Australian Government
Department of Health and Aged Care

ATAGI COVID-19 weekly meeting updates

April 2021 to November 2022

This document contains meeting updates from the Australian Technical Advisory Group on Immunisation (ATAGI), produced during the COVID-19 pandemic period.

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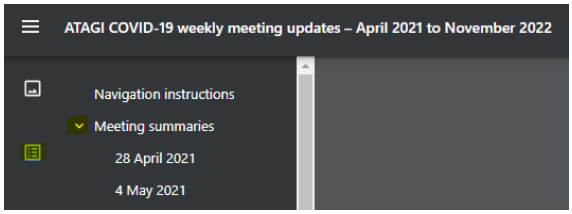

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ATAGI update following weekly COVID-19 meeting – 28 April 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 28 April 2021

Date published: 30 April 2021

Audience: General public

ATAGI met on 28 April 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia and overseas.

ATAGI considered additional information from the Therapeutic Goods Administration (TGA) including risk estimates from the European Medicines Agency and current confirmed cases and those under investigation in Australia. The latest TGA statement on TTS cases can be found here.

In addition, ATAGI also considered international case definitions for TTS from the UK and Brighton Collaboration in the US. Case definitions outline processes required in order to identify and confirm TTS cases, including imaging study, surgical or pathology findings.

The last three cases of TTS in Australia was confirmed based on a draft UK case definition.

At this time, there is no update to the ATAGI statement from 23 April 2021 in relation to the use of the AstraZeneca vaccine.

The following ATAGI / Department of Health documents have been updated or are in development:

- Provider and patient information sheets on TTS
- Consent form, Provider guide and FAQs, Information sheet on AstraZeneca and After your AstraZeneca vaccine
- Shared decision making guides
- Risk-benefit from AstraZeneca vaccine
- Clinical Guidance

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

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Australian Technical Advisory Group on Immunisation (ATAGI) weekly COVID-19 meeting on 4 May 2021 update

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 4 May 2021

Date published: 6 May 2021

Audience: General public

ATAGI met on 4 May 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia and overseas.

ATAGI considered the current status of TTS cases in Australia and internationally. Read the latest TGA COVID-19 vaccine weekly safety report.

At this time, there is no update to the ATAGI statement from 23 April 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

ATAGI continue to be regularly updated by the TGA on the TTS cases under investigation in Australia and is utilising both confirmed TTS case rates and international data to inform recommendations for AstraZeneca COVID-19 vaccine use.

Tags: Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

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ATAGI update following weekly COVID-19 meeting – 12 May 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 12 May 2021.

Date published: 13 May 2021

Audience: General public

ATAGI met on 12 May 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia and overseas.

ATAGI considered the current status of TTS cases in Australia including confirmed and probable cases. The latest TGA statement on TTS cases can be found here.

ATAGI, in collaboration with experts from the Thrombosis and Haemostasis Society of Australia and New Zealand, reviewed Australian coverage data and TTS rate analysis and considered the different patterns and spectrum of TTS cases in Australia. International data including the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and Joint Committee on Vaccination and Immunisation (JCVI) recommendation on the use of AstraZeneca COVID-19 vaccine for people aged under 40 was also considered.

At this time, there is no update to the ATAGI statement from 23 April 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

ATAGI continue to be regularly updated by the TGA on the TTS cases under investigation in Australia and will meet weekly to utilise both confirmed and probable TTS case rates and international data to inform recommendations for AstraZeneca COVID-19 vaccine use and will provide updated advice as/when further information becomes available.

ATAGI understands that of the cases of TTS confirmed by the TGA, all patients, with the exception of sadly one fatality, are recovering and are stable.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
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ATAGI update following weekly COVID-19 meeting – 19 May 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 19 May 2021.

Date published: 20 May 2021

Audience: General public

ATAGI met on Wednesday 19 May 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia and overseas.

ATAGI considered an update from the TGA on current confirmed cases and those under investigation. Read the latest TGA statement on TTS cases.

ATAGI considered updated estimates of risk of TTS by age group in Australia and note that 20 cases have been confirmed and a further 3 are considered probable in around 1.5 million doses of COVID-19 Vaccine AstraZeneca given up to 5 May 2021. Although estimates of risk based on small numbers of cases are imprecise, the risk of TTS is estimated in Australia at around:

- 2.8 per 100,000 in those <50 years; and
- 1.4 per 100,000 in those ≥50 years.

Of the cases of TTS reported after vaccination with the AstraZeneca COVID-19 Vaccine in Australia, one of these patients had a fatal outcome. All other patients are stable or recovering.

It is difficult to compare rates of TTS with those in other countries due to differences in case definition and assessment, but the rates reported in Australia are broadly similar to those reported in the UK and Europe. However, the cases seen in Australia have presented somewhat differently to those in the UK and Europe, which may reflect the high case ascertainment and early case detection in Australia.

Clinical awareness of TTS is high and suspected cases are rapidly investigated in Australia: this may explain why the majority of Australian cases have recovered or are expected to recover. Notwithstanding this, ATAGI also notes that additional data is needed to understand causal relationship for cases that are under investigation.

TTS can now be treated effectively. The Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ) have developed guidance on identification and treatment of TTS.

At this time, there is no update to the ATAGI statement from 23 April 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

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COVID-19 vaccines

Australian Government
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ATAGI update following weekly COVID-19 meeting – 26 May 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 26 May 2021.

Date published: 27 May 2021

Audience: General public

ATAGI met on Wednesday 26 May 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia and overseas.

ATAGI considered an update from the TGA on current confirmed cases and those under investigation. The latest TGA statement on TTS cases can be found here. Coverage data on COVID-19 vaccines administered up to 23 May 2021 was also considered.

ATAGI discussed the publication of the ATAGI/THANZ joint statement on TTS and the use of the COVID-19 Vaccine AstraZeneca. The statement provides updated information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the COVID-19 Vaccine AstraZeneca.

ATAGI considered updated estimates of risk of TTS by age group in Australia and note that there has been 27 confirmed cases and a further 6 are considered probable in around 1.9 million doses of COVID-19 Vaccine AstraZeneca given up to 12 May 2021.

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

- 2.6 per 100,000 in those <50 years; and
- 1.6 per 100,000 in those ≥50 years.

ATAGI notes that of the cases of TTS reported after vaccination with the AstraZeneca COVID-19 Vaccine in Australia, one of these patients had a fatal outcome, however all other patients are stable or recovering.

While some patients have required surgical procedures, many cases have presented with less severe clotting disorders that have not required prolonged hospital stay. This is likely to reflect heightened clinical awareness, as well as prompt diagnosis and effective treatment.

At this time, there is no update to the ATAGI statement from 23 April 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

Tags:

Immunisation

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Australian Government
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ATAGI update following weekly COVID-19 meeting – 2 June 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 2 June 2021.

Date published: 4 June 2021

Audience: General public

ATAGI met on Wednesday 2 June 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia and overseas.

ATAGI discussed the current Victorian outbreak, including updated case numbers. Vaccine coverage rates were also discussed and ATAGI noted the ongoing importance of increasing coverage and uptake across eligible groups, particularly people aged 70 years and over.

ATAGI considered an update from the TGA on current confirmed cases and those under investigation. Read the latest TGA statement on TTS cases, including clinical outcomes.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 31 confirmed cases reported and a further 10 are considered probable in around 2.2 million doses of COVID-19 Vaccine AstraZeneca given up to 19 May 2021.

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

- 3.1 per 100,000 in those <50 years; and
- 1.8 per 100,000 in those ≥50 years.

There were no significant differences in estimated risk by sex in those ≥50 years of age.

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

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	**3.1**
50-59	1.9
60-69	1.7
70-79	1.9
≥80	1.5

ATAGI discussed the case summary and clinical data of TTS cases. It was noted that TTS outcomes occur across a spectrum of severity from more mild cases, to cases with long term morbidity and can result in death, with one fatal case recorded to date in Australia.

ATAGI emphasised the ATAGI/THANZ joint statement on TTS and the use of the COVID-19 Vaccine AstraZeneca is an important resource. The statement provides updated information about TTS and reaffirms

ATAGI's previous advice regarding the safe use of the COVID-19 Vaccine AstraZeneca.

At this time, there is no update to the ATAGI statement from 23 April 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 9 June 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 9 June 2021.

Date published: 10 June 2021

Audience: General public

ATAGI met on Wednesday 9 June 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia and overseas.

ATAGI considered an update from the TGA on current confirmed cases and those under investigation. The latest TGA statement 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 35 confirmed cases reported and a further 13 are considered probable in around 2.5 million doses of COVID-19 Vaccine AstraZeneca given up to 25 May 2021.

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

- 3.1 per 100,000 in those <50 years
- 1.8 per 100,000 in those ≥50 years.

There were no significant differences in estimated risk by sex in those ≥50 years of age.

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

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	**3.1**
50–59	1.9
60–69	1.7
70–79	1.9
≥80	1.5

ATAGI discussed the case summary and clinical data of TTS cases. It was noted that TTS outcomes occur across a spectrum of severity from more mild cases, to cases with long term morbidity and can result in death, with two fatal cases recorded to date in Australia.

ATAGI also noted the TGA have reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the recently proposed CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a

positive test for antibodies that activate platelets (anti-PF4 antibodies)

- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the recently proposed CDC Criteria, ATAGI noted in the Australian context:

- 15 confirmed and probable TTS cases met the CDC Tier 1 definitions
- 33 confirmed and probable TTS cases met the CDC Tier 2 definitions.

The smaller number of more severe Tier 1 cases likely reflect heightened clinical awareness in Australia, early case ascertainment and prompt diagnosis and effective treatment in Australia.

ATAGI emphasised that the ATAGI/THANZ joint statement on TTS and the use of the COVID-19 Vaccine AstraZeneca is an important resource. The statement provides updated information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the COVID-19 Vaccine AstraZeneca.

At this time, there is no update to the ATAGI statement from 23 April 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
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ATAGI update following weekly COVID-19 meeting – 23 June 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 23 June 2021.

Date published: 25 June 2021

Audience: General public

ATAGI met on Wednesday 23 June 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia.

ATAGI considered an update from the Therapeutic Goods Administration (TGA) on current confirmed cases and those under investigation. The latest TGA statement 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 64 cases of confirmed or probable TTS (39 confirmed cases; 25 probable cases) in around 4.2 million doses of COVID-19 Vaccine AstraZeneca given up to 8 June 2021.

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

- 2.6 per 100,000 in those <60 years; and
- 1.6 per 100,000 in those ≥60 years.

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

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	**3.0**
50-59	2.4
60-69	1.3
70-79	1.7
≥80	1.9

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the recently proposed CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies);
- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the recently proposed CDC Criteria, ATAGI noted in the Australian context:

- 25 confirmed and probable TTS cases met the CDC Tier 1 definitions; and
- 17 confirmed and probable TTS cases met the CDC Tier 2 definitions.

ATAGI was encouraged by data demonstrating uptake of second doses of COVID-19 Vaccines, including COVID-19 Vaccine AstraZeneca. ATAGI is continuing to closely monitor international data on TTS cases and notes risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated to be 1.5 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with AstraZeneca to ensure maximal protection.

ATAGI emphasised that the ATAGI/THANZ joint statement on TTS and the use of the COVID 19 Vaccine AstraZeneca is an important resource. The statement provides updated information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

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Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 30 June 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 30 June 2021.

Date published: 1 July 2021

Audience: General public

ATAGI met on Wednesday 30 June 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia.

ATAGI considered an update from the Therapeutic Goods Administration (TGA) on current confirmed cases and those under investigation. The latest TGA statement 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 69 cases of confirmed or probable TTS (41 confirmed cases; 28 probable cases) in around 4.8 million doses of COVID-19 Vaccine AstraZeneca given up to 15 June 2021.

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
- 1.5 per 100,000 in those ≥60 years.

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

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	2.9
50-59	2.3
60-69	1.2
70-79;	1.7
≥80	2.0

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the recently proposed CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies);
- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the recently proposed CDC Criteria, ATAGI noted in the Australian context:

- 25 confirmed and probable TTS cases met the CDC Tier 1 definitions; and
- 18 confirmed and probable TTS cases met the CDC Tier 2 definitions.
- 25 confirmed and probable TTS cases do not meet either CDC Tier 1 or 2 definitions. These include cases with clots in common locations with thrombocytopenia but no evidence of anti-PF4 antibodies, including some with arterial thrombosis. Cases may be reclassified as more clinical data are received.

ATAGI was encouraged by data demonstrating uptake of second doses of COVID-19 Vaccines, including COVID-19 Vaccine AstraZeneca. ATAGI is continuing to closely monitor local and international data on TTS cases and notes risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated to be 1.6 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with AstraZeneca to ensure maximal protection.

ATAGI emphasised that the ATAGI/THANZ joint statement on TTS and the use of the COVID 19 Vaccine AstraZeneca is an important resource. The statement provides updated information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of the AstraZeneca COVID-19 vaccine.

ATAGI recommends the COVID-19 Pfizer vaccine (Comirnaty) as the preferred vaccine for those aged 16 to under 60 years. For those aged 60 years and above, the individual benefits of receiving a COVID-19 vaccine are greater than in younger people. The risks of severe outcomes with COVID-19 increase with age and are particularly high in older unvaccinated individuals. The benefit of vaccination in preventing COVID-19 with COVID-19 Vaccine AstraZeneca outweighs the risk of TTS in this age group and underpins its ongoing use in this age group.

Tags:

Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 7 July 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 7 July 2021.

Date published: 8 July 2021

Audience: General public

ATAGI met on Wednesday 7 July 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia. In addition, ATAGI continues to monitor COVID-19 epidemiology, vaccine coverage and adverse events observed following immunisation.

ATAGI considered an update from the Therapeutic Goods Administration (TGA) on current confirmed cases of TTS and those under investigation. The latest TGA statement 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 76 cases of confirmed or probable TTS (45 confirmed cases; 31 probable cases). To date around 5 million doses of COVID-19 Vaccine AstraZeneca have been administered. As of 23 June 2021, approximately 4.5 million doses of COVID-19 Vaccine AstraZeneca have been administered, made up of around 4.1 million first doses and 400,000 second doses. All rates of TTS cases are based on first doses of COVID-19 Vaccine AstraZeneca to 23 June 2021, which allows for delays in case reporting.

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

- 2.6 per 100,000 in those <60 years; and
- 1.6 per 100,000 in those ≥60 years.

A breakdown of current rates by decade of age for those aged < 60 & ≥ 60 years is included here:

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	2.9
50-59	2.5
60-69	1.2
70-79	1.7
≥80	1.9

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the recently proposed CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a

positive test for antibodies that activate platelets (anti-PF4 antibodies);

- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the recently proposed CDC Criteria, ATAGI noted in the Australian context:

- 29 confirmed and probable TTS cases met the CDC Tier 1 definitions. 15 of which occurred in those younger than 60 years; and
- 21 confirmed and probable TTS cases met the CDC Tier 2 definitions.
- 26 confirmed and probable TTS cases do not meet either CDC Tier 1 or 2 definitions. These include cases with clots in common locations with thrombocytopenia but no evidence of anti-PF4 antibodies, including some with arterial thrombosis. Cases may be reclassified as more clinical data are received.

ATAGI notes that there was a higher proportion of tier 1 cases (which are generally associated with increased morbidity) in those under 60 years of age. 54% of TTS cases in people under 60 are tier 1, compared with 29% of TTS cases in people over 60 years.

ATAGI was encouraged by data demonstrating uptake of second doses of COVID-19 Vaccines, including COVID-19 Vaccine AstraZeneca. ATAGI is continuing to closely monitor local and international data on TTS cases and notes risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated internationally to be 1.6 per million second doses). In the second doses of COVID-19 Vaccine AstraZeneca administered to date, there have been no confirmed or probable cases of TTS. ATAGI reinforced the importance of completing a two-dose schedule with the same brand to ensure maximal protection.

ATAGI emphasised that the ATAGI/THANZ joint statement on TTS and the use of the COVID 19 Vaccine AstraZeneca is an important resource. The statement provides updated information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of COVID-19 Vaccine AstraZeneca.

ATAGI recommends the COVID-19 Pfizer vaccine (Comirnaty) as the preferred vaccine for those aged 16 to under 60 years. For those aged 60 years and above, the individual benefits of receiving a COVID-19 vaccine are greater than in younger people. The risks of severe outcomes with COVID-19 increase with age and are particularly high in older unvaccinated individuals. The benefit of vaccination in preventing COVID-19 with COVID-19 Vaccine AstraZeneca outweighs the risk of TTS in this age group and underpins its ongoing use in this age group. ATAGI emphasises the risk-benefit document is an important resource to help consumers make informed decisions.

ATAGI is closely monitoring reports of other rare but potentially serious adverse events following immunisation, including myocarditis following Comirnaty and Immune Thrombocytopenia following COVID-19 Vaccine AstraZeneca.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
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ATAGI update following weekly COVID-19 meeting – 14 July 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 14 July 2021.

Date published: 15 July 2021

Audience: General public

ATAGI met on Wednesday 14 July 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia. In addition, ATAGI continues to monitor COVID-19 epidemiology including the significant COVID-19 outbreak involving the Delta variant in New South Wales, vaccine coverage and adverse events observed following immunisation.

ATAGI considered an update from the Therapeutic Goods Administration (TGA) on current confirmed cases of TTS and those under investigation. Read the latest TGA statement on TTS cases, including clinical outcomes.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 83 cases of confirmed or probable TTS (51 confirmed cases; 32 probable cases). To date around 5.4 million doses of COVID-19 Vaccine AstraZeneca have been administered.

However, noting that all rates of TTS cases are based on first doses of COVID-19 Vaccine AstraZeneca to 30 June 2021 (to account for the time to onset), as of 30 June 2021 approximately 4.9 million doses of COVID-19 Vaccine AstraZeneca have been administered, made up of around 4.3 million first doses and 0.7 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:

- 2.6 per 100,000 in those <60 years; and
- 1.7 per 100,000 in those ≥60 years.

A breakdown of current rates by decade of age for those aged < 60 & ≥ 60 years is included here:

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	3.3
50-59	2.5
60-69	1.5
70-79	1.8
≥80	1.8

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the CDC Criteria (PDF, 1.48 MB), which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies);

- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the CDC Criteria, ATAGI noted in the Australian context:

- 32 confirmed and probable TTS cases met the CDC Tier 1 definitions, 16 of which occurred in those younger than 60 years;
- 25 confirmed and probable TTS cases met the CDC Tier 2 definitions; and
- 26 confirmed and probable TTS cases do not meet either CDC Tier 1 or 2 definitions. These include cases with clots in common locations with thrombocytopenia but no evidence of anti-PF4 antibodies, including some with arterial thrombosis. Cases may be reclassified as more clinical data are received.

ATAGI is continuing to closely monitor local and international data on TTS cases. ATAGI notes that only one episode of TTS has been observed in Australia in a second dose recipient and that international data continues to demonstrate the risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated internationally to be 1.7 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with the same brand to ensure maximal protection.

ATAGI reinforces that the benefits of vaccination with COVID-19 Vaccine AstraZeneca strongly outweigh the risks of adverse effects in all Australians ≥60 years. In the context of a COVID-19 outbreak where the supply of Comirnaty (Pfizer) is constrained, ATAGI reinforces adults younger than 60 years old who do not have immediate access to Comirnaty (Pfizer) should re-assess the benefits to them and their contacts from being vaccinated with COVID-19 Vaccine AstraZeneca, versus the rare risk of a serious side effect.

ATAGI noted the following key resources on TTS and the use of the COVID 19 Vaccine AstraZeneca:

- the ATAGI/THANZ joint statement, which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine;

- the TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca COVID-19 Vaccine in different age cohorts and scenarios; and
- additional guidance on the use of COVID-19 vaccines in outbreak settings.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of COVID-19 Vaccine AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

ATAGI continues to review and closely monitor reports of other rare but potentially serious adverse events following immunisation, including myocarditis following Comirnaty and Immune Thrombocytopenia following COVID-19 Vaccine AstraZeneca. ATAGI reaffirms that the benefits of Comirnaty (currently registered for use in people aged ≥16 years in Australia) outweigh the risks of myocarditis for any age groups, and strongly recommend eligible individuals without contraindications to be offered vaccination.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 21 July 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 21 July 2021.

Date published: 23 July 2021

Audience: General public

ATAGI met on Wednesday 21 July 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia. In addition, ATAGI continues to monitor COVID-19 epidemiology including the current COVID-19 outbreak involving the Delta variant, vaccine coverage and adverse events observed following immunisation.

ATAGI considered an update from the Therapeutic Goods Administration (TGA) on current confirmed cases of TTS and those under investigation. The latest TGA statement 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 87 cases of confirmed or probable TTS (53 confirmed cases; 34 probable cases). To date around 6.1 million doses of COVID-19 Vaccine AstraZeneca have been administered.

ATAGI notes that the TGA is investigating three episodes of TTS observed in Australia in a second dose recipients. International data continues to demonstrate the risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated internationally to be 1.8 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with the same brand to ensure maximal protection.

However, noting that all rates of TTS cases are based on first doses of COVID-19 Vaccine AstraZeneca to 8 July 2021 (to account for the time to onset), as of 8 July 2021 approximately 5.3 million doses of COVID-19 Vaccine AstraZeneca have been administered, made up of around 4.4 million first doses and 0.9 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:

- 2.7 per 100,000 in those <60 years; and
- 1.6 per 100,000 in those ≥60 years.

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

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	3.5
50-59	2.5
60-69	1.4
70-79	1.9
≥80	1.7

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies);
- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the CDC Criteria, ATAGI noted in the Australian context:

- 33 confirmed and probable TTS cases met the CDC Tier 1 definitions, 17 of which occurred in those younger than 60 years;
- 25 confirmed and probable TTS cases met the CDC Tier 2 definitions; and
- 29 confirmed and probable TTS cases do not meet either CDC Tier 1 or 2 definitions. These include cases with clots in common locations with thrombocytopenia but no evidence of anti-PF4 antibodies, including some with arterial thrombosis. Cases may be reclassified as more clinical data are received.

As previously noted, younger individuals appear to be at greater risk of severe outcomes than older people. 41 cases have occurred in men and 46 cases in women, with a higher number of severe outcomes in younger women than in younger men. No sex differences are being observed in older individuals.

ATAGI reinforces that the benefits of vaccination with COVID-19 Vaccine AstraZeneca strongly outweigh the risks of adverse effects in all Australians ≥60 years. In the context of a COVID-19 outbreak where the supply of Comirnaty (Pfizer) is constrained, ATAGI reinforces adults younger than 60 years old who do not have immediate access to Comirnaty (Pfizer) should re-assess the benefits to them and their contacts from being vaccinated with COVID-19 Vaccine AstraZeneca, versus the rare risk of a serious side effect.

ATAGI noted the following key resources on TTS and the use of the COVID 19 Vaccine AstraZeneca:

- the ATAGI/THANZ joint statement, which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine;
- the TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca COVID-19 Vaccine in different age cohorts and scenarios; and
- additional guidance on the use of COVID-19 vaccines in outbreak settings.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of COVID-19 Vaccine AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

ATAGI continues to review and closely monitor reports of other rare but potentially serious adverse events following immunisation including Immune Thrombocytopenia following COVID-19 Vaccine AstraZeneca and myocarditis following Comirnaty.

ATAGI notes that the TGA are investigating 16 episodes of myocarditis observed following Comirnaty in Australia, most frequently following the 2nd dose. International data demonstrates that the rate of disease is higher in younger individuals, particularly young males. Most reported cases have been mild, self-limiting and recovered quickly, although further follow-up of these cases is ongoing. Additional information for providers and the community is expected to be published in coming days. ATAGI reaffirms that the benefits of Comirnaty (currently registered for use in people aged ≥16 years in Australia) outweigh the risks of myocarditis for any age groups, and strongly recommend eligible individuals without contraindications to be offered vaccination.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 28 July 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 28 July 2021.

Date published: 30 July 2021

Audience: General public

ATAGI met on Wednesday 28 July 2021 to review the latest developments relating to the AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS) cases in Australia. In addition, ATAGI continues to monitor COVID-19 epidemiology including the current COVID-19 outbreak involving the Delta variant and adverse events observed following immunisation.

ATAGI considered an update from the Therapeutic Goods Administration (TGA) on current confirmed cases of TTS and those under investigation. The latest TGA statement 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 90 cases of confirmed or probable TTS (54 confirmed cases; 36 probable cases). To date around 6.3 million doses of COVID-19 Vaccine AstraZeneca have been administered.

ATAGI notes that the TGA has investigated three suspected episodes of TTS observed in Australia in a second dose recipients, with an expert panel concluding these cases were unlikely to be related to vaccination. International data continues to demonstrate the risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated internationally to be 1.9 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with the same brand to ensure maximal protection.

However, noting that all rates of TTS cases are based on first doses of COVID-19 Vaccine AstraZeneca to 14 July 2021 (to account for the time to onset), as of 14 July 2021 approximately 5.7 million doses of COVID-19 Vaccine AstraZeneca have been administered, made up of around 4.6 million first doses and 1.1 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:

- 2.6 per 100,000 in those <60 years; and
- 1.7 per 100,000 in those ≥60 years.

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

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	3.2
50-59	2.4
60-69	1.5

70-79	2.1
≥80	1.7

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies);
- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the CDC Criteria, ATAGI noted in the Australian context:

- 35 confirmed and probable TTS cases met the CDC Tier 1 definitions, 17 of which occurred in those younger than 60 years;
- 26 confirmed and probable TTS cases met the CDC Tier 2 definitions; and
- 29 confirmed and probable TTS cases do not meet either CDC Tier 1 or 2 definitions. These include cases with clots in common locations with thrombocytopenia but no evidence of anti-PF4 antibodies, including some with arterial thrombosis. Cases may be reclassified as more clinical data are received.

As previously noted, younger individuals appear to be at greater risk of severe outcomes than older people. 42 cases have occurred in men and 48 cases in women, with a higher number of severe outcomes in younger women than in younger men. No sex differences are being observed in older individuals.

ATAGI reinforces that the benefits of vaccination with COVID-19 Vaccine AstraZeneca strongly outweigh the risks of adverse effects in all Australians ≥60 years. In the context of a COVID-19 outbreak where the supply of Comirnaty (Pfizer) is constrained, ATAGI reinforces adults younger than 60 years old who do not have immediate access to

Comirnaty (Pfizer) should re-assess the benefits to them and their contacts from being vaccinated with COVID-19 Vaccine AstraZeneca, versus the rare risk of a serious side effect.

ATAGI noted the following key resources on TTS and the use of the COVID 19 Vaccine AstraZeneca:

- the ATAGI/THANZ joint statement, which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine;
- the TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca COVID-19 Vaccine in different age cohorts and scenarios; and
- additional guidance on the use of COVID-19 vaccines in outbreak settings; and
- response to NSW COVID-19 outbreak.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of COVID-19 Vaccine AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

ATAGI continues to review and closely monitor reports of other rare but potentially serious adverse events following immunisation including Immune Thrombocytopenia following COVID-19 Vaccine AstraZeneca and myocarditis following Comirnaty.

ATAGI notes that the TGA are investigating 27 episodes of myocarditis observed following Comirnaty in Australia, most frequently following the second dose. International data demonstrates that the rate of disease is higher in younger individuals, particularly young males. Most reported cases have been mild, self-limiting and recovered quickly, although further follow-up of these cases is ongoing. Additional information for providers and the community is expected to be published in coming days. ATAGI reaffirms that the benefits of Comirnaty (currently registered for use in people aged ≥16

years in Australia) outweigh the risks of myocarditis for any age groups, and strongly recommend eligible individuals without contraindications to be offered vaccination.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

Australian Technical Advisory Group on Immunisation (ATAGI) weekly COVID-19 meeting on 4 August 2021 update

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 4 August 2021

Date published: 5 August 2021

Audience: General public

ATAGI met on Wednesday 4 August 2021 to review the latest developments relating to adverse events observed following immunisation with COVID-19 vaccines, including AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS), cases in Australia. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales and Queensland.

AstraZeneca COVID-19 vaccine

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 TGA statement on TTS cases, including clinical outcomes, can be found on the TGA website.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 93 cases of confirmed or probable TTS (57 confirmed cases; 36 probable cases). To date around 6.8 million doses of COVID-19 Vaccine AstraZeneca have been administered. ATAGI sadly noted a further death has been reported by the TGA this week.

International data continues to demonstrate the risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated internationally to be 1.9 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with the same brand to ensure maximal protection.

However, noting that all rates of TTS cases are based on first doses of COVID-19 Vaccine AstraZeneca to 21 July 2021 (to account for the time to onset), as of 21 July 2021 approximately 6.0 million doses of COVID-19 Vaccine AstraZeneca have been administered, made up of around 4.7 million first doses and 1.3 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:

- 2.7 per 100,000 in those <60 years; and
- 1.7 per 100,000 in those ≥60 years.

A breakdown of current rates by decade of age for those aged ≥ 50 years is included in the table below.

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	3.4
50-59	2.4
60-69	1.5
70-79	2.0
≥80	1.6

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies);
- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the CDC Criteria, ATAGI noted in the Australian context:

- 38 confirmed and probable TTS cases met the CDC Tier 1 definitions, 19 of which occurred in those younger than 60 years;
- 26 confirmed and probable TTS cases met the CDC Tier 2 definitions; and
- 29 confirmed and probable TTS cases do not meet either CDC Tier 1 or 2 definitions. These include cases with clots in common locations with thrombocytopenia but no evidence of anti-PF4 antibodies, including some with arterial thrombosis. Cases may be reclassified as more clinical data are received.

As previously noted, younger individuals appear to be at greater risk of severe outcomes than older people. 42 cases have occurred in men and 51 cases in women, with a higher number of severe outcomes in younger women than in younger men. No sex differences are being observed in older individuals.

ATAGI reinforces that the benefits of vaccination with COVID-19 Vaccine AstraZeneca strongly outweigh the risks of adverse effects in all Australians ≥60 years. In the context of a COVID-19 outbreak where the supply of Comirnaty (Pfizer) is constrained, ATAGI reinforces adults younger than 60 years old who do not have immediate access to Comirnaty (Pfizer) should re-assess the benefits to them and their contacts from being vaccinated with COVID-19 Vaccine AstraZeneca, versus the rare risk of a serious side effect.

ATAGI noted the following key resources on TTS and the use of the COVID 19 Vaccine AstraZeneca:

- the ATAGI/THANZ joint statement which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine;
- the TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca COVID-19 Vaccine 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 Delta variant of concern.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of COVID-19 Vaccine AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

ATAGI continues to review and closely monitor reports of other rare but potentially serious adverse events following immunisation including: Immune Thrombocytopenia (ITP) and Guillain Barre syndrome (GBS) following COVID-19 Vaccine AstraZeneca.

Comirnaty (Pfizer)

ATAGI notes the TGA's recent registration of Comirnaty (Pfizer) for use in children aged 12- 15 years old and has provided a recent statement on use in this cohort.

Myocarditis

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation following Comirnaty, including myocarditis.

ATAGI notes that the TGA are investigating 28 episodes of myocarditis observed following Comirnaty (Pfizer) in Australia, most frequently following the second dose. International data demonstrates that the rate of disease is higher in younger individuals, particularly young males. Most reported cases have been mild, self-limiting and recovered quickly, although further follow-up of these cases is ongoing.

ATAGI has recently published guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines. ATAGI reaffirms that the benefits of Comirnaty (Pfizer; currently registered for use in people aged ≥12 years in Australia) outweigh the risks of myocarditis for any age groups, and strongly recommend eligible individuals without contraindications to be offered vaccination.

Tags: Communicable diseases | Emergency health management | COVID-19

Australian Government
Department of Health and Aged Care

Australian Technical Advisory Group on Immunisation (ATAGI) weekly COVID-19 meeting on 11 August 2021 update

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 11 August 2021.

Date published: 12 August 2021

Audience: General public

ATAGI met on Wednesday 11 August 2021 to review the latest developments relating to adverse events observed following immunisation with COVID-19 vaccines, including AstraZeneca COVID-19 vaccine and Thrombosis and Thrombocytopenia Syndrome (TTS), cases in Australia. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, Queensland and Victoria.

AstraZeneca COVID-19 vaccine

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 TGA statement 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 104 cases of confirmed or probable TTS (59 confirmed cases; 45 probable cases). To date around 7.4 million doses of COVID-19 Vaccine AstraZeneca have been administered.

ATAGI notes that the TGA is investigating five episodes of TTS observed in Australia in second dose recipients. International data continues to demonstrate the risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated internationally to be 1.8 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with the same brand to ensure maximal protection.

Rates of TTS cases are based on first doses of COVID-19 Vaccine AstraZeneca as of 28 July 2021 (to account for the time to onset of TTS). To that date, approximately 6.6 million doses of COVID-19 Vaccine AstraZeneca have been administered, made up of around 4.9 million first doses and 1.7 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:

- 2.7 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 ≥ 50 years is included here:

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	3.4
50-59	2.5
60-69	1.5
70-79	2.1
≥80	1.6

ATAGI also noted that the TGA has reviewed Australia's confirmed and probable TTS cases and those reported by overseas regulators using the CDC Criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies);
- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

When considering Australian TTS cases in using the CDC Criteria, ATAGI noted:

- 41 confirmed and probable TTS cases met the CDC Tier 1 definitions, 20 of which occurred in those younger than 60 years. Of these 20 cases, 17 were in females and 3 in males;
- 28 confirmed and probable TTS cases met the CDC Tier 2 definitions; and
- 35 confirmed and probable TTS cases do not meet either CDC Tier 1 or 2 definitions. These include cases with clots in common locations with thrombocytopenia but no evidence of anti-PF4 antibodies, including some with arterial thrombosis. Cases may be reclassified as more clinical data are received.

These data suggest that the incidence of TTS is higher in younger people and the severity of TTS appears to be higher in younger women. These differences by sex are not seen in older people.

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

ATAGI noted the following key resources on TTS and the use of the COVID 19 Vaccine AstraZeneca:

- the ATAGI/THANZ joint statement which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine;
- the TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca COVID-19 Vaccine 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 Delta variant of concern.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of COVID-19 Vaccine AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

ATAGI continues to review and closely monitor reports of other rare but potentially serious adverse events following immunisation including: Immune Thrombocytopenia (ITP) and Guillain Barre syndrome (GBS) following COVID-19 Vaccine AstraZeneca.

Comirnaty (Pfizer)

ATAGI notes the TGA's recent registration of Comirnaty (Pfizer) for use in children aged 12- 15 years old and has provided a statement on use in this cohort.

Myocarditis

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation following Comirnaty, including myocarditis.

ATAGI notes that the TGA are investigating 34 episodes of myocarditis observed following Comirnaty (Pfizer) in Australia, most frequently following the second dose. International data demonstrates that the rate of disease is higher in younger individuals, particularly young males. Most reported cases have been mild, self-limiting and recovered quickly, although further follow-up of these cases is ongoing.

ATAGI has recently published guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines. ATAGI reaffirms that the benefits of Comirnaty (Pfizer; currently registered for use in people aged ≥12 years in Australia) outweigh the risks of myocarditis for any age groups, and strongly recommend eligible individuals without contraindications to be offered vaccination.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 18 August 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 18 August 2021.

Date published: 19 August 2021

Audience: General public

ATAGI met on Wednesday 18 August 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 current COVID-19 outbreaks involving the Delta variant, including in New South Wales, Australian Capital Territory and Victoria.

ATAGI stresses that vaccination is a key public health intervention to prevent infection, transmission and severe disease. ATAGI continues to recommend COVID-19 vaccination for all adults, and specific high-risk adolescents.

ATAGI is encouraged to note that as at 18 August 2021 over 16 million doses of COVID-19 vaccines have been administered in Australia.

AstraZeneca COVID-19 vaccine

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 TGA statement 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 112 cases of confirmed or probable TTS (62 confirmed cases; 50 probable cases). To date around 8.1 million doses of COVID-19 Vaccine AstraZeneca have been administered.

ATAGI notes that the TGA is investigating six episodes of TTS observed in Australia in second dose recipients. International data continues to demonstrate the risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose (estimated internationally to be 1.8 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with the same brand to ensure maximal protection.

Rates of TTS cases are based on first doses of COVID-19 Vaccine AstraZeneca as of 3 August 2021 (to account for the time to onset of TTS). To that date, approximately 7.0 million doses of COVID-19 Vaccine AstraZeneca have been administered, made up of around 5.0 million first doses and 2.0 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:

- 2.9 per 100,000 in those <60 years
- 1.8 per 100,000 in those ≥60 years.

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

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	3.2
50-59	2.8
60-69	1.6
70-79	2.2
≥80	1.7

ATAGI also noted that the TGA included in their weekly update a detailed breakdown of Australia's confirmed and probable TTS cases using the CDC Criteria.

ATAGI noted these data suggest that the incidence of TTS is higher in younger people and the severity of TTS appears to be higher in younger women. These differences by sex are not seen in older people.

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

ATAGI noted the following key resources on TTS and the use of the COVID 19 Vaccine AstraZeneca:

- the ATAGI/THANZ joint statement which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of the AstraZeneca COVID-19 Vaccine;
- the TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca COVID-19 Vaccine 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 Delta variant of concern.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of COVID-19 Vaccine AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

ATAGI continues to review and closely monitor reports of other rare but potentially serious adverse events following immunisation including: Immune Thrombocytopenia (ITP) and Guillain Barre syndrome (GBS) following COVID-19 Vaccine AstraZeneca.

Comirnaty (Pfizer)

ATAGI notes the TGA's recent registration of Comirnaty (Pfizer) for use in children aged 12- 15 years old and has provided a statement on use in this cohort and ATAGI is currently considering advice regarding a broader adolescent program.

Myocarditis

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation following Comirnaty, including myocarditis.

ATAGI notes that the TGA has received 149 reports of suspected myocarditis and/or pericarditis following Comirnaty (Pfizer). International data demonstrates that the rate of disease is higher in younger individuals, particularly young males. Most reported cases have been mild, self-limiting and recovered quickly, although further follow-up of these cases is ongoing.

ATAGI has recently published guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines. ATAGI reaffirms that the benefits of Comirnaty (Pfizer; currently registered for use in people aged ≥12 years in Australia) outweigh the risks of myocarditis for any age groups, and strongly recommend eligible individuals without contraindications to be offered vaccination.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 25 August 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 25 August 2021.

Date published: 27 August 2021

Audience: General public

ATAGI met on Wednesday 25 August 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 current COVID-19 outbreaks involving the Delta variant, including in New South Wales, Australian Capital Territory and Victoria.

ATAGI stresses that vaccination is a key public health intervention to prevent infection, transmission and severe disease. ATAGI continues to recommend COVID-19 vaccination for all adults, and specific high-risk adolescents.

ATAGI is encouraged to note that as at 25 August 2021, over 17 million doses of COVID-19 vaccines have been administered in Australia. ATAGI is also encouraged by emerging data from NSW 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.

AstraZeneca (Vaxzevria, formerly known as COVID-19 Vaccine 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 TGA statement 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 116 cases of confirmed or probable TTS (67 confirmed cases; 49 probable cases). To date around 8.8 million doses of AstraZeneca (Vaxzevria) have been administered.

ATAGI notes that International data continues to demonstrate the risk of TTS following a second dose of AstraZeneca (Vaxzevria) is much lower than the risk following a first dose (estimated internationally to be 1.8 per million second doses). ATAGI reinforced the importance of completing a two-dose schedule with the same brand.

Rates of TTS cases are based on first doses of AstraZeneca (Vaxzevria) as of 12 August 2021 (to account for the time to onset of TTS). To that date, approximately 7.9 million doses of AstraZeneca (Vaxzevria) have been administered, made up of around 5.4 million first doses and 2.5 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:

- 2.6 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 ≥ 50 years is included here:

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	2.5
50-59	2.7
60-69	1.6
70-79	2.1
≥80	1.6

ATAGI also noted that the TGA included in their weekly update a detailed breakdown of Australia's confirmed and probable TTS cases using the CDC Criteria.

ATAGI noted these data suggest that the incidence of TTS is higher in younger people and 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (6/115, approximately 5%) is lower than that seen in the United Kingdom (~18%).

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

Immune Thrombocytopenia

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation following AstraZeneca (Vaxzevria), 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 following AstraZeneca (Vaxzevria), 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.

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

Pfizer (Comirnaty)

ATAGI notes the TGA's recent registration of Pfizer (Comirnaty) for use in children aged 12- 15 years old and has provided a statement on use in this cohort. ATAGI is currently considering advice regarding a broader adolescent program.

Myocarditis and/or Pericarditis

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation following Pfizer (Comirnaty), including myocarditis and/or pericarditis.

ATAGI notes that the TGA is investigated 235 reports of suspected myocarditis and/or pericarditis following Pfizer (Comirnaty). 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 recovered quickly, although further follow-up of these cases is ongoing.

ATAGI has recently published guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines. ATAGI reaffirms that the benefits of Pfizer (Comirnaty, currently registered for use in people aged ≥12 years in Australia) outweigh the risks of myocarditis and/or pericarditis for any age groups, and strongly recommend eligible individuals without contraindications to be offered vaccination.

Resources

ATAGI recommends review of the following key resources:

TTS and the use of AstraZeneca (Vaxzevria)

- the ATAGI/THANZ joint statement which provides information about TTS and reaffirms ATAGI's previous advice regarding the safe use of AstraZeneca (Vaxzevria);
- the TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca (Vaxzevria) 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 Delta variant of concern.

Myocarditis and/or Pericarditis and use of Pfizer (Comirnaty)

- ATAGI and Cardiac Society of Australia and New Zealand guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines; and
- ATAGI Statement regarding vaccination of adolescents 12-15 years of age.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 1 September 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 1 September 2021.

Date published: 2 September 2021

Audience: General public

ATAGI met on Wednesday 1 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 current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 continues to recommend COVID-19 vaccination for all adults and specific high-risk adolescents.

ATAGI is encouraged to note that as at 31 August 2021, over 19 million doses of COVID-19 vaccines have been administered in Australia. ATAGI has also noted emerging data from NSW 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.

AstraZeneca (Vaxzevria)

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. Read the latest TGA statement on TTS cases, including clinical outcomes.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 125 cases of confirmed or probable TTS:

- 69 confirmed cases
- 56 probable cases.

To date around 9.6 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 1.8 per million second doses). ATAGI reinforces the importance of completing a 2-dose schedule to ensure maximal protection, with the strongest evidence for 2 doses of the same brand.

Rates of TTS cases are based on first doses of AstraZeneca as of 19 August 2021 (to account for the time to onset of TTS). To that date, approximately 8.6 million doses of AstraZeneca have been administered, made up of around 5.7 million first doses and 2.9 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.

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	2.2
50-59	2.6
60-69	1.7
70-79	2.1
≥80	1.6

ATAGI also noted that the TGA have been reporting a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. ATAGI noted these data suggest that the severity of TTS appears to be higher in younger women. These differences by gender 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/125, approximately 6%) is lower than that seen in the United Kingdom (~17%). ATAGI sadly note the TGA have reported 2 further deaths this week.

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 as 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 nvestigations 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 COVID-19 outbreak where the supply of Pfizer (Comirnaty) 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 greater Sydney, 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 ATAGI statement 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.

Pfizer (Comirnaty)

ATAGI notes the TGA's registration of Pfizer for use in children aged 12-15 years old. 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.

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 a recognised complication of COVID-19.

ATAGI notes that the TGA is investigating 293 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.

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 TTS primary care guide 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 risk-benefit document 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 Delta variant of concern.

Use of Pfizer and/or Myocarditis and/or Pericarditis

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

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

Australian Technical Advisory Group on Immunisation (ATAGI) weekly COVID-19 meeting on 8 September 2021 update

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 8 September 2021.

Date published: 9 September 2021

Audience: General public

ATAGI met on Wednesday 8 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 current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 low 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 7 September 2021, over 21 million doses of COVID-19 vaccines have been administered in Australia. ATAGI has noted emerging data from NSW 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 Pfizer and Moderna 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.

AstraZeneca (Vaxzevria)

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 TGA statement 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 132 cases of confirmed or probable TTS (74 confirmed cases; 58 probable cases). To date around 10.2 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 1.8 per million 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 25 August 2021 (to account for the time to onset of TTS). To that date, approximately 9.3 million doses of AstraZeneca have been administered, made up of around 6.0 million first doses and 3.3 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:

- 2.5 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 ≥ 50 years is included here:

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	2.0
50-59	2.9
60-69	1.6
70-79	2.0
≥80	1.7

ATAGI also noted that the TGA have been reporting a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/132, 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 one 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 COVID-19 outbreak where the supply of Pfizer (Comirnaty) 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 greater Sydney, 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 ATAGI statement 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.

Pfizer (Comirnaty)

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 370 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.

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

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.

Date published: 16 September 2021

Audience: General public

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 current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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, over 23 million doses 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 Pfizer and Moderna 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 TGA statement 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 1.9 per million 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 ≥ 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 CDC Criteria. 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 TTS primary care guide. 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 COVID-19 outbreak 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 greater Sydney 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 ATAGI statement 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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Australian Technical Advisory Group on Immunisation (ATAGI) | Communicable diseases | Emergency health management | COVID-19

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 22 September 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 22 September 2021.

Date published: 24 September 2021

Audience: General public

On Wednesday 22 September 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including urrent COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 21 September 2021, over 25 million doses 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 Pfizer and Moderna 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 TGA statement 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 141 cases of confirmed or probable TTS (77 confirmed cases; 64 probable cases). To date around 11.3 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 1.9 per

million 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 9 September 2021 (to account for the time to onset of TTS). To that date, approximately 10.6 million doses of AstraZeneca have been administered, made up of around 6.4 million first doses and 4.2 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:

- 2.3 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 ≥ 50 years is included here:

Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	1.8
50-59	2.9
60-69	1.6
70-79	2.1
≥80	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 CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/141, approximately 5.5%) is lower than that seen in other settings. ATAGI notes that the TGA is continuing to investigate 13 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 COVID-19 outbreak 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 greater Sydney 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 ATAGI statement 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 660 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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 29 September 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 29 September 2021.

Date published: 1 October 2021

Audience: General public

On Wednesday 29 September 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 28 September 2021, over 27 million doses 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 Pfizer and Moderna for use in children from 12 years of age. Following a review of current data on benefits and adverse events in adolescents, ATAGI 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 TGA statement 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 148 cases of confirmed or probable TTS (83 confirmed cases; 65 probable cases). To date around 11.6 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 1.9 per million 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 16 September 2021 (to account for the time to onset of TTS). To that date, approximately 11 million doses of AstraZeneca have been administered, made up of around 6.6 million first doses and 4.4 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 ≥ 50 years is included here:

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	1.8
50-59	3.0
60-69	1.6
70-79	2.0
≥80	2.0

ATAGI also noted that the TGA have been reporting a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/148,

approximately 5.5%) is lower than that seen in other settings. ATAGI notes that the TGA is continuing to investigate 16 probable cases of TTS following second doses and that to date, only four 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 as 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 COVID-19 outbreak 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 greater Sydney 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 ATAGI statement 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 850 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 178 suspected myocarditis reports. International data demonstrates that the rate of disease is higher in younger individuals, particularly young males and more frequently occurs following the second dose (4.7 per 100,000 second dose recipients aged 12-19 years compared with <1 per 100,000 in second dose recipient aged 30 years and older). 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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 6 October 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 6 October 2021.

Date published: 8 October 2021

Audience: General public

On Wednesday 6 October 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 5 October 2021, over 29 million doses 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 has previously noted the TGA's registration of Pfizer and Moderna for use in children from 12 years of age and 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 TGA statement 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 151 cases of confirmed or probable TTS (84 confirmed cases; 67 probable cases). To date around 12 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 1.9 per million 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 22 September 2021 (to account for the time to onset of TTS). To that date, approximately 11.5 million doses of AstraZeneca have been administered, made up of around 6.7 million first doses and 4.8 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 ≥ 50 years is included here:

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	1.8
50-59	3.0
60-69	1.5
70-79	2.0
≥80	1.8

ATAGI also noted that the TGA have been reporting a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/151; 5.3%) is

lower than that seen in other settings. ATAGI notes that the TGA is continuing to investigate 18 probable cases of TTS following second doses and that to date, six 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 as 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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

At this time, there is no update to the ATAGI statement 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 847 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 228 suspected myocarditis reports. Of these suspected cases, 145 cases of myocarditis or myopericarditis have been assessed as meeting the Brighton Collaboration case definition (level 1, 2, or 3), of which 69 cases occurred following the second dose. The TGA report details the estimated rate of myocarditis following first and second doses by age. The observed rates are consistent with international data showing a higher rate in younger individuals (particularly younger males) and following second doses. 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.

No confirmed cases of myocarditis have been reported after Moderna vaccine, noting that only a small number of first doses have been administered to date. ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases | Emergency health management

COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 13 October 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 13 October 2021.

Date published: 15 October 2021

Audience: General public

On Wednesday 13 October 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 11 October 2021, over 31 million doses 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 has previously noted the TGA's registration of Pfizer and Moderna for use in children from 12 years of age and 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 TGA statement 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 152 cases of confirmed or probable TTS (85 confirmed cases; 67 probable cases). To date around 12.5 million doses of AstraZeneca have been administered.

ATAGI notes the TGA assessment that the risk of TTS following the second dose is much lower, consistent with international investigations. 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 30 September 2021 (to account for the time to onset of TTS). To that date, approximately 11.9 million doses of AstraZeneca have been administered, made up of around 6.7 million first doses and 5.2 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
- 1.8 per 100,000 in those ≥60 years.

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

Age bracket (years)	**Estimated rate (per 100,000 AZ vaccinations)**
<50	1.9
50-59	3.0
60-69	1.5
70-79	2.1
≥80	1.7

ATAGI also noted that the TGA have been reporting a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/151; 5.3%) is lower than that seen in other settings. ATAGI notes that the TGA is

continuing to investigate 18 probable cases of TTS following second doses and that to date, six of these cases meet the case definition of confirmed TTS.

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 as 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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

At this time, there is no update to the ATAGI statement from 17 June 2021 in relation to the use of AstraZeneca, except to note that further clarification has been provided 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 994 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 269 suspected myocarditis reports. Of these suspected cases, 161 cases of myocarditis or myopericarditis have been assessed as meeting the Brighton Collaboration case definition (level 1, 2, or 3), of which 82 cases occurred following the second dose. The TGA report details the estimated rate of myocarditis following first and second doses by age. The observed rates are consistent with international data showing a higher rate in younger individuals (particularly younger males) and following second doses. 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.

No confirmed cases of myocarditis have been reported after Moderna vaccine, noting that only a small number of first doses have been administered to date. ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

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 TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca in different age cohorts and scenarios
- additional guidance on the use of COVID-19 vaccines in outbreak settings
- response to NSW COVID-19 outbreak
- additional strategies to combat the risk posed by the Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Australian Technical Advisory Group on Immunisation (ATAGI) | Communicable diseases

Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 20 October 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 20 October 2021.

Date published: 22 October 2021

Audience: General public

On Wednesday 20 October 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 18 October 2021, almost 33 million doses 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 has previously noted the TGA's registration of Pfizer and Moderna for use in children from 12 years of age and supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 1148 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 312 suspected myocarditis reports. Of these suspected cases, 175 cases of myocarditis or myopericarditis have been assessed as meeting the Brighton Collaboration case definition (level 1, 2, or 3), of which 100 cases occurred following the second dose.

ATAGI notes that the TGA report details the estimated rate of myocarditis following first and second doses by age and sex. The observed rates are consistent with international data showing a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI notes that the TGA is investigating 5 reported cases of myocarditis following Moderna vaccine, of which 2 have been assessed as meeting the Brighton Collaboration case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

Risks and benefits

ATAGI reaffirms that the benefits of Comirnaty (Pfizer) and Spikevax (Moderna)

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

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 TGA statement 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 156 cases of confirmed or probable TTS (86 confirmed cases; 70 probable cases). To date around 12.6 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 1.9 per million 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 7 October 2021 (to account for the time to onset of TTS). To that date, approximately 12.2 million doses of AstraZeneca have been administered, made up of around 6.7 million first doses and 5.5 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/151; 5.1%) is lower than that seen in other settings. ATAGI notes that the TGA is continuing to investigate 19 probable cases of TTS following second doses and that to date, six 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 as 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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

Australian Technical Advisory Group on Immunisation (ATAGI) weekly COVID-19 meeting on 27 October 2021 update

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 27 October 2021.

Date published: 29 October 2021

Audience: General public

On Wednesday 27 October 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 27 October 2021, over 35 million doses 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 has previously noted the TGA's registration of Pfizer and Moderna for use in children from 12 years of age and supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below. ATAGI also notes the announcement of a booster program using the Pfizer vaccine for those who completed their primary course of COVID-19 vaccines 6 or more months ago.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 1375 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 404 suspected myocarditis reports. Of these suspected cases, 235 cases of

myocarditis or myopericarditis have been assessed as meeting the Brighton Collaboration case definition (level 1, 2, or 3), of which 140 cases occurred following the second dose.

ATAGI notes that the TGA report details the estimated rate of myocarditis following first and second doses by age and sex. The observed rates are consistent with international data showing a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI notes that the TGA is investigating 9 reported cases of myocarditis following Moderna vaccine, of which 4 have been assessed as meeting the Brighton Collaboration case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

While data on myocarditis following booster doses of Pfizer vaccine is limited, preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Risks and benefits

ATAGI reaffirms that the benefits of Comirnaty (Pfizer) and Spikevax (Moderna)

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

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 TGA statement 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 157 cases of confirmed or probable TTS (86 confirmed cases; 71 probable cases). To date around 12.9 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 1.9 per million 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 14 October 2021 (to account for the time to onset of TTS). To that date, approximately 12.5 million doses of AstraZeneca have been administered, made up of around 6.8 million first doses and 5.7 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/157; 5.1%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 19 probable cases of TTS following second doses and that to date, six 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

ATAGI also notes that following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and AstraZeneca has not been established. However as a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and

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

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 3 November 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 3 November 2021.

Date published: 5 November 2021

Audience: General public

On Wednesday 3 November 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 2 November 2021, over 36 million doses 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 has previously noted the Therapeutic Goods Administration (TGA) registration of Pfizer and Moderna for use in children from 12 years of age and supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below. ATAGI also notes the announcement of a booster program using the Pfizer vaccine for those who completed their primary course of COVID-19 vaccines 6 or more months ago.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 1583 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 446 suspected myocarditis reports. Of these suspected cases, 253 cases of myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 155 cases occurred following the second dose.

ATAGI also notes that the TGA is investigating 15 reported cases of myocarditis following Moderna vaccine, of which 10 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from some international safety surveillance systems suggesting that the risk of myocarditis may be higher, albeit still rare following Moderna compared with Pfizer (<2 excess cases per 100,000 second dose vaccine recipients younger than 40 years). There is no evidence to suggest more severe disease with either vaccine.

While data on myocarditis following booster doses of Pfizer vaccine is limited, preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and encourage to should seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement 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 158 cases of confirmed or probable TTS (87 confirmed cases; 71 probable cases). To date around 13.1 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 1.9 per million 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 21 October 2021 (to account for the time to onset of TTS). To that date, approximately 12.7 million doses of AstraZeneca have been administered, made up of around 6.8 million first doses and 5.9 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/158; 5.1%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 19 probable cases of TTS following second doses and that to date, six 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

ATAGI also notes that following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and AstraZeneca has not been established. However as a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 10 November 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 10 November 2021.

Date published: 12 November 2021

Audience: General public

On Wednesday 10 November 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 10 November 2021, over 37 million doses 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 has previously noted the Therapeutic Goods Administration (TGA) registration of Pfizer and Moderna for use in children from 12 years of age and supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below. ATAGI also notes the announcement of a booster program using the Pfizer vaccine for those who completed their primary course of COVID-19 vaccines 6 or more months ago.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 1713 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 511 suspected myocarditis reports. Of these suspected cases, 288 cases of

myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 178 cases occurred following the second dose.

ATAGI also notes that the TGA is investigating 19 reported cases of myocarditis following Moderna vaccine, of which 13 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from some international safety surveillance systems suggesting that the risk of myocarditis may be higher, albeit still rare following Moderna compared with Pfizer (<2 excess cases per 100,000 second dose vaccine recipients younger than 40 years). There is no evidence to suggest more severe disease with either vaccine.

While data on myocarditis following booster doses of Pfizer vaccine is limited, preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and are encouraged to seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement 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 160 cases of confirmed or probable TTS (87 confirmed cases; 73 probable cases). To date around 13.2 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 1.9 per million 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 28 October 2021 (to account for the time to onset of TTS). To that date, approximately 13.0 million doses of AstraZeneca have been administered, made up of around 6.8 million first doses and 6.2 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/160; 5.0%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 21 probable cases of TTS following second doses and that to date, six 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

ATAGI also notes that following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and AstraZeneca has not been established. However as a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 17 November 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 17 November 2021.

Date published: 19 November 2021

Audience: General public

On Wednesday 17 November 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 17 November 2021, over 38 million doses 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 has previously noted the Therapeutic Goods Administration (TGA) registration of Pfizer and Moderna for use in children from 12 years of age and supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below. ATAGI also notes the announcement of a booster program using the Pfizer vaccine for those who completed their primary course of COVID-19 vaccines 6 or more months ago.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 1879 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 568 suspected myocarditis reports. Of these suspected cases, 315 cases of myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 199 cases occurred following the second dose.

ATAGI also notes that the TGA is investigating 24 reported cases of myocarditis following Moderna vaccine, of which 14 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from some international safety surveillance systems suggesting that the risk of myocarditis may be higher, albeit still rare following Moderna compared with Pfizer (<2 excess cases per 100,000 second dose vaccine recipients younger than 40 years). There is no evidence to suggest more severe disease with either vaccine.

While data on myocarditis following booster doses of Pfizer vaccine is limited, preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and are encouraged to seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement 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 163 cases of confirmed or probable TTS (87 confirmed cases; 76 probable cases). To date around 13.4 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 1.9 per million 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 4 November 2021 (to account for the time to onset of TTS). To that date, approximately 13.2 million doses of AstraZeneca have been administered, made up of around 6.9 million first doses and 6.3 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:

- 2.5 per 100,000 in those <60 years; and
- 1.9 per 100,000 in those ≥60 years.

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case

fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/163; 5.0%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 21 probable cases of TTS following second doses and that to date, six 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

ATAGI also notes that following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and AstraZeneca has not been established. However as a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 24 November 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 24 November 2021.

Date published: 26 November 2021

Audience: General public

On Wednesday 24 November 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, the 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 notes strategies to address barriers to vaccination in this important population.

As at 24 November 2021, over 38.5 million doses 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 has previously noted the Therapeutic Goods Administration (TGA) registration of Pfizer and Moderna for use in children from 12 years of age and supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below. ATAGI also notes the announcement of a booster program using the Pfizer vaccine for those who completed their primary course of COVID-19 vaccines 6 or more months ago.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 1999 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 650 suspected myocarditis reports. Of these suspected cases, 341 cases of

myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 255 cases occurred following the second dose.

ATAGI also notes that the TGA is investigating 30 reported cases of myocarditis following Moderna vaccine, of which 18 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from some international safety surveillance systems suggesting that the risk of myocarditis may be higher, albeit still rare following Moderna compared with Pfizer (<2 excess cases per 100,000 second dose vaccine recipients younger than 40 years). There is no evidence to suggest more severe disease with either vaccine.

While data on myocarditis following booster doses of Pfizer vaccine is limited, preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and are encouraged to seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement 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 164 cases of confirmed or probable TTS (87 confirmed cases; 77 probable cases). To date, around 13.4 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 1.9 per million 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 11 November 2021 (to account for the time to onset of TTS). To that date, approximately 13.3 million doses of AstraZeneca have been administered, made up of around 6.9 million first doses and 6.4 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/164; 5.0%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 21 probable cases of TTS following second doses and that to date, six 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

ATAGI also notes that following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and AstraZeneca has not been established. However as a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca in different age cohorts and scenarios
- additional guidance on the use of COVID-19 vaccines in outbreak settings
- response to NSW COVID-19 outbreak
- additional strategies to combat the risk posed by the Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 1 December 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 1 December 2021.

Date published: 3 December 2021

Audience: General public

On Wednesday 1 December 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including current COVID-19 outbreaks involving the Delta variant, including in New South Wales, 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 notes strategies to address barriers to vaccination in this important population.

As at 29 November 2021, over 39 million doses 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 has previously noted the Therapeutic Goods Administration (TGA) registration of Pfizer and Moderna for use in children from 12 years of age and supports COVID-19 vaccination in all adolescents from 12 years of age. These statements can be found in the Resources section below.

ATAGI also reinforces the importance of COVID-19 vaccine booster program. Adults who have completed their primary course of COVID-19 vaccines 6 or more months ago should receive a booster vaccine.

ATAGI are also watching data on the newly reported Omicron variant closely and have released a statement.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 2164 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 693 suspected myocarditis reports. Of these suspected cases, 354 cases of myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 238 cases occurred following the second dose.

ATAGI also notes that the TGA is investigating 37 reported cases of myocarditis following Moderna vaccine, of which 21 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

In children 12-17 years, 137 cases of myocarditis have been reported following Pfizer vaccine, with the rate following first doses estimated a 6.8 per 100,000 doses in males and 1.4 per 100,000 in females. After second doses in this age group, the rate of myocarditis is 10.6 and 2.4 per 100,000 in males and females respectively. There is not yet sufficient data following Moderna vaccine (n=14) in this age group for a meaningful analysis.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from some international safety surveillance systems demonstrating that the risk of myocarditis is higher, albeit still rare following Moderna compared with Pfizer (<2 excess cases per 100,000 second dose vaccine recipients younger than 40 years). There is no evidence to suggest more severe disease with either vaccine.

While data on myocarditis following booster doses of Pfizer vaccine is limited, preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and are encouraged to seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement on TTS cases, including clinical outcomes, can be found here. ATAGI notes that scientific studies have suggested a potential mechanism where the AstraZeneca vaccine may cause TTS, and the implications of the findings are being considered.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 166 cases of confirmed or probable TTS (88 confirmed cases; 78 probable cases). To date around 13.5 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 2 per million

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 18 November 2021 (to account for the time to onset of TTS). To that date, approximately 13.4 million doses of AstraZeneca have been administered, made up of around 6.9 million first doses and 6.5 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:

- 2.5 per 100,000 in those <60 years; and
- 1.9 per 100,000 in those ≥60 years.

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/166; <5.0%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 22 probable cases of TTS following second doses and that to date, six 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

ATAGI also notes that following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and AstraZeneca has not been established. However as a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 8 December 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 8 December 2021.

Date published: 10 December 2021

Audience: General public

On Wednesday 8 December 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including the Omicron variant of concern.

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 5 years of age and reinforces the benefits of COVID-19 boosters from 18 years of age.

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

As at 8 December 2021, almost 40 million doses 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 that on 5 December 2021, the Therapeutic Goods Administration (TGA) provided provisional registration of the Pfizer COVID-19 vaccine for use in individuals aged 5 to 11 years and recommends is use in this age group.

ATAGI also notes the TGA provided provisional registration of the Moderna COVID-19 vaccine as a booster dose in adults and as a third primary dose in immunocompromised people, and will provide advice in the near future.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 2474 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 786 suspected myocarditis reports. Of these suspected cases, 389 cases of myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 261 cases occurred following the second dose.

ATAGI also notes that the TGA is investigating 51 reported cases of myocarditis following Moderna vaccine, of which 25 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA Weekly Report noted that review by an independent Vaccine Safety Investigation Group on 7 December 2021 found that two fatal cases of myocarditis were not found to be related to vaccination based on the available information.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from some international safety surveillance systems suggesting that the risk of myocarditis may be higher, albeit still rare following Moderna compared with Pfizer (<2 excess cases per 100,000 second dose vaccine recipients younger than 40 years). There is no evidence to suggest more severe disease with either vaccine. While data from the US paediatric program (5-11 year old cohort) has not yet been formally reported, early data on the incidence of myocarditis provided by international surveillance networks have not identified concerning safety signals.

While data on myocarditis following booster doses of Pfizer vaccine is limited, preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Other adverse events following mRNA vaccines

ATAGI notes that one suspected case of multisystem inflammatory syndrome following Pfizer vaccination, however there was not enough medical information to determine if it was related to the vaccine. More information is available in the TGA Weekly Report.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and are encouraged to seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement on TTS cases, including clinical outcomes.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 169 cases of confirmed or probable TTS (88 confirmed cases; 81 probable cases). To date around 13.6 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 2 per million 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 25 November 2021 (to account for the time to onset of TTS). To that date, approximately 13.5 million doses of AstraZeneca have been administered, made up of around 6.9 million first doses and 6.4 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/169; <5.0%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 22 probable cases of TTS following second doses and that to date, five 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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). ATAGI notes two fatal cases of GBS that were assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

As a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

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

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

Date published: 18 December 2021

Audience: General public

On Wednesday 15 December 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in Australia including the Omicron variant of concern and the timing of COVID-19 booster vaccination.

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 5 years of age.

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

As at 13 December 2021, over 40 million doses 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 that the Therapeutic Goods Administration (TGA) has provided provisional registration of the Pfizer COVID-19 vaccine for use in individuals aged 5 to 11 years and recommends is use in this age group.

ATAGI also notes the TGA has provided provisional registration of the Moderna COVID-19 vaccine as a booster dose in adults and as a third primary dose in immunocompromised people.

ATAGI reinforces the benefits of COVID-19 boosters for those who completed their primary course of COVID-19 vaccines five or more months ago.

ATAGI recommends either Pfizer or Moderna COVID-19 vaccine as a booster.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 2597 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 826 suspected myocarditis reports. Of these suspected cases, 400 cases of myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 269 cases occurred following the second dose.

ATAGI also notes that the TGA is investigating 65 reported cases of myocarditis following Moderna vaccine, of which 33 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA Weekly Report noted that review by an independent Vaccine Safety Investigation Group on 7 December 2021 found that two fatal cases of myocarditis were not found to be related to vaccination based on the available information.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from several international safety surveillance systems demonstrating that the observed rate of myocarditis is higher, albeit still rare following Moderna compared with Pfizer. The highest observed differences are seen in young males after second doses. There is some evidence to suggest that the risk of myocarditis after second doses of mRNA COVID-19 vaccines may be reduced with a longer interval between primary doses (see below).

There is no evidence to suggest more severe disease with either vaccine.

While data from the US paediatric program (5–11 year old cohort) has not yet been formally reported, early data on the incidence of myocarditis provided by international surveillance networks have not

identified concerning safety signals.

ATAGI also notes that one suspected case of multisystem inflammatory syndrome following Pfizer vaccination, however there was not enough medical information to determine if it was related to the vaccine. More information is available in the TGA Weekly Report.

ATAGI notes there have been no reports of myocarditis submitted to the TGA following a booster or third dose of vaccine. Preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Dose interval

The registered interval between primary doses for the Pfizer COVID-19 vaccine is 3–6 weeks, and for the Moderna COVID-19 vaccine is 4–6 weeks.

A longer interval (up to 8 weeks) may reduce the risk of myocarditis after vaccination, particularly for people at the highest risk of this side effect (males under 30 years). A longer interval may also improve the immune response to COVID-19 vaccines.

A shorter interval (no less than 4 weeks for the Moderna COVID-19 vaccine or 3 weeks for the Pfizer COVID-19 vaccine) will provide earlier protection. This may be particularly important in outbreak situations, impending immunosuppression, or prior to international travel.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and are encouraged to seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement on TTS cases, including clinical outcomes, can be found here. There have been no reports of TTS submitted to the TGA following a booster or third dose of vaccine.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 170 cases of confirmed or probable TTS (88 confirmed cases; 82 probable cases). To date around 13.6 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 2 per million 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 December 2021 (to account for the time to onset of TTS). To that date, approximately 13.6 million doses of AstraZeneca have been administered, made up of around 6.9 million first doses and 6.7 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria (PDF, 1.48 KB). 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/170; <5.0%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 23 probable cases of TTS following second doses and that to date, five 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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). ATAGI notes two fatal cases of GBS that were assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

As a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, 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 Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years; and
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

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ATAGI update following weekly COVID-19 meeting – 22 December 2021

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 22 December 2021.

Date published: 24 December 2021

Audience: General public

On Wednesday 22 December 2021 ATAGI reviewed the latest developments relating to COVID-19 and COVID-19 vaccine safety. In addition, ATAGI continues to monitor COVID-19 epidemiology in

Australia including the Omicron variant of concern and the timing of COVID-19 booster vaccination.

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 5 years of age.

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

As at 20 December 2021, over 41 million doses 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 that the Therapeutic Goods Administration (TGA) has provided provisional registration of the Pfizer COVID-19 vaccine for use in individuals aged 5 to 11 years and recommends is use in this age group.

ATAGI also notes the TGA has provided provisional registration of the Moderna COVID-19 vaccine as a booster dose in adults and as a third primary dose in immunocompromised people.

ATAGI reinforces the benefits of COVID-19 boosters and is currently reviewing the optimal interval between primary COVID-19 vaccination and boosters.

ATAGI recommends either Pfizer or Moderna COVID-19 vaccine as a booster.

Comirnaty (Pfizer) and Spikevax (Moderna)

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 2745 reports of suspected myocarditis and/or pericarditis following Pfizer and in particular 885 suspected myocarditis reports. Of these suspected cases, 415 cases of myocarditis or myopericarditis have been assessed as meeting the CDC case definition (level 1, 2, or 3), of which 283 cases occurred following the second dose. ATAGI notes the TGA have reported 1 case following a third dose.

ATAGI also notes that the TGA is investigating 75 reported cases of myocarditis following Moderna vaccine, of which 37 have been assessed as meeting the CDC case definition (level 1, 2, or 3). ATAGI are monitoring international data on the rates of myocarditis and pericarditis.

The TGA Weekly Report noted that review by an independent Vaccine Safety Investigation Group on 7 December 2021 found that two fatal cases of myocarditis were not consistent with being caused by based on the available information.

The TGA report detailing the estimated rate of myocarditis following first and second doses by age and sex is published weekly. The observed rates in Australia are consistent with international data. These data show a higher rate in younger individuals (particularly younger males) and following second doses. 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.

ATAGI has this week again reviewed international data comparing the rates of myocarditis and pericarditis reported after Pfizer and Moderna vaccines. ATAGI notes evidence from several international safety

surveillance systems demonstrating that the observed rate of myocarditis is higher, albeit still rare following Moderna compared with Pfizer. The highest observed differences are seen in young males after second doses. There is some evidence to suggest that the risk of myocarditis after second doses of mRNA COVID-19 vaccines may be reduced with a longer interval between primary doses (see below).

There is no evidence to suggest more severe disease with either vaccine.

While data from the US paediatric program (5-11 year old cohort) has not yet been formally reported, early data on the incidence of myocarditis provided by international surveillance networks have not identified concerning safety signals.

ATAGI also notes that one suspected case of multisystem inflammatory syndrome following Pfizer vaccination, however there was not enough medical information to determine if it was related to the vaccine. More information is available in the TGA Weekly Report from 9 December 2021.

ATAGI notes there has been one report of myocarditis submitted to the TGA following a booster or third dose of vaccine. Preliminary data from Israel on the use of Comirnaty as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.

Dose interval

The registered interval between primary doses for the Pfizer COVID-19 vaccine is at least 21 days apart, and for the Moderna COVID-19 vaccine it is recommended to administer the second dose 28 days after the first dose.

A longer interval (up to 8 weeks) may reduce the risk of myocarditis after vaccination, particularly for people at the highest risk of this side effect (males under 30 years). A longer interval may also improve the immune response to COVID-19 vaccines.

A shorter interval (no less than 4 weeks for the Moderna COVID-19 vaccine or 3 weeks for the Pfizer COVID-19 vaccine) will provide earlier protection. This may be particularly important in outbreak situations, impending immunosuppression, or prior to international travel.

Risks and benefits

ATAGI reinforces that the benefits of vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) strongly outweigh the risks of myocarditis and/or pericarditis for any age group. ATAGI recommends either vaccine in those eligible. ATAGI will continue to explore potential differences in the rates of adverse events by brand and consider updated advice in the future.

People who are receiving vaccination with Comirnaty (Pfizer) and Spikevax (Moderna) should be aware of this potential complication as part of providing informed consent. People should be made aware of symptoms of myocarditis and/or pericarditis and are encouraged to seek prompt medical attention.

Vaxzevria (AstraZeneca)

Thrombosis and Thrombocytopenia Syndrome (TTS)

ATAGI considered an update from the TGA on current confirmed cases of TTS and those under investigation. The latest TGA statement on TTS cases, including clinical outcomes, can be found here. There have been no reports of TTS submitted to the TGA following a booster or third dose of vaccine.

ATAGI examined estimates of risk of TTS by age group in Australia and note that there have been 170 cases of confirmed or probable TTS (88 confirmed cases; 82 probable cases). To date around 13.6 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 2 per million 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 9 December 2021 (to account for the time to onset of TTS). To that date, approximately 13.6 million doses of AstraZeneca have been

administered, made up of around 6.9 million first doses and 6.7 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:

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

ATAGI notes that the TGA Weekly Report includes a breakdown of current rates by decade of age and a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. 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 TTS primary care guide. This may contribute to the lower-case fatality ratio observed in Australia compared to those reported internationally. The overall case fatality ratio in Australia (8/170; <5.0%) is lower than that reported in other settings. ATAGI notes that the TGA is continuing to investigate 23 probable cases of TTS following second doses and that to date, five 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 as easy bruising and bleeding from the nose or gums.

ATAGI notes that following an investigation by the TGA, the AstraZeneca Product Information has been updated to include a warning about ITP. ATAGI also notes one fatal case that was assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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). ATAGI notes two fatal cases of GBS that were assessed by an expert Vaccine Safety Investigation Group as being likely to be vaccine related.

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.

As a precautionary measure, warning statements about GBS have been added to the AstraZeneca Product Information in response to rare cases following vaccination.

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.

From 1 October 2021, all Australians aged 12 and over, including those Australians aged 60 and over, are now eligible to receive a Pfizer or Moderna COVID-19 vaccine. This means older Australians can now choose the Pfizer, Moderna, or AstraZeneca vaccine.

Everyone can now book their Pfizer vaccine through GPs and state led vaccination hubs, and the Moderna vaccine through Pharmacies in each of the states and territories.

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

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 TTS primary care guide, 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 risk-benefit document, which provides advice to help consumers make informed decisions about the risks and benefits of AstraZeneca in different age cohorts and scenarios
- additional guidance on the use of COVID-19 vaccines in outbreak settings
- response to NSW COVID-19 outbreak
- additional strategies to combat the risk posed by the Delta variant 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 statement regarding vaccination of adolescents aged 12–15 years
- ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia.

Tags: Immunisation | Australian Technical Advisory Group on Immunisation (ATAGI) | Communicable diseases

Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 12 January 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 12 January 2022.

Date published: 17 January 2022

Audience: General public

Latest recommendation updates:

- Previously, severely immunocompromised people aged 12 years and older were recommended to receive a 3rd primary dose of COVID-19 vaccine to optimise their protection. This recommendation has now been expanded to include severely immunocompromised children aged 5 to 11 years. More information available below.

In 2022, the full ATAGI committee will continue to meet weekly to ensure the timely provision of advice to the Australian Government and in turn to health care providers and consumers regarding the administration of COVID-19 vaccines in the Australian context.

ATAGI acknowledges the significant contribution that Professors Christopher Blyth and Allen Cheng made in leading the development and consideration of advice for COVID-19 vaccines throughout 2020 and 2021. From January 2022, the ATAGI COVID-19 Working Group will be led by Professor Katie Flanagan and the Deputy Chair of ATAGI, Professor Michelle Giles.

Recent ATAGI considerations

On Wednesday 12 January 2022, ATAGI met for the first time this year and reviewed the latest developments relating to COVID-19 immunisation and COVID-19 vaccine safety. ATAGI continues to monitor COVID-19 epidemiology in Australia including the Omicron variant of concern and the timing of COVID-19 booster vaccinations as outlined in our 24 December 2021 advice.

ATAGI continues to highlight that vaccination is a key public health intervention. Australia's COVID-19 vaccination program aims to protect all people in Australia from the harm caused by SARS-CoV-2, the virus that causes COVID-19. Vaccination prevents serious disease and death, and reduces disease transmission. ATAGI recommends COVID-19 vaccination for all Australians from 5 years of age.

As at 12 January 2022, over 45 million doses of COVID-19 vaccines have been administered in Australia. Booster doses of COVID-19 vaccines are likely to increase protection against infection with the Omicron variant. ATAGI encourages adults aged 18 years and over to

receive a booster dose as soon as they are eligible. Currently booster doses are recommended from 4 months after the primary course. As soon as practicalities allow, ATAGI recommends providing boosters to all eligible adults from a minimum of 3 months following the primary course. For more information see the latest ATAGI booster statement.

Dose intervals for vaccination of 5-11 year old children

ATAGI continues to recommend a 2 dose schedule for the 5-11 year old cohort of Comirnaty (Pfizer), 8 weeks apart. The interval can be shortened in special circumstances to a minimum of 3 weeks, for higher risk groups (such as those with medical risk factors for severe illness) in the context of ongoing community transmission.

This also includes severely immunocompromised children aged 5-11 years, who are now recommended to have three doses as part of the primary vaccine course. The 3rd primary dose guidance has been updated to include children aged 5 years and older. The recommended interval for the 3rd primary dose is 2 to 6 months after the 2nd dose of vaccine. ATAGI note this is consistent with the recent decision by the Centres for Disease Control.

Upcoming ATAGI considerations

ATAGI continues to review and consider the impacts of the ongoing Omicron outbreak across most jurisdictions in Australia. This includes providing a national approach to vaccine recommendations, both for the primary course and any subsequent booster doses.

The National Immunisation Program and the Australian Immunisation Register (AIR) have processes in place to identify whether an individual is up to date with recommended vaccines. ATAGI is now aiming to assist in formulating a decision framework regarding what is required to be considered ‘up to date’ with COVID-19 vaccines and the role of booster doses.

ATAGI also noted the Therapeutic Goods Administration (TGA) is considering a submission on COVID-19 vaccine from Novavax.

COVID-19 vaccine safety

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation with COVID-19 vaccines, including regular updates from the TGA. The TGA's Weekly Report provides a detailed breakdown of adverse events following immunisation.

From 10 January 2022, children aged 5-11 can access COVID-19 vaccinations.

ATAGI notes the early vaccine safety data from the US paediatric program (5-11 year old cohort) has not identified concerning safety signals in this cohort.

ATAGI also notes international evidence from the US and France that suggests vaccination may provide some protection in adolescents aged 12 and over from a rare post-infectious inflammatory condition unique to SARS-CoV-2 infection, known as Paediatric inflammatory multisystem syndrome (PIMS-TS; also known as multisystem inflammatory syndrome in children, MIS-C).

ATAGI reinforces that the benefits of vaccination with COVID-19 vaccines in Australia and people should be aware of potential risks and benefits of vaccination as part of providing informed consent.

Resources and recent statements

ATAGI recommends review of the following key resources:

- Clinical Guidance for COVID-19 vaccination providers (new look web version of the clinical guidance)
- ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised

- 24 December 2021: ATAGI Statement on the Omicron variant of concern and the timing of COVID-19 booster vaccination
- 17 December 2021: A statement from ATAGI about the COVID-19 Omicron variant.
- 12 December 2021: ATAGI recommendations on the use of Spikevax (Moderna) as a COVID-19 booster vaccine
- 10 December 2021: ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 19 January 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 19 January 2022.

Date published: 24 January 2022

Audience: General public

Latest recommendation updates

- ATAGI has updated its advice on temporary deferral of vaccination following COVID-19 infection from 6 months to 4

months.

Recent ATAGI considerations

On Wednesday 19 January 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As at 19 January 2022, over 46 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages adults aged 18 years and over to receive a booster dose as soon as they are eligible.

ATAGI continues to monitor COVID-19 epidemiology in Australia including the Omicron variant of concern and the timing of COVID-19 booster vaccinations as outlined in our 24 December 2021 advice.

Vaccination post infection

ATAGI continues to review the evidence and recommendations on vaccination post-infection in light of the recent Omicron variant.

ATAGI has decreased the time allowable for deferral of vaccination after prior SARS-CoV-2 infection to 4 months. This is due to the increased risk of re-infection with the Omicron variant, particularly for those who had a Delta variant infection in 2021.

ATAGI continues to advise that previous infection is not a contraindication to vaccination and that vaccination can occur following recovery of acute illness from COVID-19.

Currently advice states that vaccination can occur following resolution of acute illness. A precaution for all vaccination is acute illness. This may be acute systemic signs of illness or fever. This is to avoid adverse events (including common side effects of vaccination) in an already ill person or to avoid attributing illness symptoms to vaccination.

Those with prolonged symptoms of COVID-19 should be vaccinated on a case-by-case basis.

How to stay up to date with COVID-19 vaccines

ATAGI continues to develop a framework of what is considered up-to-date with COVID-19 vaccinations. This framework includes advice on how to stay up to date to have optimal personal and population vaccination benefits. This work will feed into existing processes in the National Immunisation Program and the Australian Immunisation Register (AIR) to identify whether an individual is up to date with recommended vaccines.

Novavax

ATAGI notes that the Therapeutic Goods Administration have granted provisional approval to Biocelect (on behalf of Novavax) for its COVID-19 vaccine, Nuvaxovid. ATAGI discussed recommendations on the use of Novavax in the Australian population and will release its recommendations in the coming days.

Children aged 5 to 11 years

In the weekly update from 12 January 2022, ATAGI stated the dose interval for children at higher risk of COVID-19 (e.g. some underlying medical conditions) may be shortened from 8 to 3 weeks in the context of ongoing community transmission. A list of underlying medical conditions associated with a higher risk of severe COVID-19 is available. See Clinical features of COVID-19 disease.

Upcoming ATAGI considerations

ATAGI is monitoring evidence on boosters, including boosters for people under the age of 18. There are currently no COVID-19 vaccines registered in Australia as boosters for people under the age of 18 years.

COVID-19 vaccine safety

This week the new ATAGI COVID-19 Safety Group met for the first time to monitor known and emerging serious adverse events following immunisation and other safety issues in the delivery of COVID-19 vaccines. The ATAGI COVID-19 Safety Group will provide regular updates to the ATAGI COVID-19 Working Group. The TGA's Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- Clinical Guidance for COVID-19 vaccination providers (new look web version of the clinical guidance)
- ATAGI Expanded guidance on temporary medical exemptions for COVID-19 vaccines.
- 24 December 2021: ATAGI Statement on the Omicron variant of concern and the timing of COVID-19 booster vaccination
- 10 December 2021: ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years
- 19 January 2022: Updated ATAGI recommendations on the use of a 3rd primary dose of COVID-19 vaccine in severely immunocompromised individuals

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Australian Technical Advisory Group on Immunisation (ATAGI) | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 27 January 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 27 January 2022.

Date published: 31 January 2022

Audience: General public

Latest recommendation updates:

- ATAGI has released clinical recommendations on the use of Nuvaxovid (Novavax) COVID-19 vaccine.

Recent ATAGI considerations

On Thursday 27 January 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 26 January 2022, over 48 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages all adults aged 18 years and over to receive a booster dose as soon as they are eligible.

ATAGI continues to monitor COVID-19 epidemiology in Australia including the Omicron variant of concern and the timing of COVID-19 booster vaccinations as outlined in our 24 December 2021 advice.

Booster doses for people under the age of 18 years

ATAGI has begun considerations of COVID-19 vaccine booster doses in people under the age of 18.

After the meeting, ATAGI noted that on 28 January 2022 the TGA provisionally approved the Pfizer vaccine as a booster in 16-17 year-olds. ATAGI will release recommendations on the use of boosters in this age group shortly.

Vaccination post-infection

Last week, ATAGI reduced the time allowable for deferral of vaccination following SARS-CoV-2 (the virus that causes COVID-19) infection from 6 months to 4 months. ATAGI continues to review the evidence regarding the optimal timing of vaccination following COVID-19 disease and will enhance its clinical guidance on this soon. ATAGI notes there are several reasons people may choose to be vaccinated soon after infection rather than defer to 4 months. These may include:

- if the individual is at greater risk of severe COVID-19
- if the infection occurred in the Delta period, i.e., before Omicron was introduction to Australia in late November (as evidence suggests Omicron infection is more likely in people who had the Delta variant)

- if the individual has had not completed their primary COVID-19 vaccine course and therefore has less protection against COVID-19

COVID-19 vaccine safety

This week the ATAGI COVID-19 Safety Group provided an update to the ATAGI COVID-19 Working Group. The TGA's Weekly Report provides a detailed breakdown of adverse events following immunisation.

The ATAGI COVID-19 Safety Group notes new information on vaccine safety in the 5 to 11 year old COVID-19 vaccine program is available publicly on the AusVaxSafety website.

Resources and recent statements

ATAGI recommends review of the following key resources:

- ATAGI Statement on the use of Novavax COVID-19 vaccine (Nuvaxovid)
- Clinical Guidance for COVID-19 vaccination providers (new look web version of the clinical guidance)
- 24 December 2021: ATAGI Statement on the Omicron variant of concern and the timing of COVID-19 booster vaccination
- 19 January 2022: Updated ATAGI recommendations on the use of a 3rd primary dose of COVID-19 vaccine in severely immunocompromised individuals
- A list of risk factors associated with severe COVID-19 is available in the Clinical guidance.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 2 February 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 2 February 2022.

Date published: 3 February 2022

Audience: General public

Latest recommendation updates:

- ATAGI provided advice on Pfizer boosters for individuals aged 16-17 years.

Recent ATAGI considerations

On Wednesday 2 February 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As at 2 February 2022, over 50 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

Boosters for adolescents aged 16-17 years

ATAGI recommends a booster vaccination with Comirnaty (Pfizer) COVID-19 vaccine, for all adolescents aged 16-17 years who have previously received any TGA approved or recognised vaccines for their primary vaccine schedule. This booster dose is available from 3 months after receiving their last primary dose.

The Pfizer vaccine is the only brand currently registered for use as a booster dose in this age group. ATAGI will update this advice if other vaccines are approved.

Full details of ATAGI's advice is available.

Upcoming ATAGI considerations

ATAGI is continuing to monitor evidence on the effectiveness of vaccine boosters and national vaccination coverage rates.

COVID-19 vaccine safety

The ATAGI COVID-19 Safety Group will meet again this week to monitor known and emerging serious adverse events following immunisation and other safety issues in the delivery of COVID-19 vaccines. The ATAGI COVID-19 Safety Group provides regular updates to the ATAGI COVID-19 Working Group. The Therapeutic Goods Administration (TGA) Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised .
- Clinical Guidance for COVID-19 vaccination providers (new look web version of the clinical guidance).
- 24 December 2021: ATAGI Statement on the Omicron variant of concern and the timing of COVID-19 booster vaccination.
- 10 December 2021: ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 9 February 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 9 February 2022.

Date published: 10 February 2022

Audience: General public

Latest recommendation updates:

- ATAGI provided advice on defining ‘up-to-date’ status.

Recent ATAGI considerations

On Wednesday 9 February 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 8 February 2022, over 51 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

ATAGI Advice on defining 'up-to-date' status

ATAGI recognises the importance of providing guidance on a person's 'up-to-date' vaccination status from the clinical benefit perspective and also serving as a basis for policies for the public health management of the COVID-19 pandemic in a domestic context.

ATAGI has issued new advice defining up-to-date vaccination status as defined by the number and timing of appropriate COVID-19 vaccine doses recommended for and received by an individual, according to their age and other factors.

ATAGI notes that the concept of being up-to-date with vaccination may be different to what has been required to be 'fully vaccinated', which is a term that has been used in the context of public health orders or mandates in various settings, including border control, quarantine, workplaces (e.g. aged care, health care), and in other select settings. These applications may involve legal and policy implications and are not within the remit of ATAGI but should be considered in the implementation of this advice by governments and/or private entities as appropriate.

The ATAGI COVID-19 up-to-date vaccination status recommendations will be utilised by the Australian Immunisation Register to assist in determining whether an individual has had the recommended vaccine doses.

Full details of ATAGI's advice is available here.

Upcoming ATAGI considerations

ATAGI is continuing to monitor evidence on the effectiveness of vaccine boosters and national vaccination coverage rates.

COVID-19 vaccine safety

The Therapeutic Goods Administration (TGA) Weekly Report provides a detailed breakdown of adverse events following immunisation.

Duration of observation after COVID-19 vaccination

ATAGI reaffirms its recommendation that individuals who receive a COVID-19 vaccine, regardless of the vaccine brand and the dose number, should be observed for at least 15 minutes following vaccine administration at the clinic site, in accordance with the current recommendations in the Australian Immunisation Handbook.

Some people with specific allergies as specified in the Precautions section of the current ATAGI Clinical guidance for COVID-19 vaccine providers will require observation for at least 30 minutes following administration of a COVID-19 vaccine dose.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised .

- Clinical Guidance for COVID-19 vaccination providers (new look web version of the clinical guidance).
- 24 December 2021: ATAGI Statement on the Omicron variant of concern and the timing of COVID-19 booster vaccination.
- 10 December 2021: ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 16 February 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 16 February 2022.

Date published: 21 February 2022

Audience: General public

Latest recommendation updates

- In addition to polymerase chain reaction (PCR), rapid antigen tests (RATs) (reported to the relevant jurisdictional system) are

now acceptable proof of prior infection for the purposes of temporary medical exemptions.

Recent ATAGI considerations

On Wednesday 16 February 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 15 February 2022, over 52 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

Moderna for children aged 6 to 11 years

ATAGI notes the Therapeutic Goods Administration (TGA) has provisionally approved Spikevax (Moderna) for use in children aged 6-11 years. ATAGI is currently considering the efficacy and safety data for Moderna in this age group and will be releasing recommendations soon.

Novavax use as a booster

Currently, Nuvaxovid (the Novavax COVID-19 vaccine) is registered by the TGA and recommended by ATAGI as use as a primary course vaccine only. Novavax is not yet registered or recommended for use as a booster. ATAGI is considering the available evidence regarding the efficacy and safety of Novavax as use as a booster and will update its advice in the coming weeks.

Children's vaccine dose interval

ATAGI has made recommendations that children aged 5-11 should receive Pfizer COVID-19 vaccines doses 8 weeks apart. It is appropriate to consider shortening the interval in special circumstances to a minimum of 3 weeks, including for those at high risk of severe COVID. ATAGI has now updated its advice to include all NDIS participants on the list of underlying medical conditions at higher risk of severe COVID-19 to align with previous advice for adolescents aged 12-15 years.

Parents and providers are encouraged to weigh up the benefits of earlier protection with the benefit of having a longer dose interval. A dose interval of 8 weeks may improve protection and longevity of protection from the vaccine. A longer interval may also reduce the risk of rare adverse events such as myocarditis.

Upcoming ATAGI considerations

ATAGI is continuing to monitor evidence on the long-term effectiveness of vaccine boosters and national vaccination coverage rates.

COVID-19 vaccine safety

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 18 February 2022: ATAGI guidance on temporary medical exemptions for COVID-19 vaccines.
- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised .
- Clinical Guidance for COVID-19 vaccination providers (new look web version of the clinical guidance).
- 24 December 2021: ATAGI Statement on the Omicron variant of concern and the timing of COVID-19 booster vaccination.
- 10 December 2021: ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 23 February 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 23 February 2022.

Date published: 28 February 2022

Audience: General public

Latest recommendation updates:

- ATAGI recommends Spikevax (Moderna) COVID-19 vaccine can be used for primary vaccination in children aged 6-11 years.

- The Pfizer COVID-19 vaccine continues to be available and recommended for 5-11 year old children. The Moderna COVID-19 vaccine is an alternative option for children aged 6-11 years. Pfizer remains the only vaccination available for children who are 5 years old. There are currently no vaccines licensed for children aged 4 years and under.
- Side effects reported following the Moderna COVID-19 vaccine have been mild to moderate and transient but may be more common than those following Pfizer COVID-19 vaccine.

ATAGI recommends that immunisation providers are vigilant for the potential for dosing errors with the Moderna vaccine for children.

Recent ATAGI considerations

On Wednesday 23 February 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 21 February 2022, over 53 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

ATAGI Clinical Guidance for Vaccination Providers

The ATAGI Clinical Guidance for Vaccination Providers continues to be regularly reviewed and updated with current recommendations.

Upcoming ATAGI considerations

Myocarditis Guidance

ATAGI continues to review current and emerging data regarding adverse events following COVID-19 vaccination, including rates of myocarditis. ATAGI is currently reviewing the Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines and will be releasing an update soon.

ATAGI is continuing to monitor evidence on the long-term effectiveness of vaccine boosters and national vaccination coverage rates.

COVID-19 vaccine safety

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 18 February 2022: ATAGI guidance on temporary medical exemptions for COVID-19 vaccines.
- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised .
- Clinical Guidance for COVID-19 vaccination providers (new look web version of the clinical guidance).
- 24 December 2021: ATAGI Statement on the Omicron variant of concern and the timing of COVID-19 booster vaccination.
- 10 December 2021: ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 2 March 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 2 March 2022.

Date published: 7 March 2022

Audience: General public

Latest recommendation updates

ATAGI provided updated advice on COVID-19 booster vaccinations, including recommendation that the Novavax vaccine can be used as a booster in Australians aged 18 and over where an mRNA vaccine is not suitable.

Recent ATAGI considerations

On Wednesday 2 March 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 1 March 2022, over 54 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

COVID-19 Vaccine Claims Scheme

ATAGI received an update on the implementation of the COVID-19 vaccine claims scheme.

Evidence relating to second COVID-19 booster doses

ATAGI continues to monitor evidence on the long-term effectiveness of vaccine boosters, including emerging international data on:

- effectiveness
- waning of immunity
- potential need for second booster doses.

Upcoming ATAGI considerations

ATAGI will continue to review current and emerging evidence on COVID-19 booster doses over the coming weeks, including national coverage data, as part of broader considerations around potential need for subsequent doses, particularly coming into the winter months.

COVID-19 vaccine safety

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations
- 28 February 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 18 February 2022: ATAGI guidance on temporary medical exemptions for COVID-19 vaccines.
- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 9 March 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 9 March 2022.

Date published: 11 March 2022

Audience: General public

Latest recommendation updates

ATAGI have not made any new updates since 2 March 2022.

Recent ATAGI considerations

On Wednesday 9March 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 8 March 2022, over 54 million doses of COVID-19 vaccines have been administered in Australia. ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

Upcoming ATAGI considerations

Evidence relating to second COVID-19 booster doses

ATAGI is continuing to monitor and discuss current and emerging evidence on COVID-19 booster doses, including meeting with international counterparts, reviewing data on effectiveness, waning of immunity and national vaccination coverage as part of broader considerations around potential need for subsequent booster doses, particularly coming into the winter months.

COVID-19 vaccine safety

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations
- 28 February 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 18 February 2022: ATAGI guidance on temporary medical exemptions for COVID-19 vaccines.

- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised .

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 16 March 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 16 March 2022.

Date published: 21 March 2022

Audience: General public

Latest recommendation updates

ATAGI have not made any new updates since 9 March 2022.

Recent ATAGI considerations

On Wednesday 16 March 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 14 March 2022, over 55 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI encourages parents of children aged 5-11 to make an appointment for the second dose of COVID-19 vaccine. ATAGI also encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

Upcoming ATAGI considerations

Evidence relating to second COVID-19 booster doses

ATAGI is currently finalising advice to the Minister for Health on the need for a winter dose of COVID-19 vaccine, particularly for older people, who are at a high risk of severe disease.

The development of this advice is based on a thorough review of all the current and emerging evidence on COVID-19 booster doses, including data on effectiveness, waning of immunity, international program settings, national vaccination coverage and operational flexibility where appropriate.

ATAGI will continue to regularly review the data on use of COVID-19 boosters and the epidemiology in Australia during autumn and winter, updating advice to the Government as required.

COVID-19 vaccine safety

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations
- 28 February 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 18 February 2022: ATAGI guidance on temporary medical exemptions for COVID-19 vaccines.
- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised .

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags:

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Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 23 March 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 23 March 2022.

Date published: 28 March 2022

Audience: General public

Latest recommendation updates

ATAGI have provided recommendations on a winter booster dose of COVID-19 vaccine to increase vaccine protection before winter for specified population groups who are at greatest risk of severe illness from COVID-19 and who have received their primary vaccination course and first booster dose.

These groups are:

- Adults aged 65 years and older
- Residents of aged care or disability care facilities
- People aged 16 years and older with severe immunocompromise (as defined in the ATAGI statement on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised)
- Aboriginal and Torres Strait Islander people aged 50 years and older.

The additional winter booster dose can be given from 4 months or longer after the person has received their first booster dose, or from 4 months after a confirmed SARS-CoV-2 infection, if infection occurred since the person's first COVID-19 booster dose.

For other groups not listed above, there is insufficient evidence of the benefits of an additional booster dose to make recommendations at this time. ATAGI will continue to monitor emerging evidence and may recommend an additional dose for these groups in the future.

ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible.

For more information on COVID-19 boosters.

Recent ATAGI considerations

On Wednesday 23 March 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 22 March 2022, over 55 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI encourages parents of children aged 5-11 to make an appointment for the second dose of COVID-19 vaccine.

Ongoing ATAGI considerations

ATAGI is continuing to look at emerging evidence on the use of COVID-19 vaccines and treatments as part of its ongoing review of current recommendations.

ATAGI is also reviewing evidence on the use of Comirnaty (Pfizer) as a booster in adolescents aged 12-15 years, including data on serious illness, epidemiology and international use in this age group.

COVID-19 vaccine safety

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations
- 28 February 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 18 February 2022: ATAGI guidance on temporary medical exemptions for COVID-19 vaccines.
- 3 February 2022: ATAGI Statement on booster doses for adolescents 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine.
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are

severely immunocompromised .

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 30 March 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 30 March 2022.

Date published: 7 April 2022

Audience: General public

Latest recommendation updates

ATAGI Clinical Guidance and other provider resources have been updated with information on additional winter booster doses.

ATAGI have published advice on the use of sedation for COVID-19 vaccination which provides a broad overview of the principles for the use of sedation as one of a range of measures to assist in the safe administration of COVID-19 vaccines.

Recent ATAGI considerations

On Wednesday 30 March 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 29 March 2022, over 56 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI encourages parents of children aged 5-11 to make an appointment for the second dose of COVID-19 vaccine.

ATAGI encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible. More information on COVID-19 boosters.

Ongoing ATAGI considerations

ATAGI is continuing to review all available and emerging evidence on the use of COVID-19 vaccines and treatments as part of its ongoing review of current recommendations.

ATAGI is also continuing to review evidence on the use of COVID-19 booster doses in adolescents aged 12-15 years, including data on serious illness, epidemiology and international use in this age group, including use in those with immuno-compromising conditions.

COVID-19 vaccine safety

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation.

Resources and recent statements

ATAGI recommends review of the following key resources:

- 6 April 2022: ATAGI advice on use of sedation for COVID-19 vaccination
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations
- 28 February 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 18 February 2022: ATAGI guidance on temporary medical exemptions for COVID-19 vaccines
- 3 February 2022: ATAGI Statement on booster doses for adolescents aged 16 to 17 years
- 24 January 2022: ATAGI statement on the use of Novavax COVID-19 vaccine
- 19 January 2022: Updated ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 20 April 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 20 April 2022.

Date published: 21 April 2022

Audience: General public

Latest recommendation updates

- ATAGI advice on COVID-19 boosters in adolescents aged 12-15 years
- ATAGI advice on the use of sedation for COVID-19 vaccination has been published
- ATAGI advice on COVID-19 vaccine administration errors has been updated for additional booster dose administration errors.

Recent ATAGI considerations

On Wednesday 20 April 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 19 April 2022, over 57 million doses of COVID-19 vaccines have been administered in Australia.

Use of Booster doses in adolescents aged 12-15 years

On 8 April 2022 TGA provisionally approved the Pfizer COVID-19 vaccine as a booster in people aged 12-15 years. ATAGI released advice that it does not recommend booster doses of Pfizer COVID-19 vaccine in this age group, at this time.

ATAGI is continuing to consider evidence on the benefits and risks of boosters in this age group including the epidemiology, adverse events, and evidence of groups at higher risk of severe disease or groups that will benefit from further doses. ATAGI will update recommendations if required.

ATAGI continues to recommend young people aged 5 to 15 years receive a primary course of a COVID-19 vaccine, including those who may have previously had COVID-19. For most people this is 2 doses, or 3 primary doses for people who are severely immunocompromised.

ATAGI also encourages anyone aged 16 years and over to receive a booster dose as soon as they are eligible. More information on COVID-19 boosters is available on the Department of Health COVID-19

booster vaccine advice page.

Ongoing review of evidence and recommendations

As part of an ongoing review of current recommendations on the use of COVID-19 vaccines in Australia, ATAGI have been reviewing information relating to SARS-CoV-2 seroprevalence, modelling of COVID-19 in Australia and current epidemiology, and COVID-19 treatments.

Ongoing review of adverse events and safety information

The ATAGI COVID-19 Safety Group have undertaken a review of current and emerging data regarding rare adverse events of myocarditis and pericarditis following COVID-19 vaccination. Further information will be available shortly.

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 6 April 2022: ATAGI advice on the use of sedation for COVID-19 vaccination
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations

- 28 February 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 27 April 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 27 April 2022.

Date published: 29 April 2022

Audience: General public

Latest recommendation updates

- Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines including updates to mRNA COVID-19 vaccine dose

intervals and rates of myocarditis and pericarditis

- ATAGI clinical guidance for COVID-19 vaccine providers including updates to mRNA COVID-19 vaccine dose intervals and timing of vaccination post infection

Recent ATAGI considerations

On Wednesday 27 April 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 26 April 2022, over 57 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI Advice on mRNA COVID-19 vaccine dose intervals

The recommended dose interval for the 2 doses of the primary course of mRNA COVID-19 vaccines was previously:

- 3 to 6 weeks for Comirnaty (Pfizer)
- 4 to 6 weeks for Spikevax (Moderna).

ATAGI now recommends the dose interval between primary doses should be extended to 8 weeks.

The extended dose interval of 8 weeks has been shown to improve the immune response to vaccination and therefore may improve effectiveness. A longer dose interval may also reduce the risk of myocarditis and pericarditis. The longer dose interval is particularly recommended for groups at higher risk of this side effect (those under the age of 40 years).

The dose interval can be reduced (to a minimum of 3 weeks for Pfizer or 4 weeks for Moderna) for people at higher risk of severe COVID-19 (including older adults and people with underlying medical conditions), in an outbreak setting, or prior to international travel.

The risk of myocarditis and pericarditis following Nuvaxovid (Novavax) vaccine is unknown.

Providers can consider extending the interval between 2 primary doses of Novavax to 8 weeks (from a minimum of 3 weeks) to potentially improve effectiveness and reduce any potential risk of myocarditis and pericarditis.

ATAGI Advice on COVID-19 vaccination post infection

ATAGI have updated their advice on when people who have had SARS-CoV-2 infection should receive a subsequent COVID-19 vaccine dose. It is now recommended that all people should wait for 3 months after confirmed SARS-CoV-2 (the virus that causes COVID-19) infection before they receive their next COVID-19 vaccine dose. The next scheduled dose should then be given as soon as possible after this period.

This updated advice reflects the lower risk of reinfection with the Omicron variant within the first 3 months following a confirmed infection, particularly if prior COVID-19 vaccine doses have been received. It also recognises the Delta variant is no longer circulating in Australia and in the past 3 months Omicron has been the dominant variant. This advice may change if future variants of SARS-CoV-2 emerge.

Waiting for a 3-month period after infection before COVID-19 vaccination is intended to optimise protection for that person. A longer gap between infection and vaccination is likely to lead to a better immune response and result in longer protection from reinfection.

This change in recommendation applies to all people who are recommended to receive COVID-19 vaccination (i.e., from 5 years and above), regardless of how many COVID-19 vaccine doses they have received. It does not apply to other vaccines (for example, influenza vaccinations) which can continue to be administered as usual.

ATAGI will continue to review the evidence on protection from vaccination and infection and may update advice if required, including if a new variant emerges or another circumstance arises to cause COVID-19 vaccination to become more urgent.

For more information see: www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance.

Ongoing review of evidence and recommendations

As part of an ongoing review of current recommendations on the use of COVID-19 vaccines in Australia, ATAGI have been reviewing evidence relating to need for 4th (winter) doses of COVID-19 vaccine for at risk groups, including disability and those with certain co-morbidities and considerations will continue over the coming weeks.

Ongoing review of adverse events and safety information

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 29 April 2022: Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
- 29 April 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 4 May 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 4 May 2022.

Date published: 9 May 2022

Audience: General public

Latest recommendation updates

ATAGI have not published any updated advice or recommendations since 29 April 2022.

Recent ATAGI considerations

On Wednesday 4 May 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 4 May 2022, over 57 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI considered data on COVID-19 booster uptake and continued an examination of evidence relating to need for 4th (winter) doses of COVID-19 vaccine for at risk groups, including disability and those with certain co-morbidities.

Ongoing review of adverse events and safety information

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

ATAGI note the TGA Weekly Report from 5 May 2022 acknowledged a number of reports of suspected myocarditis and/or pericarditis in people who have received the Nuvaxovid (Novavax) vaccine. After assessing these against a set of internationally accepted criteria, the TGA determined one case was likely to represent myocarditis and 10 were likely to represent pericarditis.

TGA reporting indicates that to 1 May 2022 about 127,500 doses of Novavax have been administered in Australia, with the TGA receiving 632 reports of suspected adverse events. To date, no safety signals have been identified for Novavax based on this limited number of reports.

ATAGI continue to meet regularly and work with the TGA to consider safety of COVID-19 vaccines.

Resources and recent statements

More information can be found in the following resources:

- 29 April 2022: Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
- 29 April 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 11 May 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 11 May 2022.

Date published: 12 May 2022

Audience: General public

Latest recommendation updates

ATAGI have not published any updated advice or recommendations since 29 April 2022.

Recent ATAGI considerations

On Wednesday 11 May 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 10 May 2022, over 58 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI considered data on Omicron vaccine effectiveness in New South Wales and continued to examine evidence relating to need for 4th (winter) doses of COVID-19 vaccine for at risk groups, including individuals with disability and individuals with medical comorbidities.

Ongoing review of adverse events and safety information

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 29 April 2022: Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
- 29 April 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine

- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations.

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 18 May 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 18 May 2022.

Date published: 23 May 2022

Audience: General public

Latest recommendation updates

ATAGI have not published any updated advice or recommendations since 29 April 2022.

Recent ATAGI considerations

On Wednesday 18 May 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 17 May 2022, over 58 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI note the increasing number of influenza notifications occurring nationally and continue to encourage all eligible groups to receive an influenza vaccine as soon as possible.

Following a review of evidence relating to need for 4th (winter) doses of COVID-19 vaccine for at risk groups, ATAGI are finalising advice for expanded groups recommended to receive a 4th dose to protect against severe disease.

ATAGI continue to emphasise the importance of remaining up to date with COVID-19 vaccinations by receiving the primary course and a booster dose, with three doses providing protection against severe disease, hospitalisation and death for healthy people.

Ongoing review of adverse events and safety information

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 29 April 2022: Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
- 29 April 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation COVID-19

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 25 May 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 25 May 2022.

Date published: 27 May 2022

Audience: General public

Latest recommendation updates

- Expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19 including updated advice on groups recommended to receive an additional (Winter) booster.

Recent ATAGI considerations

On Wednesday 25 May 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 23 May 2022, over 58 million doses of COVID-19 vaccines have been administered in Australia.

Following a thorough examination of local and international evidence on the use of COVID-19 vaccines, booster doses and epidemiology, ATAGI have recommended the COVID-19 booster rollout program be expanded. A winter booster dose is now recommended for people aged 16-64 years who have:

- a medical condition that increases their risk of severe COVID-19 illness; and
- a disability with significant or complex health needs or multiple comorbidities which increase the risk of poor outcomes from COVID-19.

The Australian Government has accepted this recommendation and this change will take effect from Monday 30 May 2022.

The primary goal of the Australian COVID-19 vaccine program is to minimise the risk of severe disease, including hospitalisation and death, from COVID-19.

As such, ATAGI have recommended this change to ensure those who are at greater risk of developing severe disease receive the best possible protection throughout the winter months.

Healthy people aged 16 to 64 who do not have a risk factor for severe disease and who have received three doses of COVID-19 vaccine are not recommended to receive a winter booster dose at this time. This includes health care workers and pregnant women who do not have other risk factors.

People who are due for the winter dose but have had a recent infection of COVID-19 should delay their winter booster until 3 months after their infection.

ATAGI continue to emphasise the importance of remaining up to date with COVID-19 vaccinations by receiving the primary course and a booster dose, with three doses providing protection against severe disease, hospitalisation and death for healthy people.

ATAGI will continue to monitor disease modelling and the epidemiology of COVID-19 and may recommend wider vaccination to combat rapid increases in disease transmission in the future if the need arises.

ATAGI also recommends everyone in Australia over the age of 6 months should receive an influenza vaccination. Influenza vaccinations can be given at the same time as COVID-19 vaccines and should not be delayed.

Evidence for boosters for people aged 12-15 years and impact of vaccination on long COVID

As part of the regular review into existing recommendations, ATAGI considered new data on burden of COVID-19 disease (benefits of vaccination), risk of side effects (risks of vaccination), international recommendations and uncertainties in the current evidence with respect to COVID-19 booster use in people aged 12-15 years.

ATAGI also considered information on prolonged symptoms after COVID-19 (also known as long COVID) and the impacts of vaccination on long COVID.

ATAGI will continue to review all available and emerging evidence on the use of COVID-19 vaccines and long COVID.

Ongoing review of adverse events and safety information

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 25 May 2022: Expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 29 April 2022: Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
- 29 April 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation COVID-19

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 1 June 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 1 June 2022.

Date published: 6 July 2022

Audience: General public

Latest recommendation updates

ATAGI have not made any recommendations since 25 May 2022.

Recent ATAGI considerations

On Wednesday 1 June 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 30 May 2022, 59 million doses of COVID-19 vaccines have been administered in Australia.

With increasing numbers of influenza infections, ATAGI recommends everyone in Australia over the age of 6 months should receive an influenza vaccination. The influenza vaccine can be given at the same time as a COVID-19 vaccine and should not be delayed.

As part of an ongoing review of existing recommendations, ATAGI continues to examine data with respect to COVID-19 booster use in people aged 12-15 years and is currently finalising advice for those in this cohort most at risk of severe disease.

ATAGI will continue to review all available and emerging evidence on the use of COVID-19 vaccines.

Ongoing review of adverse events and safety information

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Next meeting

The next ATAGI COVID-19 Working Group meeting will be held in late June. The Working Group will continue to progress its work out of session during this time.

Resources and recent statements

More information can be found in the following resources:

- 25 May 2022: Expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 29 April 2022: Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
- 29 April 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine
- 2 March 2022: ATAGI updated advice on COVID-19 booster vaccinations

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation COVID-19

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 29 June 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 29 June 2022.

Date published: 5 July 2022

Audience: General public

Latest recommendation updates

- Recommendations on the use of Nuvaxovid (Novavax) COVID-19 boosters for people aged 18 years and older have been updated.

Recent ATAGI considerations

On Wednesday 29 June 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 28 June 2022, over 60 million doses of COVID-19 vaccines have been administered in Australia.

Novavax boosters

On 9 June 2022 the Therapeutic Goods Administration provisionally approved Nuvaxovid (Novavax) COVID-19 vaccine for use as a booster dose in people aged 18 years and older.

ATAGI have updated their recommendations for use of Novavax COVID-19 vaccine as a booster dose. mRNA vaccines (Pfizer and Moderna) remain the preferred COVID-19 vaccines for use as a booster dose in people aged 18 years and older.

Although not preferred, AstraZeneca or Novavax can be used as a booster dose in the following circumstances:

- People who have a contraindication to mRNA vaccines (including those who have had a serious adverse event following mRNA vaccines, e.g., a history of anaphylaxis or myocarditis attributed to an mRNA vaccine)
- People who do not prefer an mRNA vaccine.

Review of additional booster (winter) doses

As outlined in ATAGI statements on winter booster doses (25 March 2022 and 25 May 2022), ATAGI continue to review evidence on the need for winter booster doses for people outside of the currently identified high-risk groups.

The primary goal of the Australian COVID-19 vaccine program is to minimise the risk of severe disease, including hospitalisation and death, from COVID-19.

This week ATAGI reviewed epidemiology, vaccine protection, and disease severity in healthy people aged 16 to 64 years (not currently recommended to receive an additional booster dose).

In the coming weeks ATAGI will review information including epidemiology, and variant-specific vaccines for COVID-19. Recommendations may be updated as required.

ATAGI continue to emphasise the importance of remaining up to date with COVID-19 vaccinations by receiving the primary course and one or two booster doses according to eligibility. The booster doses provide additional protection against severe disease, hospitalisation and death as compared with the primary course.

ATAGI also recommends everyone in Australia over the age of 6 months should receive an influenza vaccination. Influenza vaccinations can be given at the same time as COVID-19 vaccines and should not be delayed.

Impact of COVID-19 on children aged 6 months to 5 years

ATAGI have begun reviewing data on the impact of COVID-19 on children aged 6 months to 5 years, including the burden of disease in this age group. Currently, there are no TGA-approved COVID-19 vaccines for use in this age group.

Separate to COVID vaccines, all children aged 6 months to less than 5 years are at particular risk of influenza and recommended and funded under the National Immunisation Program to receive an influenza vaccine to help protect them.

Ongoing review of adverse events and safety information

The TGA Weekly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 25 May 2022: Expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 29 April 2022: Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines
- 29 April 2022: ATAGI Clinical Guidance for COVID-19 vaccine providers
- 8 April 2022: ATAGI statement on use of booster doses in adolescents aged 12-15 years
- 25 March 2022: ATAGI recommendations on a winter booster dose of COVID-19 vaccine

More information can be found on the Department of Health website, with resources for both providers and patients.

Tags: Immunisation COVID-19

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 6 July 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 6 July 2022.

Date published: 19 July 2022

Audience: General public

Latest recommendation updates

- ATAGI updated recommendations for a 4th (winter) dose of COVID-19 vaccine including updated advice on groups recommended to receive a 4th dose (winter booster).

Recent ATAGI considerations

On Wednesday 6 July 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 6 July 2022, over 60 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI reviewed epidemiology, modelling, vaccine protection, and disease severity in healthy people aged 16 to 64 years (not currently recommended to receive an additional booster dose). As a result of this review, ATAGI recommended:

- All adults aged 50 years or older to receive a 4th dose of a COVID-19 vaccine.
- The interval between recent SARS-CoV-2 infection or the first booster dose and a winter dose is now 3 months.

ATAGI also advised that adults aged 30 to 49 years who wish to reduce their risk of infection can also receive a 4th dose of a COVID-19 vaccine.

The Australian Government has accepted these recommendations and this change will take effect from 11 July 2022.

The primary goal of the Australian COVID-19 vaccine program is to minimise the risk of severe disease, including hospitalisation and death, from COVID-19.

As outlined in ATAGI statements on winter booster doses (25 March 2022 and 25 May 2022), ATAGI continue to review evidence on the need for booster doses for people outside of the currently identified groups.

ATAGI has updated its recommendations for a 4th dose of COVID-19 vaccine to help reduce severe disease from the emerging surge of Omicron BA.4 and BA.5 subvariant infections, and to reduce the burden on Australian hospitals and the healthcare system in coming months.

The number of people ill from respiratory virus infections, including from COVID-19, has increased over the past few months, placing an increased strain on the Australian healthcare system, particularly hospitals. In addition, the number of people in Australia infected with the SARS-CoV-2 is expected to rise in the coming weeks.

The additional groups as listed above are in addition to the groups already recommended to receive a winter COVID-19 booster:

- all adults over 65 years of age
- residents of an aged care or disability care facility
- people who are severely immunocompromised (this will be their 5th dose)
- Aboriginal or Torres Strait Islander people aged 50 years or older
- people aged 16 and over with a medical condition that increases the risk of severe COVID-19 illness
- people aged 16 and over with disability, significant or complex health needs, or multiple comorbidities which increase the risk of a poor outcome

ATAGI notes that coverage with the first booster and 4th doses of COVID-19 vaccine in those people who are already eligible is suboptimal, and emphasises the importance of rapidly increasing vaccine uptake, particularly in older adults and older adults with complex medical needs. Adults aged 65 years or older who have not yet received a winter dose of COVID-19 vaccine should get this as soon as possible.

Reaching a higher level of coverage of the COVID-19 winter booster dose in older adults, including those aged 50 to 64 years, is likely to reduce the number of COVID-19 related hospitalisations over the coming months.

ATAGI advises that other public health and social measures will have the greatest impact against the surge in infections. This may include increased use of masks, working from home and increasing the use of

antiviral treatment in people diagnosed with COVID-19, including in people aged 50 years and above.

Reduction in interval between recent SARS-CoV-2 infection and booster dose

ATAGI recommends the 4th dose be given 3 months after the first booster dose of COVID-19 vaccine or 3 months after a recent SARS-CoV-2 infection, whichever is the most recent.

This interval has been reduced from 4 months to 3 months to provide earlier protection from the additional vaccine over the coming winter months.

ATAGI also recommends everyone in Australia over the age of 6 months should receive an influenza vaccination. Influenza vaccinations can be given at the same time as COVID-19 vaccines and should not be delayed.

ATAGI will continue to monitor disease modelling and the epidemiology of COVID-19 and may recommend wider vaccination to combat rapid increases in disease transmission in the future if the need arises.

Ongoing review of adverse events and safety information

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 7 July 2022: ATAGI updated recommendations for a winter dose of COVID-19 vaccine | Australian Government Department of Health and Aged Care
- 9 June 2022 – on the use of a first booster dose in adolescents aged 12-15 years
- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12-15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags: Immunisation COVID-19

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 13 July 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 13 July 2022

Date published: 19 July 2022

Audience: General public

Latest recommendation updates

ATAGI have not published any updated advice or recommendations since 7 July 2022.

Recent ATAGI considerations

On Wednesday 13 July 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 11 July 2022, over 60 million doses of COVID-19 vaccines have been administered in Australia.

Impact of COVID-19 vaccination on children aged 6 months to 4 years

ATAGI have continued reviewing data on the impact of COVID-19 vaccination on children aged 6 months to 4 years, including the burden of disease in this age group in both Australian and international contexts.

Currently, there are no TGA-approved vaccines for use in this age group.

Reinfection and timing of COVID-19 vaccine doses

ATAGI notes there is now a difference between the interval that defines re-infection (4 weeks) and the recommended minimum interval between infection and subsequent vaccine doses (3 months) as per the 8 July 2022 statement from the Australian Health Protection Principal Committee (AHPPC).

Evidence suggests that BA.4/5 is associated with a higher re-infection rate compared to previous variants, and this is likely to be due to immune evasion.

However, there are few data on the additional protection provided by boosters if given soon after infection. Immunologically, a longer time interval between vaccines enhances the 'booster response' and subsequent clinical protection, particularly against severe COVID-19 disease. The COVID-19 vaccines have a modest, short duration of impact against infection and as the primary aim of the program is optimising protection from severe disease, a 3-month interval therefore remains optimal. There is also some evidence that vaccine doses given at a shorter interval may be associated with a higher rate of pericarditis and myocarditis, but the relevance of this for the interval between infection and vaccination is not yet known. More information is available in the guidance on myocarditis and pericarditis following COVID-19 vaccination.

ATAGI is therefore still recommending a 3-month minimum interval between infection and subsequent doses, noting this is also consistent with the advice from other countries, which are generally recommending intervals of between 3 and 6 months.

ATAGI continues to monitor evidence regarding these intervals and may update recommendations as further information becomes known.

Use of a 4th dose in pregnancy

Pregnant women aged 30 years and over are now eligible to receive a 4th dose of COVID-19 vaccine. Similar to non-pregnant adults in this age group ATAGI does not specifically recommend the vaccine but encourages a discussion with their regular medical provider to review their individual health needs and the benefits and risks of a 4th dose.

While there are no particular maternal or fetal safety concerns from use of COVID-19 vaccines in pregnant women, ATAGI notes that there is limited experience with 4th doses in pregnant women at this time.

Studies have shown that unvaccinated pregnant women are at higher risk of severe outcomes compared to non-pregnant women, although these studies were from early in the pandemic. There are a paucity of data on severe outcomes during the Omicron wave in vaccinated pregnant women. ATAGI's previous winter dose advice recommended that anyone aged 16 years or more with a medical risk factor should receive a 4th dose, this includes women who are pregnant or planning

pregnancy. The Shared decision making guide for women who are pregnant, breastfeeding or planning pregnancy will be updated in due course.

Ongoing review of adverse events and safety information

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 7 July 2022: ATAGI updated recommendations for a winter dose of COVID-19 vaccine | Australian Government Department of Health and Aged Care
- 9 June 2022 – on the use of a first booster dose in adolescents aged 12-15 years
- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12-15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags: Immunisation COVID-19

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 20 July 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 20 July 2022.

Date published: 21 July 2022

Audience: General public

Latest recommendation updates

ATAGI have not published any updated advice or recommendations since 7 July 2022.

Recent ATAGI considerations

On Wednesday 20 July 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 19 July 2022, over 61 million doses of COVID-19 vaccines have been administered in Australia.

ATAGI received a presentation on the World Health Organisation Technical Advisory Group on COVID-19 Vaccine Composition (WHO TAG-CO-VAC) current considerations in relation to emerging SARS-CoV-2 Variants of Concern (VOC) and the impact on the performance of COVID-19 vaccines.

Impact of COVID-19 vaccination on children aged 6 months to 4 years

ATAGI note on 19 July 2022 the Therapeutic Goods Administration provisionally approved the Moderna COVID-19 vaccine (SPIKEVAX) for use in children from 6 months of age.

ATAGI have continued reviewing data on the impact of SARS-CoV-2 infection on children aged 6 months to <5 years, including the burden of disease in this age group in both Australian and international contexts.

ATAGI will provide advice to the Minister for Health on the use of COVID-19 vaccines in this age group in due course.

Ongoing review of adverse events and safety information

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 7 July 2022 – ATAGI updated recommendations for a winter dose of COVID-19 vaccine | Australian Government Department of Health and Aged Care
- 9 June 2022 – on the use of a first booster dose in adolescents aged 12-15 years
- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12-15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 27 July 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 27 July 2022.

Date published: 29 July 2022

Audience: General public

Latest recommendation updates

ATAGI have not published any recommendations since 7 July 2022. Recent meeting deliberations can be found on the ATAGI page.

Recent ATAGI considerations

On Wednesday 27 July 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 25 July 2022, over 61 million doses of COVID-19 vaccines have been administered in Australia.

Impact of COVID-19 vaccination on children aged 6 months to 4 years

Following the TGA provisional approval of the Moderna COVID-19 vaccine (SPIKEVAX) for use in children from 6 months of age on 19 July 2022, ATAGI have continued to discuss use of COVID-19 vaccines for children aged 6 months to 4 years, including considerations around program implementation and healthcare provider training.

ATAGI is currently finalising advice to the Minister for Health and Aged Care on the use of COVID-19 vaccines in this age group.

Ongoing review of COVID-19 vaccine safety

ATAGI has a COVID19 vaccine safety subgroup that continues to meet fortnightly. As part of this ongoing review of safety information, ATAGI has considered international and Australian safety data which shows that the risk of myocarditis and pericarditis appears to be higher with Moderna's than Pfizer's COVID-19 vaccine and is highest in younger males aged 16-30 years.

Although most cases have a relatively mild and self-limiting course, follow up studies suggest that a small proportion of cases have myocardial scarring, the long-term significance of which is uncertain.

Studies also suggest that the risk of myocarditis is higher following second dose compared to first and third doses, where there is a short interval between vaccine doses, (i.e. less than 8-weeks) and in males

compared to females.

ATAGI emphasises that the overwhelming benefits of vaccination in protecting against COVID-19 greatly outweigh the very low risk of post-vaccination myocarditis or pericarditis.

Following the full ATAGI committees deliberations this week, ATAGI have not changed the current vaccine recommendations for primary course or booster doses of COVID-19 vaccines.

COVID-19 vaccination providers and patients are encouraged to review the Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines, which will be updated shortly with further information on safety data to allow individuals and healthcare providers to make an informed risk-benefit decision.

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Consideration of Novavax COVID-19 vaccination of children aged 12-17 years

ATAGI note on 28 July 2022 the Therapeutic Goods Administration (TGA) provisionally approved the Nuvaxovid (Novavax) COVID-19 vaccine for use in children from aged 12 – 17 years.

ATAGI have commenced a review of data on the use of Novavax COVID-19 vaccine in this age group and will provide advice to the Minister for Health and Aged Care in due course.

Resources and recent statements

More information can be found in the following resources:

- 7 July 2022: ATAGI updated recommendations for a winter dose of COVID-19 vaccine | Australian Government Department of Health and Aged Care

- 9 June 2022 – on the use of a first booster dose in adolescents aged 12-15 years
- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12-15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 3 August 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 3 August 2022

Date published: 4 August 2022

Audience: General public

Latest recommendation updates

- ATAGI recommendations on COVID-19 vaccine use in children aged 6 months to <5 years.

Recent ATAGI considerations

On Wednesday 3 August 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 1 August, over 62 million doses of COVID-19 vaccines have been administered in Australia.

Impact of COVID-19 vaccination on children aged 6 months to under 5 years

Following careful deliberation, ATAGI has recommended COVID-19 vaccination for children aged 6 months to under 5 years age with severe immunocompromise, disability, and those who have complex and/or multiple health conditions which increase the risk of severe COVID-19.

Details of the ATAGI decision can be found in the recommendations on COVID-19 vaccine use in children aged 6 months to <5 years. This ATAGI recommendation follows the TGA provisional approval of the Moderna COVID-19 vaccine (SPIKEVAX) for use in children from 6 months of age on 19 July 2022.

The Australian Government is working with state and territory governments, and health professionals, to expand the rollout to the highest risk children aged 6 months to under 5 years from 5 September 2022.

ATAGI does not currently recommend COVID-19 vaccination for children in this age group not in the listed high-risk categories for severe COVID-19. In making its recommendation, ATAGI carefully considered disease burden in this age group, as well as the efficacy and safety of the Moderna vaccine in this cohort.

This age group is one of the least likely to experience severe outcomes of COVID-19 such as hospitalisation and death. In the rare instances of severe outcomes, underlying medical conditions or immunocompromise are frequently present.

ATAGI continues to review the evidence on the disease burden and epidemiology, vaccine supply, emerging data on vaccine use and availability of any new COVID-19 vaccines for this age group and will update recommendations as required.

Consideration of Novavax COVID-19 vaccination for children aged 12-17 years

ATAGI note on 28 July 2022 the Therapeutic Goods Administration (TGA) provisionally approved the Nuvaxovid (Novavax) COVID-19 vaccine for use in children from aged 12 – 17 years.

ATAGI have continued their review of data on the use of Novavax COVID-19 vaccine in this age group and will provide advice to the Minister for Health and Aged Care in due course.

Review of COVID-19 booster doses for adolescents aged 12-15 years

As part of a regular review into existing recommendations, ATAGI considered new data on burden of COVID-19 disease (benefits of vaccination), risk of side effects (risks of vaccination), and international recommendations on COVID-19 booster use in people aged 12-15 years.

ATAGI's recommendation from 9 June 2022 regarding the use of a booster dose of COVID-19 vaccine in people aged 12-15 years remains unchanged.

ATAGI recommends that a first booster dose of the Comirnaty (Pfizer) COVID-19 vaccine may be given to the following adolescents aged 12-15 years who have completed a primary course of vaccination 3 or more months ago:

- those who are severely immunocompromised
- those who have a disability with significant or complex health needs
- those who have complex and/or multiple health conditions that increase the risk of severe COVID-19.

ATAGI does not recommend that a first booster dose of COVID-19 vaccine be given to all adolescents aged 12-15 years. There is insufficient evidence of severe disease in otherwise healthy adolescents in this age group who have already received two primary doses of a COVID-19 vaccine.

ATAGI continues to recommend that all adolescents aged 12-15 years complete a primary vaccine course of 2 doses of COVID-19 vaccine, 8 weeks apart. A third primary dose from 2 months after dose 2 is recommended for those who are severely immunocompromised.

Ongoing review of COVID-19 vaccine safety

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 7 July 2022 – ATAGI updated recommendations for a winter dose of COVID-19 vaccine | Australian Government Department of Health and Aged Care
- 9 June 2022 – on the use of a first booster dose in adolescents aged 12-15 years

- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12-15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

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ATAGI update following weekly COVID-19 meeting – 24 August 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 24 August 2022.

Date published: 26 August 2022

Audience: General public

Latest recommendation updates

- ATAGI recommendations on use of Novavax vaccine for adolescents aged 12-17 years

Recent ATAGI considerations

On Wednesday 24 August 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 22 August, 63 million doses of COVID-19 vaccines have been administered in Australia.

Novavax COVID-19 vaccination for children aged 12-17 years

On 28 July 2022 the Therapeutic Goods Administration (TGA) provisionally approved Nuvaxovid (Novavax) COVID-19 vaccine (Biocelect Pty Ltd/Novavax Inc) for use in adolescents aged 12-17 years.

ATAGI has evaluated data on immunogenicity, efficacy, safety, and in international settings to make recommendations on the use of Novavax COVID-19 vaccine in this age group.

The Australian Government has accepted advice from ATAGI that adolescents aged 12-17 years can receive the Novavax COVID-19 vaccine for their primary course of COVID-19 vaccination. For more information, see the ATAGI recommendations on use of Novavax vaccine for adolescents aged 12-17 years.

Adolescents aged 12-17 years will be able to book in to receive Novavax COVID-19 vaccine from 5 September 2022.

Consideration of variant vaccines

As part of an ongoing review of current and emerging data from both Australia and international settings, ATAGI examined information with respect to the future role of COVID-19 variant vaccines in Australia's vaccine program, including Moderna's bivalent COVID-19 vaccine, Spikevax Bivalent Zero/Omicron.

ATAGI continue to emphasise the importance of remaining up to date with the COVID-19 vaccinations recommended for your age or individual health needs.

Ongoing review of COVID-19 vaccine safety

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 7 July 2022: ATAGI updated recommendations for a winter dose of COVID-19 vaccine | Australian Government Department of Health and Aged Care
- 9 June 2022 – on the use of a first booster dose in adolescents aged 12-15 years
- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12-15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags: Immunisation | Communicable diseases | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following weekly COVID-19 meeting – 31 August 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their weekly meeting on 31 August 2022.

Date published: 2 September 2022

Audience: General public

Latest recommendation updates

ATAGI have not published any recommendations since 25 August 2022. Recent meeting deliberations can be found on the ATAGI page.

Recent ATAGI considerations

On Wednesday 31 August 2022, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 29 August, over 63 million doses of COVID-19 vaccines have been administered in Australia.

Consideration of variant vaccines

On 29 August 2022 the Therapeutic Goods Administration (TGA) granted provisional approval for the Moderna bivalent COVID-19 vaccine, Spikevax Bivalent Zero/Omicron.

Following this announcement, ATAGI have continued to discuss the role of this new bivalent COVID-19 vaccine in Australia's COVID-19 vaccination program and are currently finalising advice to the Minister for Health and Aged Care on the use of this vaccine.

ATAGI continue to emphasise the importance of receiving the COVID-19 vaccinations recommended for your age or individual health needs.

Ongoing review of COVID-19 vaccine safety

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 25 August 2022: 25 August 2022: Novavax vaccine for adolescents aged 12–17 years
- 7 July 2022: ATAGI updated recommendations for a winter dose of COVID-19 vaccine
- 9 June 2022 – on the use of a first booster dose in adolescents aged 12–15 years
- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12–15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI update following COVID-19 meeting – 7 September 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their meeting on 7 September 2022. ATAGI are now meeting every fortnight on COVID-19 related issues.

Date published: 14 September 2022

Audience: General public

Latest recommendation updates

Updates have been made to the ATAGI clinical guidance to reflect recommendations for Moderna primary course in children aged 6 months to under 5 years, and Novavax primary course in adolescents 12 to 17 years.

Recent meeting deliberations can be found on the ATAGI page.

Recent ATAGI considerations

On Wednesday 7 September, ATAGI met to consider the latest developments relating to COVID-19 immunisation. As of 6 September, over 63 million doses of COVID-19 vaccines have been administered in Australia.

Moderna bivalent variant vaccine

Following from the Therapeutic Goods Administration (TGA) provisional approval for the Moderna bivalent COVID-19 vaccine, Spikevax Bivalent Zero/Omicron (Moderna bivalent booster) on 29 August 2022, ATAGI have recommended that the Moderna bivalent booster can be used in people aged 18 years and older for the first or second booster dose (i.e. the third or fourth dose for most people), according to the current ATAGI recommendations for booster doses.

The booster dose of COVID-19 vaccine should be given at least 3 months after the most recent COVID-19 vaccine dose or previous SARS-CoV-2 infection.

While booster vaccination with a variant-containing vaccine may not necessarily 'match' the circulating variant, it is anticipated to induce a broad immune response to current SARS-CoV-2 variants.

ATAGI considers receiving all recommended COVID-19 vaccine doses to be a more important factor in obtaining optimal protection against severe COVID-19 than which variant is contained within the dose. ATAGI continue to emphasise the importance of receiving the COVID-19 vaccinations recommended for your age or individual health needs.

In the coming weeks, patients will be able to access the Moderna bivalent booster as an option, along with the other registered COVID-19 vaccines. The Moderna bivalent booster and original COVID-19 vaccines (various brands) will continue to be available in the near future. Eligible individuals can receive whichever COVID-19 booster vaccine is available to them.

ATAGI recommends that any person who has not yet received a first or recommended second COVID-19 booster dose, arrange to receive their booster soon, using either the Moderna bivalent booster or an alternative original vaccine.

For more information on booster doses, visit www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-your-vaccination/booster-doses#booster-doses

Pfizer 6 months to under 5 years COVID-19 vaccine

On 30 June 2022 TGA granted provisional determination to Pfizer in relation to its COVID-19 vaccine (Comirnaty) for use in individuals 6 months to under 5 years. Currently, the only COVID-19 vaccine provisionally approved in this age group is the Moderna COVID-19 vaccine.

ATAGI has considered evidence in relation to the Pfizer COVID-19 vaccine in this age group including immunogenicity, safety and reactogenicity, and disease burden in this age group. This week ATAGI discussed its use as an alternative to the Moderna vaccine in this age group.

If registered by the TGA ATAGI will make recommendations on its use in this age group.

Pfizer 5-to-11-year COVID-19 booster doses

ATAGI also considered evidence in relation to the Pfizer COVID-19 vaccine as a booster in the 5-to-11-year age cohort including disease burden, durability of protection against infection and severe disease, immunogenicity, safety, and international recommendations.

Currently, there is no recommendation for children 5 to 11 years to receive booster vaccinations. If the booster dose is registered by the TGA, ATAGI will make recommendations on its use in this age group.

Children aged 5 to 11 years are currently recommended to have a primary course (2 doses for most people) of a COVID-19 vaccine.

ATAGI COVID-19 meetings

The ATAGI COVID-19 Working Group meetings will reduce in frequency to fortnightly, and the Weekly Updates will in future be published on an as-needed basis. To stay up to date with COVID-19 announcements, visit the Department of Health and Aged Care website.

Ongoing review of COVID-19 vaccine safety

The TGA Fortnightly Report provides a detailed breakdown of adverse events following immunisation, including Australian rates of myocarditis and pericarditis.

Resources and recent statements

More information can be found in the following resources:

- 12 September 2022: ATAGI statement on use of the Moderna bivalent Original/Omicron vaccine
- Recent updates: ATAGI Clinical guidance on the use of COVID-19 vaccines
- 25 August 2022: Novavax vaccine for adolescents aged 12-17 years
- 7 July 2022: ATAGI updated recommendations for a winter dose of COVID-19 vaccine | Australian Government Department of Health and Aged Care
- 9 June 2022 – on the use of a first booster dose in adolescents aged 12-15 years

- 25 May 2022 – expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19
- 8 April 2022 – on use of booster doses in adolescents aged 12-15 years

More information can be found on the Department of Health and Aged Care website, with resources for both providers and patients.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Australian Government
Department of Health and Aged Care

ATAGI update on boosters following COVID-19 meeting on 11 November 2022

An update from the Australian Technical Advisory Group on Immunisation (ATAGI) following their meeting on 11 November 2022.

Date published: 14 November 2022

Audience: General public

ATAGI has reviewed its booster dose advice (November 2022) for COVID-19 vaccines in the context of increasing case numbers in Australia and the emergence of the XBB and BQ.1 Omicron subvariants.

ATAGI wishes to provide the following updates:

- ATAGI has made no new recommendations at this time, including no changes to the number of COVID-19 vaccine booster doses recommended.
- ATAGI emphasises the importance of remaining up to date with recommended doses of COVID- 19 vaccines, especially for people aged 65 years and older and those at higher risk of severe COVID-19:
    - As of 9 November 2022, 5.5 million eligible people living in Australia (27.8% of the eligible population) had not received a first booster dose, and 3.2 million people aged 50 years and older (42.7%) had not received a second booster dose.[1]
    - Adults aged 30 to 49 years can consider a second booster dose, and 4.4 million people aged 30-49 years (84%) have not yet received one.[1]
    - Under-vaccinated people are at an increased risk of severe illness and death. Staying up to date with vaccine recommendations is an important way a person can protect themselves in the current context of increased COVID-19 cases.
    - ATAGI continues to recommend that all people defer COVID-19 vaccination for 3 months after a confirmed SARS-CoV-2 infection. The next scheduled dose should then be given as soon as possible.
    - Eligible individuals can receive either a bivalent or original COVID-19 vaccine, whichever is available to them. Both bivalent and original vaccines result in an improvement in the immune response against Omicron subvariants.
- The increase in COVID-19 cases in Australia commenced a few weeks ago. It is unclear when the wave will peak or end. Any reduction in community transmission in Australia from an additional booster dose in people who are already up to date is likely to be minimal.
- A recent wave of the XBB subvariant in Singapore was of short duration and of small size. Severe disease and death were rare in people who had received at least two doses of a COVID-19 vaccine.[2]
- ATAGI notes the following measures recommended by health officials during the current increase in COVID-19 cases:
    - people are advised to use masks in indoor public places and crowded settings [3]

    - people who test positive for COVID-19 or feel unwell should stay at home until symptoms resolve [3]
    - People eligible for oral COVID-19 treatments, should speak with their doctor before they get sick to see if COVID-19 antivirals are right for them.[4]
- ATAGI continues to actively review the role of booster doses in the COVID-19 vaccination program. New booster dose recommendations are anticipated in early 2023 in preparation for winter. Future recommendations will aim to provide ongoing clear guidance across all groups including time since last dose and definitions of eligibility.

References

1. Department of Health and Aged Care, Australian government. COVID-19 vaccine roll-out, 10 November 2022. Available from: COVID-19 vaccine rollout – 10 November 2022 (Accessed 13 November 2022)
2. Ministry of Health, Singapore. Update on COVID-19 situation and measures to protect healthcare capacity. 2022. Available from: Update On Covid-19 Situation and Measures to Protect Healthcare Capacity (Accessed 13 November 2022)
3. Department of Health and Aged Care, Australian government. New COVID-19 variant leads to increase in cases. 2022. Available from: New COVID-19 variant leads to increase in cases (Accessed 13 November 2022)
4. Department of Health and Aged Care, Australian government. Oral treatments for COVID-19. 2022. Available from: Oral treatments for COVID-19 (Accessed 13 November 2022)

Tags:

Australian Technical Advisory Group on Immunisation (ATAGI)

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Coronavirus (COVID-19)