

17 September 2021 Coronavirus (COVID-19) health alert





Australian Government

Department of Health



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ATAGI update following weekly COVID-19 meeting – 15 September 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 15 September 2021.

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ATAGI met on Wednesday 15 September 2021 to review the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including <u>current COVID-19 outbreaks</u> involving the <u>Delta variant</u>, including in <u>New South Wales</u>, Australian Capital Territory and Victoria.

ATAGI stresses that vaccination is a key public health intervention to prevent infection, transmission and severe disease due to SARS-CoV-2. ATAGI recommends COVID-19 vaccination for all Australians from 12 years of age.

ATAGI notes the lower but increasing vaccine coverage in Aboriginal and Torres Strait Islander populations and is encouraged by strategies to address barriers to vaccination in this important population.

As at 13 September 2021, <u>over 23 million doses</u> of COVID-19 vaccines have been administered in Australia. ATAGI has noted emerging national data demonstrating that only a small proportion of patients with severe COVID-19 were reported to be vaccinated, consistent with a high vaccine effectiveness against severe disease.

ATAGI notes the TGA's registration of <u>Pfizer</u> and <u>Moderna</u> for use in children from 12 years of age. ATAGI has reviewed the evidence and now supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the Therapeutic Goods Administration (TGA) on current confirmed cases of TTS and those under investigation. The latest <u>TGA statement</u> on TTS cases, including clinical outcomes, can be found here.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 134 cases of confirmed or probable TTS (75 confirmed cases; 59 probable cases). To date around 10.8 million doses of AstraZeneca have been administered.

ATAGI notes that International data continues to demonstrate the risk of TTS following a second dose of AstraZeneca is much lower than the risk following a first dose (estimated internationally to be <u>1.9 per million</u> second doses). ATAGI reinforces the importance of completing a two-dose schedule to ensure maximal protection, with the strongest evidence for two doses of the same brand.

Rates of TTS cases are based on first doses of AstraZeneca as of 2 September 2021 (to account for the time to onset of TTS). To that date, approximately 10 million doses of AstraZeneca have been administered, made up of around 6.2 million first doses and 3.8 million second doses.

Although estimates of risk based on small numbers of cases are imprecise, the risk of TTS is estimated in Australia at around:

- 2.4 per 100,000 in those <60 years; and
- 1.8 per 100,000 in those ≥60 years.

A breakdown of current rates by decade of age for those aged \geq 50 years is included here:

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	1.8
50-59	2.8
60-69	1.6
70-79	2.0
≥802.0	1.9

ATAGI also noted that the TGA have been reporting a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the <u>CDC Criteria</u>. ATAGI noted these data suggest that the severity of TTS appears to be higher in younger women. These differences by sex are not seen in older people.

Outcomes have generally been better with early presentation and recognition of the symptoms and appropriate treatment as outlined in the <u>TTS primary care guide</u>. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/134, approximately 6%) is lower than that seen in other settings. ATAGI notes that the TGA is continuing to investigate 11 probable cases of TTS following second doses and that to date, only two of these cases have been definitively linked to vaccination.

Immune Thrombocytopenia

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation with AstraZeneca, including Immune Thrombocytopenia (ITP). It is important for those vaccinated to be aware of some of the symptoms that may be associated with ITP, such easy bruising and bleeding from the nose or gums.

Guillain-Barre Syndrome

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation with AstraZeneca, including Guillain-Barre Syndrome (GBS). It is important for those vaccinated to be aware of some of the symptoms that may be associated with GBS, such as muscle weakness, unusual sensation (numbness, pins and needles) and unsteadiness while walking. ATAGI notes this condition can occur in the absence of vaccination and that investigations into whether the reported events are causally linked to vaccination is ongoing.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with AstraZeneca in preventing severe COVID-19 strongly outweigh the risks of adverse effects in all Australians ≥60 years. In the context of a <u>COVID-19 outbreak</u> where the supply of Comirnaty (Pfizer) is constrained, ATAGI reinforces adults younger than 60 years old who do not have immediate access to Pfizer should re-assess the benefits to them and their contacts from being vaccinated with AstraZeneca, versus the rare risk of a serious side effect. In areas with significant outbreaks including <u>greater Sydney</u> and Melbourne, all individuals aged 18 years and above should strongly consider getting vaccinated with any available vaccine including AstraZeneca.

At this time, there is no update to the <u>ATAGI statement</u> from 17 June 2021 in relation to the use of AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

Comirnaty (Pfizer)

Myocarditis and/or Pericarditis

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation with Pfizer, including myocarditis and/or pericarditis. These conditions can occur in the absence of vaccination and are also a recognised complication of COVID-19.

ATAGI notes that the TGA is investigating 457 reports of suspected myocarditis and/or pericarditis following Pfizer. International data demonstrates that the rate of disease is higher in younger individuals, particularly young males and more frequently occurs following the second dose. Most reported cases have been mild, self-limiting and have recovered quickly, although further follow-up of these cases is ongoing. ATAGI noted that a small number of cases were more severe, requiring hospitalisation. More information can be found in the TGA

Weekly Report.

Risks and benefits

ATAGI reaffirms that the benefits of Pfizer outweigh the risks of myocarditis and/or pericarditis for any age group and strongly recommend eligible individuals without contraindications to be offered vaccination.

Resources

ATAGI recommends review of the following key resources:

Use of AstraZeneca and/or TTS

- the ATAGI/THANZ joint statement which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of AstraZeneca;
- the <u>TTS primary care guide</u>, which provides advice for providers on the consideration and management of suspected TTS cases, noting the importance of early presentation and recognition of TTS;
- the <u>risk-benefit document</u>, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca in different age cohorts and scenarios; and
- additional guidance on the use of COVID-19 vaccines in outbreak settings;
- response to NSW COVID-19 outbreak; and
- additional strategies to combat the risk posed by the <u>Delta variant</u> of concern.

Use of Pfizer and/or Myocarditis and/or Pericarditis

- ATAGI and Cardiac Society of Australia and New Zealand guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines;
- ATAGI <u>statement regarding vaccination of adolescents aged 12–15 years</u>; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

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