COVID-19 vaccination – summary for immunisation providers

25 July 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 25 July 2021

National

The Therapeutic Goods Administration has approved Comirnaty (the Pfizer vaccine) for use in people aged 12–15 years. The Australian Technical Advisory Group on Immunisation (ATAGI) is reviewing the evidence on the safety and efficacy of the Pfizer vaccine in this age group and is in the process of developing updated recommendations. These will be made available shortly.

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

ATAGI advice for outbreak settings

The Australian Technical Advisory Group on Immunisation (ATAGI) has issued the following guidance for an outbreak setting:

- The benefits of vaccination with COVID-19 Vaccine AstraZeneca (AstraZeneca vaccine) strongly outweigh the risks of adverse effects in those aged ≥60 years, and vaccination is essential for this group.
- Every effort should be made to support vaccination of people in priority groups (e.g. older people, healthcare workers, disability and aged care workers, and those with listed medical comorbidities).
- In the context of a COVID-19 outbreak where the supply of Comirnaty (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.
- In outbreak situations an interval of between 4 and 8 weeks is preferred for the AstraZeneca vaccine.
- All people who receive the AstraZeneca vaccine should be provided with information about common and rare but serious side effects, including the symptoms and signs of the thrombosis with thrombocytopenia syndrome (TTS). If anyone experiences these side effects, they should seek immediate medical attention.
- Any additional unallocated supplies of both the Pfizer vaccine and the AstraZeneca vaccine should be prioritised to populations and areas of greatest risk of COVID-19.
- Recommendations around the use of the Pfizer vaccine remain unchanged in outbreak settings.

Related resource: **ATAGI statement on use of COVID-19 vaccines in an outbreak setting**

New South Wales

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 addition, people in areas where outbreaks are occurring can receive the second dose of the AstraZeneca vaccine 4 to 8 weeks after the first dose, rather than the usual 12 weeks, to bring forward optimal protection.

Patients are advised:

- If you are 60 years and older and have not yet been vaccinated, please book a COVID-19 vaccination appointment immediately. You can now receive your second AstraZeneca vaccine dose 6–8 weeks after your first dose.
- If you have had your first dose of AstraZeneca vaccine but your second dose appointment is not within the next 4 weeks, ask your GP to bring your appointment forward. You can now receive your second AstraZeneca vaccine dose 6–8 weeks after your first dose.
- If you are aged 40–59 years, have not yet been vaccinated and are unable to obtain an appointment for the Pfizer vaccine, please discuss your circumstances with your GP. You may be able to get the AstraZeneca vaccine based on your risk and the likely benefits for you. NSW Health vaccination clinics are also able to provide the AstraZeneca vaccine to people older than 40 years.
- Anyone aged 18–39 years wishing to get the AstraZeneca vaccine is encouraged to talk to their GP.

Related resources: **ATAGI statement** **and** **NSW Health website**

Pregnant women

Pregnant women should be routinely offered the Pfizer vaccine at any stage of pregnancy and are now newly eligible as a priority group for this vaccine. Pregnant women with COVID-19 have an increased risk of severe illness and adverse pregnancy outcomes. The Pfizer vaccine is the preferred COVID-19 vaccine for women who are pregnant because of the amount of safety data available for this vaccine in pregnancy.

Women who received their first dose of the AstraZeneca vaccine and are pregnant can receive either the AstraZeneca vaccine or the Pfizer vaccine for their second dose, although Pfizer vaccine is preferred.

Related resource: **COVID-19 vaccine clinical considerations for pregnant women**

Current ATAGI clinical advice (as at 17 June 2021)

What's new

The Therapeutic Goods Administration has approved Comirnaty for use in people aged 12-15 years of age. ATAGI is reviewing the evidence on the safety and efficacy of Comirnaty in this age group and is in the process of developing updated recommendations. These will be made available shortly.

Comirnaty (Pfizer vaccine) is preferred over COVID-19 Vaccine AstraZeneca (AstraZeneca vaccine) for people aged <60 years and recommended in people with a past history of cerebral venous sinus thrombosis (CVST), heparin-induced thrombocytopenia (HIT), idiopathic splanchnic (mesenteric, portal, splenic) thrombosis or antiphospholipid syndrome with thrombosis.

Why has the advice changed

- The risk of TTS appears to be higher in those aged <60 years than in older adults. Refer to risk of TTS table by age below.
- Younger adults have a lower likelihood of having severe outcomes from COVID-19 than older adults.

Key recommendations

- The Pfizer vaccine is preferred over the AstraZeneca vaccine in people aged <60 years.
- The Pfizer vaccine should be routinely offered to pregnant women at any stage of pregnancy, and to women who are breastfeeding or planning pregnancy.
- Co-administration of COVID-19 vaccine with other vaccines is not routinely recommended. A minimum 7-day interval is advised between administration of a COVID-19 vaccine and any other vaccine, including influenza vaccine. This interval can be shortened (including same day administration) in special circumstances.

Notification of adverse events following immunisation should be made to the Therapeutic Goods Association (TGA) and through the specified reporting mechanisms for your state or territory. Details for reporting an AEFI are available on the TGA website for providers and patients.

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

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

Age, years	Total cases
<30	1
30–39	1
40–49	4
50–59	22
60–69	19
70–79	26
80+	12
All ages	87 (41 men, 46 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 which 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

The only absolute contraindications to a COVID-19 vaccine are:

- anaphylaxis after a previous dose of the same vaccine
- anaphylaxis to any component of the vaccine, including:
    - anaphylaxis to polyethylene glycol (PEG) for the Pfizer vaccine
    - anaphylaxis to polysorbate 80 for the AstraZeneca vaccine
- thrombosis with thrombocytopenia occurring after the first dose of the AstraZeneca vaccine
- other serious adverse events attributed to the first dose of a COVID-19 vaccine.

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.
- 89% of cases occurred within 30 minutes of vaccination.
- The Pfizer vaccine contains 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

Guillain-Barre Syndrome (GBS)

- GBS has been rarely reported after the AstraZeneca vaccine to the Therapeutic Goods Administration (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.

Myocarditis and pericarditis

- A causal link to the vaccine has not yet been established but international regulators are investigating this.
- The TGA continues to monitor reports of myocarditis and pericarditis following reports of a signal for a possible safety concern in the US and Israel in young men. Almost all cases were considered mild and resolved within a few days.

Other adverse events of special interest being reported on are capillary leak syndrome and immune thrombocytopenia (ITP).

Related resource: **TGA Weekly safety report (including number of cases/adverse events)**

COVID-19 vaccine safety surveillance

AusVaxSafety (as at 18 July 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.

More than 1.5 million participants have reported adverse events 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

	Comirnaty (generic name BNT162b2)	**COVID-19 Vaccine AstraZeneca**
Sponsor	Pfizer Australia Pty Ltd	AstraZeneca Pty Ltd
Approval age for use	≥12 years	≥18 years
Presentation	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	0.3 mL (30 µg) per dose	0.5 mL per dose
Schedule	2 doses, at least 21 days apart	2 doses, 12 weeks apart (minimum 4 weeks apart). Shortened interval of 4 to 8 weeks is recommended during local outbreaks.
Administration route	Intramuscular injection into deltoid muscle	Intramuscular injection into deltoid muscle
Ingredients (List of excipients)	• ((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 dihydrate • Sucrose • Water for injections	• Histidine • Histidine hydrochloride monohydrate\ • Sodium chloride • Magnesium chloride hexahydrate • Disodium edetate (EDTA) • Sucrose • Ethanol absolute • Polysorbate 80 • Water for injection

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
Past SARS-CoV-2 infection	Yes, vaccination be deferred for up to six months after the acute illness in those who have had PCR-confirmed SARS-CoV-2 infection
Under 60 years had dose 1 of AZ	Current recommendation is continue with AZ as dose 2 2 if no serious adverse events after dose 1

Related resources:

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

NCIRS COVID-19 vaccines: Frequently asked questions

Eligibility criteria

Newly eligible

- All adults aged 40-49 years
- All Aboriginal and Torres Strait Islander people aged 16 to 49 years
- NDIS participants aged 16 years and older, and unpaid and informal carers of NDIS participants of any age
- Pregnant women
- Temporary visa holders aged under 50 years who are currently in Australia and have been approved for return travel to Australia through the travel exemption process
- Adults aged 18-39 years can choose to receive the AstraZeneca vaccine.

Already eligible

- All adults aged 50 and older
- Quarantine and border workers and their household contacts
- Health care workers
- Aged care and disability care residents and staff
- People aged 16 and over with an underlying medical condition or significant disability
- Critical and high-risk workers aged 16 and over including defence, police, fire, emergency services and meat processing.
- Individuals with an Australian Border Force outwards travel exemption in an eligible category

Remaining cohorts

- All adults aged 16-39 years
- Children aged under 16 (pending TGA approval of COVID-19 vaccines in children aged under 16 years)

Related resource: **Eligibility for the COVID-19 vaccine**

Answering patients' questions and concerns about COVID-19 vaccines

NCIRS COVID-19 vaccines: Frequently asked questions

COVID-19 vaccines – Is it true?

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

- **Accessing the Australian Immunisation Register**
- **Specialist immunisation services**
- **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**