COVID-19 vaccination – summary for immunisation providers

22 October 2021

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 22 October 2021

National

Additional doses of COVID-19 vaccines

- ATAGI recommends maximising first and second dose vaccine uptake across the community.
- ATAGI recommends a third primary dose of COVID-19 vaccine in people with severe immunocompromise, to be given 2–6 months after their second dose. An mRNA vaccine (Comirnaty or Spikevax) is preferred for the third dose, but Vaxzevria is also acceptable.
- ATAGI is monitoring and reviewing data from overseas which will be used to inform future strategies on additional doses.
- Additional booster doses for other populations may be required in the future but no recommendation has been made. Further information is expected at the end of October.

Current ATAGI clinical advice (as at 8 October 2021)

What's new

- ATAGI recommends a third primary dose of COVID-19 vaccine for people with severe immunocompromise, to be given 2–6 months after their second dose. An mRNA vaccine (Comirnaty or Spikevax) is preferred for the third dose, but Vaxzevria is also acceptable.

Key recommendations

- Vaccination for protection against COVID-19 is currently recommended for all people aged ≥12 years.
- The Pfizer vaccine is preferred over the AstraZeneca vaccine in people aged <60 years on the basis of the higher risk and observed severity of thrombosis and thrombocytopenia syndrome (TTS). The AstraZeneca vaccine can be used in adults aged <60 years if the person has made an informed decision based on an understanding of the risks and benefits. In outbreak settings, adults aged <60 years should strongly consider taking the AstraZeneca vaccine if they are unable to access the Pfizer vaccine.
- The Pfizer vaccine is provisionally registered by the TGA in people aged ≥12 years and is given in a two-dose schedule. Short-term efficacy against symptomatic COVID-19 is about 95% from 7 days after the second dose in people aged ≥12 years.
- The Moderna vaccine is provisionally registered in people aged ≥12 years and is given in a two-dose schedule. Short-term efficacy against symptomatic COVID-19 is approximately 94% from 2 weeks after the second dose in people aged ≥18 years, and similar in adolescents aged 12–17 years.
- COVID-19 vaccine is recommended for people who are immunocompromised because of their increased risk of severe illness with COVID-19. People with severe immunocompromise are recommended to receive a third dose of a COVID-19 vaccine, 2–6 months after their second dose. An mRNA COVID-19 vaccine (i.e. Comirnaty or Spikevax) is preferred for this third dose, but Vaxzevria is also acceptable in certain circumstances.
- Pregnant people aged 12 years and older are a priority group for vaccination and should be offered the Pfizer or Moderna vaccine at any stage of pregnancy.
- Past infection with SARS-CoV-2 is not a contraindication to vaccination; however, it is recommended that vaccination be deferred for up to 6 months after the acute illness in those who have had PCR-confirmed SARS-CoV-2 infection.
- The preferred minimum interval between receipt of a COVID-19 vaccine and any other vaccine, including influenza vaccine, is 7 days. A shorter interval (i.e. less than 7 days, including co-administration) is acceptable in some settings.
- The same COVID-19 vaccine for the two doses of the primary course should be used but there are special circumstances in which an alternate brand may be recommended for the second dose.

Related resources:

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

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

ATAGI recommendations on the use of COVID-19 vaccines in all young adolescents in Australia

COVID-19 vaccination – Clinical advice on the use of a different COVID-19 vaccine as the second dose

Risk of thrombosis with thrombocytopenia syndrome (TTS)

For every 100,000 AstraZeneca vaccinations (as at 30 June 2021)

Age, years	Potential harms
18–29	1.9 blood clots (TTS)*
30–39	1.6 blood clots (TTS)*
40–49	5.0 blood clots (TTS)*
50–59	2.7 blood clots (TTS)
60–69	1.4 blood clots (TTS)
70–79	1.8 blood clots (TTS)
80+	1.9 blood clots (TTS)

*estimates of risk are uncertain as rates are based on small numbers of vaccinations in people under 50 in Australia

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

Total confirmed and probable TTS cases by age and CDS classification

(as at 21 October 2021)

Age, years	Total cases
<30	8
30–39	5
40–49	10
50–59	36
60–69	37
70–79	41
80+	19
All ages	156 (79 men, 77 women)

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**

Risk of myocarditis and pericarditis (updated 19 August 2021)

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.

Related resources

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

Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines

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 17 October 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.

Over 4 million participants have responded to surveys with 43.6% 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 30 August 2021)

	Vaxzevria (COVID-19 Vaccine AstraZeneca)	**Comirnaty**	**Spikevax**
Sponsor	AstraZeneca Pty Ltd	Pfizer Australia Pty Ltd	Moderna Australia Pty Ltd
Approval age for use	≥18 years	≥12 years	≥18 years
Presentation	Multi-dose vial without preservative, each vial containing 10 doses in 5 mL	Multi-dose vial without preservative, each vial containing 6 doses in 0.45 mL	Multi-dose vial without preservative, each vial containing 10 doses in 5 mL
Volume/Strength	0.5 mL per dose	0.3 mL (30 µg) per dose	0.5 mL per dose
Schedule and dose interval	2 doses, 12 weeks apart (minimum 4 weeks apart). Shortened interval of 4 to 8 weeks is recommended during local outbreaks.	2 doses, at least 21 days apart	2 doses, 28 days apart
Administration route	Intramuscular injection into deltoid muscle	Intramuscular injection into deltoid muscle	Intramuscular injection, preferably into deltoid muscle

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 dihydrate8ehydrate • Sucrose • Water 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%	94%
Use of diluent	Not required	Required – dilute with sterile 0.9% NaCl without preservative	Not required
Number of doses per vial NB: Depending on the type of syringe and needle used, additional doses may be extracted.	8 doses in 4mL 10 doses in 5mL	6 doses in 0.45mL	10 doses in 5mL

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

Vaccine advice for special populations

Special populations	Can they be vaccinated?
Pregnant, breastfeeding and planning pregnancy	Yes, preferred Pfizer 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 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 and Moderna vaccines

You are eligible for the Pfizer and Moderna vaccine if you are:

- 12 years of age and older*

Eligibility for the AstraZeneca vaccine

You are eligible for the AstraZeneca vaccine if you are aged 60 years or 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: https://covid-vaccine.healthdirect.gov.au/eligibility?lang=en

Answering patients' questions and concerns about COVID-19 vaccines

NCIRS COVID-19 vaccines: Frequently asked questions

COVID-19 vaccines – Is it true?

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

- **NCIRS COVID-19 vaccines: Frequently asked questions**
- **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**