterol • Trometamol • Trometamol hydrochloride • SucroseWater for injections	• Heptadecan-9-yl 8-[2-hydroxyethyl-(6-oxo-6-undecoxyhexyl)amino]octanoate • Cholesterol • Distearoylphosphatidylcholine • 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG) • Trometamol • Trometamol hydrochloride • Acetic acid • Sodium acetate trihydrate • Sucrose • Water for injection
Efficacy (after second dose)	62% to 73%	95%	91%	94%

Related resources:

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years

Vaccine advice for special populations

Special populations	**Can they be vaccinated?**
Pregnant, breastfeeding and planning pregnancy	Yes, preferred Pfizer or Moderna vaccine (for age)
Clotting issues	• No if TTS occurred after the first dose of the AstraZeneca vaccine • Yes with the Pfizer vaccine for people with a past history of cerebral venous sinus thrombosis (CVST), heparin induced thrombocytopenia (HIT), idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis or antiphospholipid syndrome with thrombosis.

	• Yes. People with a history of the following conditions can receive the AstraZeneca vaccine:
	  • deep vein thrombosis or DVT (a type of blood clot usually in the leg or arm)
	  • pulmonary embolism (a type of blood clot in the lungs)
	  • stroke
	  • heart attack
	  • a family history of blood clots
	  • current or past thrombocytopenia (low platelet count)
	  • those taking an anticoagulant medication
	
	These conditions do not increase the risk of TTS.

Immunocompromised	High risk of severe COVID-19 Either vaccine acceptable. Pfizer vaccine preferred for people aged <60 years. A third primary dose of COVID-19 vaccine in people with severe immunocompromise, to be given 2–6 months after their second dose. See ATAGI advice.
Past SARS-CoV-2 infection	Yes, there is no need to delay primary vaccination or booster vaccination if an individual has completely recovered from COVID-19. Read more in NCIRS COVID-19 vaccines: Frequently asked questions.
Individual under 60 years of age had dose 1 of AstraZeneca vaccine	Current recommendation is continue with AstraZeneca vaccine as dose 2 if no serious adverse event after dose 1

Related resources:

ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021 (Pages 10-11)

NCIRS COVID-19 vaccines: Frequently asked questions

Eligibility criteria

Eligibility for the Pfizer vaccine

- 12 years of age and older*

Eligibility for the paediatric Pfizer vaccine

- 5–11 years of age*

Eligibility for the Moderna vaccine

- 12 years of age and older*

Eligibility for the AstraZeneca vaccine

- 60 years of age and older

If you are aged 18–59 years, you can choose to receive the AstraZeneca vaccine:

- following an appropriate assessment of suitability by a qualified health professional and
- if you provide verbal or written consent.

***** Some states and territories will amend their eligibility based on their COVID-19 situation, vaccine supply and uptake. Please stay up to date with information from your local state or territory department of health.

Related resources:

ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years

Vaccine clinic finder

Answering patients' questions and concerns about COVID-19 vaccines

NCIRS COVID-19 vaccines: Frequently asked questions

NCIRS COVID-19 and children: Frequently asked questions

COVID-19 vaccines – Is it true?

VaxFACTS

Medical exemption

Discussion guide for providers

A discussion guide to support immunisation providers have discussions with patients seeking a medical exemption to a COVID-19 vaccine is available. This guide is informed by research in vaccine communication, de-escalation and clinical experience. It has conversational tips designed to help the patient consider their options and make a plan and, where necessary, manage any conflict. Access this guide here.

Case numbers and doses given

Case numbers

Number of COVID-19 cases by source of infection nationally and for each state and territory

Vaccines doses

Daily total vaccine doses (Commonwealth and state and territory jurisdictions)

Other resources

Vaccination reporting and specialist guidance

- **Specialist immunisation services**
- **Accessing the Australian Immunisation Register**
- **ASCIA Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination Position Statement**
- **ASCIA Allergy and COVID-19 Vaccination - Guide for health professionals**
- **ASCIA Immunodeficiency, Autoimmunity and COVID-19 Vaccination - Guide for health professionals**
- **COVID-19 vaccines and cancer: Health professional guidance**