ATTACHMENT A

SCHEDULE OF DOCUMENTS – FOI 2917

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14	16 June 21	4	ATAGI TTS meeting outcomes 16 June 2021	REI	section 22 – part section 47C – part section 47E – part section 47F – part
15	16 June 21	12	ATAGI TTS meeting chat log 16 June 2021	E	section 47C – full section 47F - part

[1] E = Exempt in full, R = Release in full, REI = Release with exempt and irrelevant material removed.

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ATAGI statement on revised recommendations on the use of COVID-19 Vaccine AstraZeneca, 17 June 2021

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on the AstraZeneca COVID-19 vaccine in response to new vaccine safety concerns.

Date published: 17 June 2021

Type: News

Intended audience: General public

Summary

The Australian Technical Advisory Group on Immunisation (ATAGI) recommends the COVID-19 Pfizer vaccine (Comirnaty) as the preferred vaccine for those aged 16 to under 60 years. This updates the previous preferential recommendation for Comirnaty over COVID-19 Vaccine AstraZeneca in those aged 16 to under 50 years. The recommendation is revised due to a higher risk and observed severity of thrombosis and thrombocytopenia syndrome (TTS) related to the use of AstraZeneca COVID-19 vaccine observed in Australia in the 50-59 year old age group than reported internationally and initially estimated in Australia.

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.

People of any age without contraindications who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events should receive a second dose of the same vaccine. This is supported by data indicating a substantially lower rate of TTS following a second COVID-19 Vaccine AstraZeneca dose in the United Kingdom (UK).

Background

The Australian COVID-19 vaccination program has the overarching goal of protecting all people in Australia from the harm caused by the novel coronavirus SARS-CoV-2.

On 8 April 2021, ATAGI recommended that Comirnaty was the preferred vaccine for people under the age of 50 years due to local and international reports of thrombosis and thrombocytopenia syndrome (TTS) following COVID-19 Vaccine AstraZeneca.

Based on available international data at that time, the estimated risk of TTS was 4-6 per million cases following a first dose of COVID-19 Vaccine AstraZeneca. Given the ongoing risk of COVID-19 outbreaks, low vaccine coverage, and increasing rate of severe COVID-19 outcomes in older individuals, it was considered that the benefits of COVID-19 Vaccine AstraZeneca outweighed the risk in those over 50 years. As such, no preferential recommendation for

either vaccine was made in this age group. This advice was reinforced on 23 April 2021 and has been reviewed weekly by ATAGI since then.

Principles underpinning the revised recommendations

In making the decision to revise the previous recommendation, ATAGI has considered several factors that have been monitored closely, including:

- The potential risk of severe illness and death from COVID-19 over the coming months
- Minimising harms to people due to adverse events following immunisation
- Australian data on the age-specific risks and severity of TTS following COVID-19 Vaccine AstraZeneca
- The expected vaccine supply over the months ahead
- The impacts of any change in recommendation on the COVID-19 vaccine program.

The benefits of vaccination to prevent COVID-19

There is an ever-present risk of COVID-19 in Australia while the population remains largely susceptible to infection. Recent events in Victoria have demonstrated how rapidly outbreaks can spread despite intensive contact tracing and public health action. As at 16 June 2021, 63% of people aged 70 years and older and 25% of those aged 18 years and older have received at least one dose of a COVID-19 vaccine.

The risk of severe COVID-19 is strongly related to increasing age. In 2020, for every 100 people with COVID-19 aged between 50-59 years, around 14 were hospitalised and 3 required admission to an intensive care unit (ICU). One in every 600 people with COVID-19 in this age group died. In contrast, for every 100 people aged 70-79 years with COVID-19, around 38 were hospitalised, 7 were admitted to ICU and 4 died (ie. 24 deaths in 600). Therefore, the benefit of vaccination in preventing COVID-19 is greater in older people. If an outbreak occurred comparable to the first wave in Australia, the benefits in preventing severe COVID-19 would outweigh the risks of TTS due to COVID-19 Vaccine AstraZeneca in older adults, as illustrated in Weighing up the potential benefits against the risk of harm from COVID-19 Vaccine AstraZeneca.

ATAGI acknowledges the difficulty in balancing the small risk of a clinically significant adverse event related to vaccination with COVID-19 Vaccine AstraZeneca against the need to protect individuals and the community against the ongoing threat of COVID-19, together with ongoing limitations and uncertainties about the supply of alternative COVID-19 vaccines. ATAGI emphasises that this advice is specific to the context that there is currently no or limited community transmission in most of Australia and would be different in other countries.

The risks of TTS after COVID-19 Vaccine AstraZeneca

From early April to 16 June 2021, 60 cases of confirmed or probable TTS have been reported in Australia. This includes an additional seven cases reported in the past week in people between 50-59 years, increasing the rate in this age group from 1.9 to 2.7 per 100,000 AstraZeneca vaccine doses. The revised estimates of risk associated with first doses of COVID-19 Vaccine AstraZeneca are listed in the table below.

Age	Estimated risk of TTS per 100,000 AstraZeneca vaccine doses (first dose)
<50 years	3.1
50-59 years	2.7
60-69 years	1.4
70-79 years	1.8
80+ years	1.9

TTS is a serious condition in a proportion of individuals who develop it. The overall case fatality rate in Australia (3%; 2 deaths among 60 cases) is lower than has been reported internationally. This is likely to reflect increased detection due to heightened awareness, as well as early diagnosis and treatment. A spectrum of severity of illness has been reported in Australia, from fatal cases and those with significant morbidity, to relatively milder cases. TTS appears to be more severe in younger people.

There are different ways in which the severity of TTS can be measured. The US Centers for Disease Control and Prevention (CDC) defines “tier 1” cases as clots involving unusual sites, such as the veins of the brain (cerebral venous sinus thrombosis) or abdomen (splanchnic thrombosis); these are generally more severe and may potentially lead to long term health complications. In those under 60 years, 52% of TTS episodes are occurring in tier 1 sites compared with 28% in those 60 years and older. Other markers of severity include the requirement for intensive care (33% of TTS in those under 60 years; 15% of TTS cases in those 60 years and older), and fatal cases (both occurring in those < 60 years).

Second dose recommendations for COVID-19 Vaccine AstraZeneca

ATAGI supports completion of a two-dose schedule with COVID-19 Vaccine AstraZeneca, based on current evidence. The risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose. The UK has reported 23 TTS cases in 15.7 million people after receiving a second dose, an estimated rate of 1.5 per million second doses (compared to a reported risk of 14.2 per million first doses in the UK).

People of any age without contraindications who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events should receive the second dose.

Recommendations

- ATAGI advises that Comirnaty is preferred over COVID-19 Vaccine AstraZeneca from the age of 16 to under 60 years. This is based on recent data regarding TTS cases in Australia and a reassessment of current age-specific risks and benefits of vaccination.
- ATAGI considers the benefit of vaccination in preventing COVID-19 with COVID-19 Vaccine AstraZeneca outweighs the risk of TTS in people aged 60 and above. For this age group, the 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.
- COVID-19 Vaccine AstraZeneca can be used in adults aged under 60 years for whom Comirnaty is not available, the benefits are likely to outweigh the risks for that individual and the person has made an informed decision based on an understanding of the risks and benefits.

- People of any age without contraindications who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events should receive the second dose.
- ATAGI reinforces the importance of providing clear communications to people who have received or are considering COVID-19 Vaccine AstraZeneca, and notes guidance documents for consumers, for primary care and for hospitals are being continually revised to accommodate this new recommendation.

Next steps

ATAGI is continuing to monitor the evidence regarding the risks of TTS and the epidemiology of COVID-19, and will continue to review recommendations. Further modifications may be recommended as additional COVID-19 vaccine supply and emerging evidence become available. ATAGI reinforces that due to the ongoing risk of COVID-19, maximising vaccine coverage is a priority, particularly in those at greatest risk of severe COVID-19.

ATAGI is currently working with general practitioners, emergency physicians and haematologists to update clinical advice on TTS for consumers and primary care.

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

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ATAGI statement on use of COVID-19 vaccines in an outbreak setting

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of COVID-19 vaccines in an outbreak setting.

Date published: 13 July 2021

Type: News

Intended audience: General public

ATAGI recommendations on the use of COVID-19 vaccines are stated in the Clinical guidance on use of COVID-19 vaccine in Australia in 2021[1]. ATAGI has reviewed its clinical advice in the setting of increasing community COVID-19 cases in Australia. Recommendations for non-outbreak settings remain unchanged.

This statement addresses the specific application of these recommendations in the setting of a significant COVID-19 outbreak involving the Delta variant. This includes:

1. the re-assessment of benefits versus risks of COVID-19 Vaccine AstraZeneca for adults under 60 years old
2. updated advice about the optimal interval between the two doses of COVID-19 Vaccine AstraZeneca in an outbreak setting.

Recommendations on the use of Comirnaty, the Pfizer COVID-19 vaccine, are unchanged. The jurisdiction(s) where the COVID-19 outbreak occurs will determine when and where these recommendations are applicable, i.e. the response should be based on current epidemiology of the disease.

Recommendations

1. ATAGI reinforces that the benefits of vaccination with COVID-19 Vaccine AstraZeneca strongly outweigh the risks of adverse effects in those ≥60 years, and that vaccination is essential for this group in the context of an outbreak.
2. Every effort should be made to support vaccination of people in priority groups (e.g., older people, healthcare workers, disability and aged care workers, and those with listed medical comorbidities).
3. In the context of a COVID-19 outbreak where the supply of Comirnaty (Pfizer) is constrained, 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.
4. While the recommended interval between the first and second doses of COVID-19 Vaccine AstraZeneca is between 4 and 12 weeks, in outbreak situations an interval of between 4 and 8 weeks is preferred. Therefore, people in an outbreak situation who received their first dose of COVID-19 Vaccine AstraZeneca more than 4 weeks ago should contact their vaccine provider to arrange their second dose as soon as possible. In non-outbreak settings, the preferred interval between doses of COVID-19 Vaccine AstraZeneca remains at 12 weeks.

5. All people who receive COVID-19 Vaccine AstraZeneca should be provided with information about common and rare but serious side effects, including the symptoms and signs of the thrombosis with thrombocytopenia syndrome (TTS). They should be advised that if they experience any signs or symptoms consistent with TTS, they should seek immediate medical attention.
6. Any additional unallocated supplies of both Comirnaty (Pfizer) and COVID-19 Vaccine AstraZeneca should be prioritised to populations and areas of greatest risk of COVID-19.
7. Recommendations around the use of Comirnaty (Pfizer) remain unchanged in outbreak settings.

Background

Vaccination is a key public health intervention to prevent infection, transmission and severe disease. In the context of the current COVID-19 outbreak with the new more transmissible Delta (B.1.617.2) variant, ATAGI has reviewed its previous advice on the use of COVID-19 vaccines, along with new information regarding the virus. Currently in Australia, the supply of Comirnaty (Pfizer) remains constrained, while access to COVID-19 Vaccine AstraZeneca is relatively easier.

The Delta variant is more infectious than other strains of SARS-CoV-2. It is unclear if the Delta variant causes more severe disease. Some countries have reported that infections with this variant are associated with higher risk of hospitalisation, need of intensive care, and death, even after differences in age or other factors are accounted for.[2,3] In Australia, more infections in the community means that there will be more people with COVID-19 requiring hospitalisations and intensive care unit (ICU) admissions. In addition, the effectiveness of vaccination against infection with a single dose of COVID-19 vaccine, either Comirnaty (Pfizer) or COVID-19 Vaccine AstraZeneca is notably lower against infections with the Delta variant compared with other strains. A two-dose course of vaccination offers optimal protection against both infection and hospitalisation.

Benefits and risks of COVID-19 Vaccine AstraZeneca in outbreak situations

The benefits to the individual of being vaccinated include avoiding severe COVID-19 outcomes, such as hospitalisation, intensive care unit admission and death, as well as chronic post-COVID-19 conditions ('long COVID'). Other benefits of vaccination including reducing the risk of passing the virus to close contacts including family, friends and work colleagues, and the potential to help reduce community spread of the virus. In outbreak settings, the benefits of COVID-19 Vaccine AstraZeneca are increased compared with non-outbreak settings. When the virus is spreading in the community it is critical that as many people as possible are vaccinated as quickly as possible.

In both outbreak and non-outbreak situations, ATAGI considers the benefits of COVID-19 prevention to outweigh the small risk of adverse events including TTS in those 60 years or older. ATAGI therefore reinforces the benefits of vaccination with COVID-19 Vaccine AstraZeneca in these individuals.

In outbreak settings, such as that currently occurring in Sydney, the benefits of vaccination are greater. Given the changes to the risk-benefit equation, ATAGI recommends adults under 60 years who do not have immediate access to Comirnaty (Pfizer) should re-assess the need for vaccination with AstraZeneca given these greater benefits. This changing risk-benefit balance is illustrated in previously published scenarios.[4] For context, the current cumulative risk of COVID-19 for residents of Sydney to 11 July 2021 is approximately 10 per 100,000 and is increasing by 2 additional cases per 100,000 per day. Although overall this is comparable to the Australian first wave (cumulative incidence 29 per 100,000), the ongoing risk would be considerably greater in some parts of Sydney and for specific populations. For example, in Fairfield Local Government Area, the cumulative risk to date is >100 per 100,000 and has increased by >10 cases per 100,000 per day in the past week.

COVID-19 Vaccine AstraZeneca is associated with a small but significant risk of adverse events following immunisation. The most important of these is TTS, a rare but potentially serious adverse event.[5] ATAGI has previously advised that it is important to: a) weigh up the benefits of vaccination, when compared with the risks of harm of TTS from COVID-19 Vaccine AstraZeneca and b) be aware of the symptoms and signs of TTS in order to get prompt and effective treatment in the rare situation that TTS occurs. The latest cumulative estimates of the rates of TTS by age group, and a discussion of the spectrum of severity of TTS are available in the ATAGI update following weekly COVID-19 meeting – 7 July 2021 and the Therapeutic Goods Administration COVID-19 vaccine weekly safety report.[6,7]

Recommended interval between COVID-19 Vaccine AstraZeneca doses in outbreak situations

Earlier trials of COVID-19 Vaccine AstraZeneca suggested that there is a trend towards a higher vaccine efficacy with a longer interval between the two doses of this vaccine. The protective efficacy against symptomatic COVID-19 was 55% (95% confidence intervals [CI]: 33, 70%) when the two doses were given 4 weeks apart, compared to 81% (95% CI: 60, 91%) when given 12 weeks apart.[8] On this basis, ATAGI recommends a routine preferred interval of 12 weeks between the first and second dose of COVID-19 Vaccine AstraZeneca, but noted that "shortening the interval from 12 weeks to no less than 4 weeks between doses is acceptable and may be appropriate in certain circumstances, for example, imminent travel or anticipated risk of COVID-19 exposure."[1]

The protection of vaccines against infection and hospitalisation with the recently-emerging Delta variant have been studied internationally. A single dose of COVID-19 Vaccine AstraZeneca reduces the risk of symptomatic infection by around 30% (95% CI: 24%, 35%) and hospitalisation by 71% (95% CI: 51, 83%).[9] However, two doses of COVID-19 Vaccine AstraZeneca reduces the risk of symptomatic infection even further, by 67% (95% CI: 61%, 72%), and the risk of hospitalisation by 92% (95% CI: 75, 97%).[9] Thus, shortening the gap between first and second doses will bring forward short term protection, which is expected to be beneficial in outbreak situations. On this basis, an interval of between 4 and 8 weeks between the first and second doses of COVID-19 Vaccine AstraZeneca is preferred in an outbreak situation. In non-outbreak settings, the preferred interval between doses of COVID-19 Vaccine AstraZeneca remains at 12 weeks.

A similar incremental benefit in protection following second doses of Comirnaty (Pfizer) is observed but given the short dosing interval (of 3 to 6 weeks), these recommendations are unchanged in outbreak and non-outbreak settings.

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

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

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) in response to the NSW COVID-19 outbreak.

Date published: 24 July 2021

Type: News

Intended audience: General public

Summary

All individuals aged 18 years and above in greater Sydney, including adults under 60 years of age, should strongly consider getting vaccinated with any available vaccine including COVID-19 Vaccine AstraZeneca. This is on the basis of the increasing risk of COVID-19 and ongoing constraints of Comirnaty (Pfizer) supplies. In addition, people in areas where outbreaks are occurring can receive the second dose of the AstraZeneca vaccine 4 to 8 weeks after the first dose, rather than the usual 12 weeks, to bring forward optimal protection.

Detail

ATAGI continues to closely monitor the epidemiology of COVID-19 in New South Wales, Victoria and South Australia. The outbreak in NSW continues to grow and the risk of disease, particularly in the greater Sydney area, is likely to continue to be significant over coming weeks.

ATAGI reaffirms our previous advice that in a large outbreak, the benefits of the COVID-19 Vaccine AstraZeneca are greater than the risk of rare side effects for all age groups.

In the context of the current risk of COVID-19 in NSW and with the ongoing constraints on Comirnaty (Pfizer) vaccine supplies, all adults in greater Sydney should strongly consider the benefits of earlier protection with COVID-19 Vaccine AstraZeneca rather than waiting for alternative vaccines

Maximal protection requires two doses of vaccine, but even a single dose of either vaccine provides substantial protection (by more than 70%) against hospitalisation. A single dose of COVID-19 Vaccine AstraZeneca partially reduces transmission by around half and therefore may also benefit close contacts and the community. It should be noted that there is a delay of 2-3 weeks after receiving a first dose of vaccine and being protected from COVID-19.

A second reason for ATAGI to recommend that individuals strongly consider vaccination at this time is emerging data about severity of disease. The Delta variant may be more severe than the original SARS-CoV-2 strain. The proportion of people less than 60 years requiring hospitalisation appears to be higher than was reported in outbreaks with the original SARS-CoV-2 strain. This reinforces the benefit of protection with any available vaccine.

People considering vaccination should be informed of the benefits and risks and give informed consent. People who receive COVID-19 Vaccine AstraZeneca should be aware of the symptoms of thrombosis with thrombocytopenia syndrome (TTS), and when to seek prompt medical attention. Early detection of TTS means that people can get treatment and this can improve their outcomes.

ATAGI has previously issued advice recommending a shorter interval between the first and second doses of COVID-19 Vaccine AstraZeneca of 4-8 weeks in an outbreak (versus the routine 12 week interval) so that maximal protection against COVID-19 can be achieved earlier.

ATAGI also reinforces that the interval between the first and second doses of Comirnaty (Pfizer) is 3-6 weeks, providing flexibility in managing available supplies of vaccines, whilst also noting two doses are required for optimal protection. Spacing Comirnaty (Pfizer) to a routine interval of 6 weeks would allow limited vaccine supplies to be redirected to obtain first dose protection in outbreak areas of greatest need.

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

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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

Type: News

Intended 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: Communicable diseases | Emergency health management | Immunisation | Coronavirus (COVID-19) | COVID-19 vaccines

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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

Type: News

Intended 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: Communicable diseases | Emergency health management | Immunisation | Coronavirus (COVID-19) | COVID-19 vaccines

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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

Type: News

Intended 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: Communicable diseases | Emergency health management | Immunisation | Coronavirus (COVID-19) | COVID-19 vaccines

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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

Type: News

Intended 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: Communicable diseases | Emergency health management | Immunisation | Coronavirus (COVID-19) | COVID-19 vaccines

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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

Type: News

Intended 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: Communicable diseases | Emergency health management | Immunisation | Coronavirus (COVID-19) | COVID-19 vaccines

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Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine weekly safety report - 24-06-2021

Release date Thursday, 24 June 2021

Previous reports

The Therapeutic Goods Administration (TGA) closely monitors suspected side effects (also known as adverse events) from the use of COVID-19 vaccines. Importantly, adverse events reported to the TGA are often not caused by the vaccine itself. Learn more about causality (//www.tga.gov.au/about-daen-medicines#causality).

Learn about the TGA's COVID-19 vaccine safety monitoring and reporting (//www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting) activities or report a suspected side effect (//www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine).

Summary

- The most frequently reported suspected side effects (//www.tga.gov.au/#section-544) associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Five additional cases of blood clots with low blood platelets (//www.tga.gov.au/section-547) have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the UK case definition, three were confirmed and two were deemed probable TTS. However, following reassessment of a previously reported case as being unlikely to be TTS, there is only a net increase of four cases. This brings the total number of cases of TTS to 64.
- We are also monitoring reports of suspected myocarditis and pericarditis following vaccination with Comirnaty and suspected Guillain-Barre Syndrome following vaccination with the AstraZeneca vaccine. No causal association with either vaccine has been established at this stage.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues (//www.tga.gov.au/tga-safety-monitoring-medicines#steps).

In the week of 14-20 June 2021 we received 2,018 AEFI reports for COVID-19 vaccines.

Since the beginning of the vaccine rollout to 20 June 2021, the TGA has received 318 reports of death in people who have recently been vaccinated.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported after vaccination and monitors signals that may relate to vaccine safety. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths. To date, our review of cases and analysis of reporting patterns does not suggest that the vaccine caused these deaths, other than for the TTS cases.

Total adverse event reports to 20 June 2021

4.8	31,641	6,590,741
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
21,799	9,592	253
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.1	New South Wales	3.5
Northern Territory	4.5	Queensland	4.7
South Australia	4.3	Tasmania	6.9
Victoria	6.1	Western Australia	4.1

Most commonly reported vaccine side effects

The AEFI most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally. They include headache, muscle and joint pain, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 14-20 June 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 14-20 June 2021 were headache, muscle pain, dizziness, fatigue and nausea.

Adverse events reported for Aboriginal and Torres Strait Islander people

When someone reports a suspected side effect to the TGA, we ask them to include patient ethnicity on the reporting form to help us identify any differences between particular populations. This information is not always given, so our data on ethnicity is not comprehensive. However, what we do receive gives us a useful indication of vaccine safety in different populations.

Since the beginning of the vaccine rollout to 20 June 2021, the reporting rate of side effects following vaccination of Aboriginal and Torres Strait Islander people is 3.1 reports per 1000 vaccine doses. This is slightly lower than for the total population (4.8 reports per 1000 vaccine doses), which may reflect incomplete reporting of ethnicity given that fewer than 20% of reports received by the TGA include information on ethnicity.

The nature of the side effects reported to the TGA for Aboriginal and Torres Strait Islander people are similar to the total population with the most common being headache, muscle and joint pain, fatigue, fever and chills, and lethargy.

Based on the information reported to the TGA, none of the TTS cases so far has been identified as being in an Aboriginal or Torres Strait Islander person.

Further information on adverse event reports in Aboriginal and Torres Strait Islander people is published in the ongoing AusVaxSafety survey (https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines).

AstraZeneca COVID-19 vaccine

We continue to receive reports of side effects to the AstraZeneca vaccine as it continues to be used in Australia. The reports are generally consistent with what is being observed internationally and most are expected side effects that we know occur after vaccination and resolve within a few days.

Thrombosis with thrombocytopenia syndrome (TTS

The TGA and other medicines regulators around the world continue to closely monitor and investigate TTS. This is a rare event involving serious blood clots with a low blood platelet count. It is triggered by the immune system's response to the AstraZeneca vaccine and is different from other clotting conditions.

On 17 June 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) recommended (https://www.health.gov.au/news/atagi-statement-on-revised-recommendations-on-the-use-of-covid-19-vaccine-astrazeneca-17-june-2021) that Pfizer's Comirnaty vaccine be preferred over the AstraZeneca vaccine for those aged 16–60 years old. Previously ATAGI recommended Comirnaty over the AstraZeneca vaccine for those aged 16–50 years old. ATAGI updated their recommendations due to emerging evidence in Australia of a higher risk and severity of TTS with the first AstraZeneca dose in the 50–59 year age group.

People aged 50–59 years old who have already received the first dose of the AstraZeneca vaccine should complete their two-dose schedule as the risk of TTS after the second dose is extremely low. For example, in the UK where many more AstraZeneca doses have been given, the risk of TTS (which includes confirmed, probable and possible cases) was estimated to be 1.5 cases per million with the second dose compared to 14.2 cases per million with the first dose.

Since last week's report, a further five reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS likely to be linked to the AstraZeneca vaccine and; review of additional clinical information has led to a previously reported probable case now being considered unlikely to be TTS. (Table 1).

Table 1: Newly confirmed and probable TTS cases for the week of 18-24 June 2021‡

New confirmed TTS	**New probable TTS**
Three new cases: • 51, 54 and 60-year-old women from NSW	Two new cases: • 59-year-old woman from Victoria • 95-year-old man from NSW

‡As previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021), the TGA determines whether a report is likely to represent TTS by assessing cases against a consistent set of criteria, based on the case definitions established by the UK's Medicines and Healthcare products Regulatory Agency.

One previously reported case from South Australia was reclassified from confirmed to probable following revised clinical information being provided to the TGA. This takes the total Australian reports assessed as TTS following the AstraZeneca vaccine to 39 confirmed cases and 25 probable cases, with a total of 64 cases overall from approximately 4.2 million doses of the AstraZeneca vaccine.

When assessed against the criteria used by the US Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf), fewer than half of them are classified as Tier 1 cases, which involve clots in an unusual location, such as the brain or abdomen (Table 2). Of note, Tier 1 cases tend to have more serious outcomes than Tier 2 cases.

Based on the information we have, about half of the Tier 1 cases had clots in the brain (cerebral venous sinus thrombosis - CVST) and half had clots in the abdomen (splanchnic vein thrombosis). Of those with clots in the brain, around half also had other another clot in the leg (deep vein thrombosis - DVT) or the lungs (pulmonary embolism - PE). The Tier 2 and unclassified TTS cases had only the more common clots like deep vein thrombosis or pulmonary embolism.

Table 2: Total confirmed and probable TTS cases by age and CDC classification

Age	**Total cases**	**CDC classification†**		
		Tier 1	Tier 2	Not classified
<30 years	1	-	-	1
30-39	1	1	-	-
40-49	4	4	-	-
50-59	18	8	4	6
60-69	12	3	4	5
70-79*	18	6	5	7
80+	10	3	4	3
All ages	64 **(32 men, 32 women)***	25	17	22

† The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) and a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) and a low platelet count and anti-PF4 antibodies
- Not classified = case does not meet the criteria for Tier 1 or Tier 2 (for example clots in common locations with low platelet count but no evidence of anti-PF4 antibodies).

* Please note last week's report had two minor errors that have been corrected in the above. They related to the number of cases in men and women, and a 69-year-old patient was incorrectly included in the 70-79 year old age group.

Cases have most often occurred about two weeks after vaccination, although the time to onset (or diagnosis) has ranged from one to 44 days (Table 3). In some cases with a longer time to diagnosis, patients had experienced symptoms at an earlier stage but complicating factors, including symptoms from comorbidities, may have delayed a clear diagnosis. Approximately one in four TTS cases has required Intensive Care Unit (ICU) treatment, although all but five patients have since been released from ICU.

Table 3: Time to onset, treatment and outcomes for TTS cases*

Time to onset/ diagnosis (days)	Median (range)	12 (1-44)
Treated in ICU	At any point	14
	Currently	5
Outcome	Discharged	43
	In hospital	19
	Fatal	2

*Data is based on the most recent medical information available to the TGA

Updated reporting rates of TTS in Australia were published in a statement from ATAGI published on 17 June 2021 (https://www.health.gov.au/news/atagi-statement-on-revised-recommendations-on-the-use-of-covid-19-vaccine-astrazeneca-17-june-2021). Compared to information published by the UK's medicine regulator (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting), the fatality rate is lower in Australia (3% in Australia compared to 18% in the UK).

While TTS is very rare, it is appreciated that some people may have concerns that they can discuss with their doctor. This is essential to allow people to make an informed choice.

Anyone who has been vaccinated should seek immediate medical attention if they develop any of the following symptoms after vaccination:

- severe or persistent headache or blurred vision
- shortness of breath, chest pain, leg swelling or persistent abdominal pain
- unusual skin bruising and/or pinpoint round spots beyond the site of vaccination.

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

Guillain-Barre Syndrome (GBS)

To 20 June 2021, the TGA has received 38 reports of suspected Guillain-Barre Syndrome (GBS) following approximately 4.2 million doses of the AstraZeneca vaccine. GBS is a rare immune disorder that causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking. In many cases it resolves within months but can sometimes take up to two years. GBS can occur following an infection or other immunisations such as the influenza vaccines.

A causal link between GBS and the AstraZeneca vaccine has not been confirmed in Australia or overseas and it is unclear if these cases are related to vaccination or occurred coincidentally. GBS is currently being assessed by the Pharmacovigilance Risk Assessment Committee in Europe (https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-3-6-may-2021) and the TGA will report on this investigation when more information is available. We continue to monitor and investigate Australian reports of GBS along with other serious adverse event reports that relate to the nervous system. Part of this investigation will look more closely at whether these suspected cases meet the clinical criteria for GBS, and will compare the number of observed cases to those expected generally for different age groups and time points following vaccination.

Up-to-date information about the expected side effects of the AstraZeneca COVID-19 vaccine can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=COVID-19%20Vaccine%20AstraZeneca) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=COVID-19%20Vaccine%20AstraZeneca&r=/) (for health professionals).

Comirnaty (Pfizer) vaccine

Side effects to the Comirnaty vaccine continue to be reported to the TGA and are consistent with what has been observed in the clinical trials and by other medicine regulators overseas.

Side effects with first and second doses of the Comirnaty vaccine

Data from an ongoing survey of Australians after they receive a COVID-19 vaccine (AusVaxSafety (https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines)) suggests that side effects are more common after the second dose of Comirnaty compared to the first dose. In the survey, 37% of respondents said they had a reaction to the first dose compared to 60% after the second dose. This reflects what was found in the clinical trials of Comirnaty (https://www.nps.org.au/australian-prescriber/articles/bnt162b2-vaccine-for-prevention-of-covid-19), with a higher proportion of people experiencing expected vaccine side effects such as fatigue, headache, muscle and joint pain and fever after the second dose than after the first dose. Interestingly, the opposite was found in trials of the AstraZeneca vaccine (https://www.nps.org.au/australian-prescriber/articles/chadox1-s-vaccine-for-prevention-of-covid-19) with side effects being less common after the second dose.

In the AusVaxSafety survey, the most common reactions with both Comirnaty doses were injection site pain, fatigue, headache and muscle aches. These are known and expected side effects of vaccines generally and mostly resolve within a day or two.

A similar pattern of reporting for Comirnaty is also observed in our database at the TGA with more reports of side effects with the second dose (4.2 per 1000 doses) compared to the first dose (3.1 per 1000 doses). The most common side effects reported to the TGA are similar to those seen in the AusVaxSafety survey.

Myocarditis and pericarditis

The TGA continues to monitor reports of myocarditis (inflammation of the heart) and pericarditis (inflammation of the membrane around the heart) following reports of a signal for a possible safety concern in the US (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html) and Israel (https://www.gov.il/en/departments/news/01062021-03) in young men. Almost all cases were considered mild and resolved within a few days. A causal link to the vaccine has not yet been established but international regulators are investigating this.

Myocarditis and pericarditis often occur following a viral infection and most cases are mild with no long-term effects. Severe cases may cause damage to the heart muscle although this is very rare.

Since last weeks' report (13–20 June 2021), the TGA has received four new reports – three reports of suspected myocarditis and one report of suspected pericarditis following immunisation with the Comirnaty vaccine. These reports will be considered as part of TGA's ongoing investigation.

We encourage people to report symptoms that could suggest myocarditis or pericarditis such as chest pain, shortness of breath and palpitations, particularly after the second dose of Comirnaty.

Up-to-date information about Pfizer Comirnaty can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=Comirnaty) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=comirnaty) (for health professionals).

Useful links

TGA COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines)

Australian Government Department of Health COVID-19 vaccines (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines) hub

AusVaxSafety (http://www.ausvaxsafety.org.au) (active surveillance activities and information)

COVID-19 vaccine symptom checker (https://www.healthdirect.gov.au/symptom-checker/tool)

Database of Adverse Event Notifications (DAEN) (https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx)

The latest from ATAGI – published 17 June 2021 (https://www.health.gov.au/news/atagi-statement-on-revised-recommendations-on-the-use-of-covid-19-vaccine-astrazeneca-17-june-2021)

Updated advice on COVID-19 vaccination during pregnancy (https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women)

Top 3 COVID-19 vaccine questions – AstraZeneca for under 60s, over 60s, and side effects (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-astrazeneca-for-under-60s-over-60s-and-side-effects)

Top 3 COVID-19 vaccine questions – New ATAGI advice, second doses and Pfizer access (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-new-atagi-advice-second-doses-and-pfizer-access)

URL: https://www.tga.gov.au/node/938385 (https://www.tga.gov.au/node/938385)

Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine weekly safety report - 01-07-2021

Release date Thursday, 1 July 2021

Previous reports

Vaccination against COVID-19 is the single most effective way to reduce severe illness and death from infection. Two COVID-19 vaccines (//www.tga.gov.au/covid-19-vaccines) are currently in use in Australia – the AstraZeneca vaccine and the Comirnaty (Pfizer) vaccine. Like all medicines, the vaccines have side effects (also known as adverse events). The overwhelming majority of these are mild and resolve within a few days. The Therapeutic Goods Administration (TGA) closely monitors suspected side effects. Importantly, adverse events reported to the TGA are often not caused by the vaccine itself. Learn more about causality (//www.tga.gov.au/about-daen-medicines#causality).

Learn about the TGA's COVID-19 vaccine safety monitoring and reporting (//www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting) activities or report a suspected side effect (//www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine).

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Five additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, two were confirmed and three were deemed probable TTS. This brings the total number of cases of TTS to 69 out of 4.8 million doses to date.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues (//www.tga.gov.au/tga-safety-monitoring-medicines#steps).

In the week of 21-27 June 2021 we received 1459 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination and monitors signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 27 June 2021, there have been over 7.3 million doses of COVID-19 vaccines administered. The TGA has received and reviewed 335 reports of deaths in people who have recently been vaccinated and found that two were definitely linked to vaccination. These were both TTS cases related to the AstraZeneca vaccine.

Total adverse event reports to 27 June 2021

4.6 Reporting rate per 1000 doses	33,807 Total AEFI reports received	7,374,666 Total doses administered
23,235 Total reports for AZ vaccine	10,314 Total reports for Comirnaty	263 Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.0	New South Wales	3.4
Northern Territory	4.4	Queensland	4.4
South Australia	4.1	Tasmania	6.6
Victoria	5.8	Western Australia	4.0

Most commonly reported vaccine side effects

The most common adverse effects following immunisation (AEFI) reported to the TGA are predictable and have been observed with vaccines generally. They include headache, muscle and joint pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 21-27 June 2021 were headache, muscle pain, fever, nausea and fatigue.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 21-27 June 2021 were headache, dizziness, nausea, muscle pain, and lethargy.

AstraZeneca COVID-19 vaccine

We continue to receive reports of side effects to the AstraZeneca vaccine. The reports are generally consistent with what is being observed internationally and most are expected side effects that we know occur after vaccination and resolve within a few days.

Thrombosis with thrombocytopenia syndrome (TTS)

The TGA and other medicines regulators around the world continue to closely monitor and investigate TTS. This is a rare event involving serious blood clots with a low blood platelet count. It is triggered by the immune system's response to the AstraZeneca vaccine and is different from other clotting conditions.

On the 17 June, the Australian Technical Advisory Group on Immunisation (ATAGI) recommended (https://www.health.gov.au/news/atagi-statement-on-revised-recommendations-on-the-use-of-covid-19-vaccine-astrazeneca-17-june-2021) that Pfizer's Comirnaty vaccine be preferred over the AstraZeneca vaccine for those aged 16–60 years old. However, while Comirnaty is preferred for under 60s, the AstraZeneca vaccine remains approved by the TGA (and most other major regulators) for those 18 and over.

People under 60 years of age who have already received their first AstraZeneca dose should complete the two-dose schedule as the risk of TTS after the second dose is extremely low (1.6 cases per million second doses based on UK data). Updated reporting rates of TTS in Australia were published in a statement from ATAGI on 25 June 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-23-june-2021).

People under the age of 60 years can also have the AstraZeneca vaccine if they choose. Information is available to help people weigh up the benefits and risks of receiving the AstraZeneca vaccine (https://www.health.gov.au/sites/default/files/documents/2021/06/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca_0.pdf). While TTS is very rare, some people may have concerns that they can discuss with their doctor. This is essential to allow people to make an informed choice about vaccination.

People should seek immediate medical attention if they develop any of the following symptoms after vaccination:

- severe or persistent headache or blurred vision
- shortness of breath, chest pain, leg swelling or persistent abdominal pain
- unusual skin bruising and/or pinpoint round spots beyond the site of vaccination.

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

TTS cases to date

Since last week's report, a further five reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS likely to be linked to the AstraZeneca vaccine (Table 1).

Table 1: Newly confirmed and probable TTS cases for the week of 25 June-1 July 2021‡

New confirmed TTS	New probable TTS

New confirmed TTS	**New probable TTS**
Two new cases: • 52-year-old woman from WA • 59-year-old woman from Victoria	Three new cases: • 64-year-old woman from NSW • 77 and 83-year-old men from NSW

‡As previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021), the TGA determines whether a report is likely to represent TTS by assessing cases against a consistent set of criteria, based on the case definitions established by the UK's Medicines and Healthcare products Regulatory Agency.

This takes the total Australian reports assessed as TTS following the AstraZeneca vaccine to 41 confirmed cases and 28 probable cases, with a total of 69 cases overall from approximately 4.6 million doses of the AstraZeneca vaccine.

When assessed against the criteria used by the US Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf), fewer than half of the cases reported to TGA are classified as Tier 1 cases, which involve clots in an unusual location, such as the brain or abdomen (Table 2). Of note, Tier 1 cases tend to have more serious outcomes than Tier 2 cases. Tier 1 cases were less common in older people. Approximately one quarter of cases were classified as Tier 1 in patients aged 60 years or older, compared to approximately half the case in people aged less than 60 years.

Based on the information we have, about half of the Tier 1 cases had clots in the brain (cerebral venous sinus thrombosis - CVST) and half had clots in the abdomen (splanchnic vein thrombosis). Of those with clots in the brain, around half also had another clot in the leg (deep vein thrombosis - DVT) or the lungs (pulmonary embolism - PE). The Tier 2 and unclassified TTS cases had only the more common clots like deep vein thrombosis or pulmonary embolism.

Table 2: Total confirmed and probable TTS cases to date by age and CDC classification

Age	**Total cases**	**CDC classification†**		
		Tier 1	Tier 2	Not classified
<30 years	1	-	1	-
30-39	1	1	-	-
40-49	4	4	-	-
50-59	20	9	6	5
60-69	13	3	4	6
70-79	19	6	5	8
80+	11	3	4	4
All ages	**69** **(34 men, 35 women)**	26	20	23

† The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) **and** a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) and a low platelet count **and** anti-PF4 antibodies
- Not classified = case does not meet the criteria for Tier 1 or Tier 2 (for example clots in common locations with **low** platelet count but no evidence of anti-PF4 antibodies).

Cases have most often occurred about two weeks after vaccination, although the time to onset (or diagnosis) has ranged from one to 44 days (Table 3). In some cases with a longer time to diagnosis, patients had experienced symptoms at an earlier stage but complicating factors, including symptoms from comorbidities, may have delayed a clear diagnosis. Approximately one in four TTS cases has required Intensive Care Unit (ICU) treatment, although all but three patients have since been released from ICU.

Table 3: Time to onset, treatment and outcomes for TTS cases*

Time to onset/ diagnosis (days)	Median (range)	12 (1-44)
Treated in ICU	At any point†	18
	Currently	3
Outcome	Discharged	51
	In hospital	16
	Fatal	2

*Data is based on the most recent medical information available to the TGA
†Last week's report had an error in the ICU data. Three patients that were in ICU were not included in the total for patients that received ICU treatment at any point. This has been corrected above.

The TGA has sadly been advised by its UK counterpart, the Medicines and Healthcare products Regulatory Agency (MHRA) (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency), of the death of a woman in the UK five weeks after receiving her first dose of the AstraZeneca vaccine in Australia.

While some of her symptoms, imaging results and pathology tests suggested TTS, the woman had another very serious and recent underlying health condition and UK authorities have ordered a post-mortem to assess whether this condition, along with the impact of long plane and car travel from Australia to the UK, had a role in her death.

Her family has requested privacy, and we pass on our condolences to them at this sad time.

It is not known whether she was an Australian citizen or permanent resident.

Immune thrombocytopenia (ITP)

The TGA is closely monitoring reports of immune thrombocytopenia (ITP) and investigating whether there may be a link with the AstraZeneca vaccine. This is in light of cases reported to the TGA and a recent Scottish study suggesting a small increase in the risk of ITP (1 in 100,000 vaccinated people) (https://www.nature.com/articles/s41591-021-01408-4#article-info).

To 27 June 2021, the TGA has received 36 cases of suspected ITP in people who had received the AstraZeneca vaccine and two cases in people who received the Comirnaty vaccine. Although many of these individuals have recovered or are recovering, one person who had received the AstraZeneca vaccine sadly died. The TGA has convened an external Vaccine Safety Investigation Group of clinical experts and consumer representatives to review this fatality and assess whether it could have been related to the vaccine. The TGA will report on the outcome of this investigation when it becomes available. We extend our sincerest condolences to the individual's family and loved ones.

ITP is a rare bleeding disorder which occurs when the immune system mistakenly destroys platelets, which help blood to clot. It causes minor bruising in some people but others may develop severe bleeding. ITP can occur after the immune system is activated, for example by a viral infection or vaccination, and has been reported with other vaccines for hepatitis B, measles, mumps, rubella and influenza.

Capillary leak syndrome

Cases of capillary leak syndrome following immunisation with the AstraZeneca vaccine have been reported overseas (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting). Two of these eight cases had a history of capillary leak syndrome. This is a very rare but severe relapsing-remitting condition where fluid from small blood vessels (capillaries) leaks into surrounding tissues. It is not well understood what triggers a relapse.

The TGA received one case of a patient who died from multi-organ failure but had signs of capillary leakage reported previously (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021). Although there was a temporal link with the vaccine, an expert Vaccine Safety Investigation Group was unable to establish a causal link as other causes could not be ruled out.

The TGA is in discussions with the sponsor about including information on capillary leak syndrome in the Product Information as a precautionary measure.

Up-to-date information about the expected side effects of the AstraZeneca COVID-19 vaccine can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=COVID-19%20Vaccine%20AstraZeneca) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=COVID-19%20Vaccine%20AstraZeneca&r=/) (for health professionals).

Comirnaty (Pfizer) vaccine

Side effects to the Comirnaty vaccine continue to be reported to the TGA and are consistent with what has been observed in the clinical trials and by other medicine regulators overseas.

Myocarditis and pericarditis

The TGA continues to monitor reports of myocarditis (inflammation of the heart) and pericarditis (inflammation of the membrane around the heart) following a safety concern in the US (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html) and Israel (https://www.gov.il/en/departments/news/01062021-03).

To 27 June 2021, the TGA has received 26 cases of suspected myocarditis or pericarditis. During this time, approximately 2.9 million Comirnaty doses have been given. Eight of the TGA reports were in men and 18 were in women. One of the men was 18 years old and another was 23 years old, while the others were aged 41–72 years. The women were aged 23–47 years old. At the time of reporting, the majority of individuals had recovered or were recovering.

Overseas cases of myocarditis and pericarditis have mostly been in young men after the second Comirnaty dose. As we have limited experience of Comirnaty in this age group and after the second dose, the TGA is considering international evidence in our ongoing investigation of this issue.

On 23 June 2021, a review by the US CDC's Advisory Committee on Immunization Practices advised that myocarditis and pericarditis following the Comirnaty vaccine (https://www.hhs.gov/about/news/2021/06/23/statement-following-cdc-acip-meeting-nations-leading-doctors-nurses-public-health-leaders-benefits-vaccination.html) are extremely rare side effects which are usually mild. The US Food and Drug Administration (FDA) has since added a warning to the product information. (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021)

The TGA is actively considering the need for updates to the approved Product Information, and has sought advice from the Advisory Committee on Vaccines on this issue.

We know that myocarditis and pericarditis are much more common with COVID-19 infection and the risks to the heart can be more severe in this context. The benefits of protection against COVID-19 far outweigh these rare and generally mild side effects.

We encourage people to seek medical attention if they experience symptoms that could suggest myocarditis or pericarditis such as of chest pain, shortness of breath and palpitations. Typically these have occurred within seven days of vaccination, particularly after the second dose of Comirnaty.

Up-to-date information about Pfizer Comirnaty can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=Comirnaty) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=comirnaty) (for health professionals).

Useful links

TGA COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines)

Australian Government Department of Health COVID-19 vaccines (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines) hub

AusVaxSafety (http://www.ausvaxsafety.org.au) (active surveillance activities and information)

COVID-19 vaccine symptom checker (https://www.healthdirect.gov.au/symptom-checker/tool)

Database of Adverse Event Notifications (DAEN) (https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx)

The latest from ATAGI – published 25 June 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-23-june-2021)

Updated advice on COVID-19 vaccination during pregnancy (https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women)

Top 3 COVID-19 vaccine questions – Delta variant, vaccination and breastfeeding, and more vaccine types (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-delta-variant-vaccination-and-breastfeeding-and-more-vaccine-types)

URL: https://www.tga.gov.au/node/938437 (https://www.tga.gov.au/node/938437)

Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine weekly safety report - 08-07-2021

Release date Thursday, 8 July 2021 Previous reports

Vaccination against COVID-19 is the single most effective way to reduce severe illness and death from infection. Two COVID-19 vaccines (//www.tga.gov.au/covid-19-vaccines) are currently in use in Australia – AstraZeneca and Comirnaty (Pfizer). Like all medicines, the vaccines can have side effects (also known as adverse events). The overwhelming majority of these are mild and resolve within a few days. The Therapeutic Goods Administration (TGA) closely monitors suspected side effects. Importantly, adverse events reported to the TGA are often not caused by the vaccine itself. Learn more about causality (//www.tga.gov.au/about-daen-medicines#causality).

Learn about the TGA's COVID-19 vaccine safety monitoring and reporting (//www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting) activities or report a suspected side effect (//www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine).

Summary

- The most frequently reported suspected side effects (http://#section-599) associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- An external Vaccine Safety Investigation Group (VSIG), convened by the TGA on 2 July 2021, concluded that a very rare but fatal case of immune thrombocytopenia (ITP) in a 61-year-old woman who had received the AstraZeneca vaccine was likely to be related to immunisation.
- Seven additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, three were confirmed TTS and four were deemed probable TTS. This brings the total number of cases of TTS to 76 out of five million doses to date.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues (//www.tga.gov.au/tga-safety-monitoring-medicines#steps).

In the week of 28 June - 4 July 2021 we received 1,646 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination. We also monitor signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 4 July 2021, over 8.2 million doses of COVID-19 vaccines have been given. The TGA has received and reviewed 355 reports of deaths in people who have recently been vaccinated and found that only three were linked to immunisation. These deaths were all related to the first dose of the AstraZeneca vaccine – two were TTS cases and one was a case of ITP (reported below).

Total adverse event reports to 4 July 2021

4.4 Reporting rate per 1000 doses	36,387 Total AEFI reports received	8,255,473 Total doses administered
24,795 Total reports for AZ vaccine	11,321 Total reports for Comirnaty	276 Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.8	New South Wales	3.2
Northern Territory	4.2	Queensland	4.1
South Australia	4.0	Tasmania	6.6
Victoria	5.7	Western Australia	3.9

Most commonly reported vaccine side effects

The most common adverse effects following immunisation reported to the TGA are predictable and have been observed with vaccines generally. They include headache, muscle pain, fever, chills, nausea and injection site reactions.

The most common reactions reported for the AstraZeneca vaccine in the week 28 June – 4 July 2021 were headache, fatigue, muscle pain, fever and nausea.

The most common reactions reported for the Comirnaty (Pfizer) vaccine in the week of 28 June – 4 July 2021 were headache, muscle pain, lethargy, fever and nausea.

Interpreting information on vaccine adverse event reports

We are aware that false claims are circulating based on misinterpretation of adverse event information published by medicine regulators. To improve transparency, the TGA makes adverse event reports publicly available in the Database of Adverse Event Notifications (DAEN (//www.tga.gov.au/database-adverse-event-notifications-daen)). Similar information is published by other regulators overseas. When interpreting this information, it is important to understand that many of these events may not be caused by vaccine.

The TGA encourages reporting of adverse events even if people are uncertain or only suspicious that it is related to a vaccine or medicine. This supports our scientists and health professionals to use the data to look for new safety signals. Reporting of adverse events, such as the death of anyone who has received a vaccine, is mandatory for health professionals in some states, even if they know it is unrelated to immunisation. It is therefore important to remember that the number of adverse events and deaths is not an indicator of the safety of the vaccines. Detailed investigation and expert review of this data and individual cases are required to assess whether there is a link between an event and the vaccine.

It is important when looking for information about COVID-19 vaccines to consider whether the source of the information is credible. Useful websites such as 'COVID vaccines – is it true? (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true)' help to debunk false claims and misleading rumours. Other reliable resources are listed at the end of this report.

AstraZeneca COVID-19 vaccine

We continue to receive reports of side effects to the AstraZeneca vaccine. The reports are generally consistent with what is being observed internationally and most are expected side effects that we know occur after vaccination and resolve within a few days. So far, approximately five million doses of the AstraZeneca have been administered.

Immune thrombocytopenia (ITP)

The TGA is closely monitoring reports of ITP in light of a case in a 61-year-old woman from Western Australia who developed severe ITP after receiving the AstraZeneca vaccine. Sadly the woman died and we extend our sincerest condolences to her family and loved ones.

An external Vaccine Safety Investigation Group (VSIG) of clinical experts and consumer representatives, convened on 2 July 2021, concluded that the woman's death was likely linked to the vaccine. This was based on the lack of strong evidence for other causes and the occurrence of the event being within a plausible time period after vaccination. While the woman had experienced a recent viral illness that could have theoretically caused ITP, the panel felt that the unusual severity of the event suggested that vaccination was a more likely cause.

ITP is a rare bleeding disorder that occurs when the immune system mistakenly destroys platelets, which help blood to clot. It can occur after the immune system is activated, for example by a viral infection or vaccination, and has been reported with other vaccines for hepatitis B, measles, mumps, rubella and influenza. Up to a third of people with ITP will have no symptoms at all, or have only minor bruising. However, about 5% develop severe bleeding.

The risk of ITP associated with the AstraZeneca vaccine is still being investigated and characterised. Preliminary findings from a recent Scottish study (https://www.nature.com/articles/s41591-021-01408-4#article-info) estimate the risk of ITP to be about 1 case per 100,000 AstraZeneca doses. To 4 July 2021, the TGA has received 36 reports of suspected ITP. The TGA continues to investigate this issue and we will report more information when it is known.

We encourage people to seek medical attention if they experience signs and symptoms that could suggest ITP, such as unusual skin bruising or clusters of small red or purple spots that do not lose their colour when pressed. Unusual bleeding is another sign, for example bleeding from the nose or mouth that is hard to stop, or blood in the urine or stools.

Thrombosis with thrombocytopenia syndrome (TTS)

The TGA and other international medicines regulators continue to closely monitor and investigate TTS. This is a rare event involving serious blood clots with a low blood platelet count. It is triggered by the immune system's response to the AstraZeneca vaccine and is different from other clotting conditions. Updated reporting rates of TTS in Australia were published in a statement from Australian Technical Advisory Group on Immunisation (ATAGI) on 1 July 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-30-june-2021).

While Pfizer's Comirnaty vaccine is preferred over the AstraZeneca vaccine for those aged 16–60 years old, as recommended by ATAGI (https://www.health.gov.au/news/atagi-statement-on-revised-recommendations-on-the-use-of-covid-19-vaccine-astrazeneca-17-june-2021), the AstraZeneca vaccine remains approved by the TGA (and most other major regulators) for those aged 18 and over.

Information is available to help people weigh up the benefits and risks of receiving the AstraZeneca vaccine (https://www.health.gov.au/sites/default/files/documents/2021/06/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca_0.pdf). While TTS is very rare, some people may have concerns that they can discuss with their doctor. This is essential to allow people to make an informed choice about vaccination.

People should seek immediate medical attention if they develop any of the following symptoms after vaccination:

- severe or persistent headache or blurred vision
- shortness of breath, chest pain, leg swelling or persistent abdominal pain
- unusual skin bruising and/or pinpoint round spots beyond the site of vaccination.

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

VSIG review of possible TTS following a second dose of the AstraZeneca vaccine

The VSIG held on 2 July also reviewed a case of a 73-year-old man with possible TTS following his second dose of the AstraZeneca vaccine. On further investigation, the panel concluded that the case was unlikely to be related to vaccination as the patient had a very mild and transient form of thrombocytopenia, a common clot in the leg and he did not have anti-PF4 antibodies. In addition, the patient had an underlying condition known to increase the risk of blood clots.

To date, there have been no confirmed or probable case of TTS in Australia that occurred after the second AstraZeneca dose. People under 60 years of age who have already received their first AstraZeneca dose should complete the two-dose schedule as the risk of TTS after the second dose is extremely low (1.6 cases per million second doses based on UK data).

TTS cases to date

Since last week's report, a further seven reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS likely to be linked to the AstraZeneca vaccine (Table 1).

Table 1: Newly confirmed and probable TTS cases for the week of 25 June-1 July 2021‡

New confirmed TTS	New probable TTS
Three new cases: • 59-year-old woman and a 59-year-old man from Victoria • 72-year-old woman from South Australia	Four new cases: • 60 and 68-year-old women and a 71-year-old man from NSW • 82-year-old woman from Western Australia

‡As previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021), the TGA determines whether a report is likely to represent TTS by assessing cases against a consistent set of criteria, based on the case definitions established by the UK's Medicines and Healthcare products Regulatory Agency.

In addition to the new cases identified above, one previously reported case was reclassified from probable to confirmed. This takes the total Australian reports assessed as TTS following the AstraZeneca vaccine to 45 confirmed cases and 31 probable cases, with a total of 76 cases overall from approximately five million doses of the AstraZeneca vaccine.

When assessed against the criteria used by the US Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf), fewer than half of the cases reported to TGA are classified as Tier 1 cases which tend to have more serious outcomes. Tier 1 cases involve clots in an unusual location, such as the brain or abdomen (Table 2). The Tier 2 and unclassified TTS cases had only the more common clots like deep vein thrombosis or pulmonary embolism.

Table 2: Total confirmed and probable TTS cases to date by age and CDC classification

Age	**Total cases**	**CDC classification†**		
		Tier 1	Tier 2	Not classified
<30 years	1	-	1	-
30-39	1	1	-	-
40-49	4	4	-	-
50-59	22	10	6	6
60-69	15	4	5	6
70-79	21	7	5	9
80+	11	3	4	5
All ages	76 (36 men, 40 women)	29	21	26

† The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) and a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) and a low platelet count and anti-PF4 antibodies
- Not classified = case does not meet the criteria for Tier 1 or Tier 2 (for example clots in common locations with low platelet count but no evidence of anti-PF4 antibodies).

Cases have most often occurred about two weeks after vaccination, although the time to onset (or diagnosis) has ranged from one to 54 days (Table 3). In some cases with a longer time to diagnosis, patients had experienced symptoms at an earlier stage but complicating factors, including symptoms from comorbidities, may have delayed a clear diagnosis. A little over one in four TTS cases has required Intensive Care Unit (ICU) treatment, although all but six patients have since been released from ICU.

Table 3: Time to onset, treatment and outcomes for TTS cases*

Time to onset/ diagnosis (days)	Median (range)	12 (1-54)
Treated in ICU	At any point	22
	Currently	6
Outcome	Discharged	52
	In hospital	22
	Fatal	2

*Data is based on the most recent medical information available to the TGA

Guillain-Barre Syndrome (GBS)

The TGA has been closely monitoring reports of GBS since the beginning of the COVID-19 vaccine rollout as GBS has been associated with other types immunisations such as influenza vaccines (https://academic.oup.com/cid/article/58/8/1149/355966). To 4 July 2021, the TGA has received 52 reports of suspected GBS following vaccination with the AstraZeneca vaccine.

GBS is a rare immune disorder that causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking. In many cases it resolves within months but can sometimes take up to two years.

A causal link between GBS and the AstraZeneca vaccine has not been confirmed in Australia or overseas. However, the TGA is currently doing a detailed investigation of GBS reports along with other serious adverse event reports that relate to the nervous system. This involves looking more closely at whether these suspected cases meet the clinical criteria for GBS, and comparing the number of observed cases to those that would be expected generally in unvaccinated people. We are also collaborating with our international regulatory counterparts and awaiting the results of an assessment of this issue by the European Medicines Agency.

Up-to-date information about the expected side effects of the AstraZeneca COVID-19 vaccine can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=COVID-19%20Vaccine%20AstraZeneca) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=COVID-19%20Vaccine%20AstraZeneca&r=/) (for health professionals).

Comirnaty (Pfizer) vaccine

Side effects to the Comirnaty vaccine continue to be reported to the TGA and are consistent with what has been observed in the clinical trials and by other medicine regulators overseas. So far, approximately 3.2 million doses of the Comirnaty vaccine have been administered.

Myocarditis and pericarditis

The TGA continues to monitor reports of myocarditis (inflammation of the heart) and pericarditis (inflammation of the membrane around the heart) following a safety concern in the US (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html) and Israel (https://www.gov.il/en/departments/news/01062021-03).

To 4 July 2021, the TGA has received 38 cases of suspected myocarditis or pericarditis – 13 reports were in men and 25 were in women. Of the men, five were aged 17–23 years, while the others were aged 41–72 years. The women were aged 22–65 years old with the most aged in their 20s and 30s. At the time of reporting, the majority of individuals had recovered or were recovering.

Overseas cases of myocarditis and pericarditis have mostly been in young men after the second Comirnaty dose. As we have limited experience of Comirnaty both in this age group and after the second dose, the TGA is considering international evidence in its ongoing investigation of this issue.

On 23 June 2021, a review by the US CDC's Advisory Committee on Immunization Practices advised that myocarditis and pericarditis following the Comirnaty vaccine (https://www.hhs.gov/about/news/2021/06/23/statement-following-cdc-acip-meeting-nations-leading-doctors-nurses-public-health-leaders-benefits-vaccination.html) are extremely rare side effects which are usually mild. The US Food and Drug Administration (FDA) has since added a warning to the product information. (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021)

The TGA is currently working with Pfizer to add a warning statement to the Product Information and include myocarditis and pericarditis as an adverse event identified through post-marketing experience.

We know that myocarditis and pericarditis are much more common with COVID-19 infection and the risks to the heart can be more severe in this context. The benefits of protection against COVID-19 far outweigh these rare and generally mild side effects.

We encourage people to seek medical attention if they experience symptoms that could suggest myocarditis or pericarditis such as of chest pain, shortness of breath and palpitations. Typically these have occurred within seven days of vaccination, and more commonly after the second dose of Comirnaty.

Up-to-date information about Pfizer Comirnaty can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=Comirnaty) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=comirnaty) (for health professionals).

Useful links

COVID vaccines – is it true? (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true)

Top 3 COVID-19 vaccine questions – COVID-19 vaccines and aged care, symptoms after vaccine, and mixing vaccines– 1 July 2021 (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-covid-19-vaccines-and-aged-care-symptoms-after-vaccine-and-mixing-vaccines)

Top 3 COVID-19 vaccine questions – COVIDSafe after vaccine, Delta variant symptoms and mask wearing – 30 June 2021 (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-covidsafe-after-vaccine-delta-variant-symptoms-and-mask-wearing)

The latest from ATAGI – published 1 July 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-30-june-2021)

TGA COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines)

Australian Government Department of Health COVID-19 vaccines (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines) hub

AusVaxSafety (http://www.ausvaxsafety.org.au) (active surveillance activities and information)

COVID-19 vaccine symptom checker (https://www.healthdirect.gov.au/symptom-checker/tool)

Database of Adverse Event Notifications (DAEN) (https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx)

Advice on COVID-19 vaccination during pregnancy (https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women)

URL: https://www.tga.gov.au/node/938508 (https://www.tga.gov.au/node/938508)

Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine weekly safety report - 15-07-2021

Release date Thursday, 15 July 2021 Previous reports

Vaccination against COVID-19 is the single most effective way to reduce severe illness and death from infection. Two COVID-19 vaccines (//www.tga.gov.au/covid-19-vaccines) are currently in use in Australia – AstraZeneca and Comirnaty (Pfizer). Like all medicines, the vaccines can have side effects (also known as adverse events). The overwhelming majority of these are mild and resolve within a few days. The Therapeutic Goods Administration (TGA) closely monitors suspected side effects. Importantly, adverse events reported to the TGA are often not caused by the vaccine itself. Learn more about causality (//www.tga.gov.au/about-daen-medicines#causality).

Learn about the TGA's COVID-19 vaccine safety monitoring and reporting (//www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting) activities or report a suspected side effect (//www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine).

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- As reported by South Australian Health authorities on 12 July 2021, sadly a 72-year-old woman from South Australia has died from TTS following vaccination with a first dose of the AstraZeneca vaccine. This case was confirmed to be linked to the vaccine and was reported in last weeks' report.
- Seven additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the United Kingdom (UK) case definition, four were confirmed and three were deemed probable TTS. This brings the total number of cases of TTS to 83 from 5.4 million doses administered to date.
- We continue to closely monitor reports of immune thrombocytopenia (ITP) and Guillain-Barre Syndrome (GBS) following vaccination with the AstraZeneca vaccine and myocarditis and pericarditis with the Comirnaty vaccine.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues (//www.tga.gov.au/tga-safety-monitoring-medicines#steps).

In the week of 5-11 July 2021 we received 1,705 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination. We also monitor signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 11 July 2021, over 9.1 million doses of COVID-19 vaccines have been given. The TGA has received and reviewed 377 reports of deaths in people who have recently been vaccinated and found that four were linked to immunisation. These deaths were all related to the first dose of the AstraZeneca vaccine – three were TTS cases and one was a case of ITP.

Total adverse event reports to 11 July 2021

4.3	39,077	9,149,817
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
26,302	12,495	288

Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.5	New South Wales	3.1
Northern Territory	3.9	Queensland	4.0
South Australia	3.8	Tasmania	6.6
Victoria	5.6	Western Australia	3.8

Most commonly reported vaccine side effects

The most common adverse effects following immunisation reported to the TGA are predictable and have been observed with vaccines generally. They include headache, muscle pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 5-11 July 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 5-11 July 2021 were headache, muscle pain, lethargy, injection site reactions and nausea.

Adverse events reported for Aboriginal and Torres Strait Islander people

When someone reports a suspected side effect to the TGA, we ask them to include patient ethnicity on the reporting form to help us identify any differences between particular populations. Almost half of the reports include this information which gives us a useful indication of vaccine safety in different populations. We previously reported that only 20% of reports included ethnicity (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-24-06-2021), but this has been revised to almost 50% following further analysis of our data.

Since the beginning of the vaccine rollout to 11 July 2021, the reporting rate of side effects following vaccination of Aboriginal and Torres Strait Islander people is 2.5 reports per 1000 vaccine doses. The nature of the side effects reported for Aboriginal and Torres Strait Islander people are similar to the total population with the most common being headache, muscle pain, fever, nausea and lethargy.

Based on the information reported to the TGA, none of the TTS cases so far has been identified as being in an Aboriginal or Torres Strait Islander person.

Further information on adverse event reports in Aboriginal and Torres Strait Islander people is published in the ongoing AusVaxSafety survey (https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines).

Interpreting information on vaccine adverse event reports

We are aware that false claims are circulating based on misinterpretation of adverse event information published by medicine regulators. To improve transparency, the TGA makes adverse event reports publicly available 90 days after they are received in the Database of Adverse Event Notifications (DAEN (//www.tga.gov.au/database-adverse-event-notifications-daen)). Similar information is published by other regulators overseas. When interpreting this information, it is important to understand that many of these events may not be caused by vaccine.

The TGA encourages reporting of adverse events even if people are uncertain or only suspicious that it is related to a vaccine or medicine. This supports our scientists and health professionals to use the data to look for new safety signals. Reporting of adverse events, such as the death of anyone who has received a vaccine, is mandatory for health professionals in some states, even if they know it is unrelated to immunisation. It is therefore important to remember that the number of adverse events and deaths is not an indicator of the safety of the vaccines. Detailed investigation and expert review of individual case reports and the data as a whole are required to assess whether there is a link between an event and the vaccine.

It is important when looking for information about COVID-19 vaccines to consider whether the source of the information is credible. Useful websites such as 'COVID vaccines – is it true? (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true)' help to debunk false claims and misleading rumours. Other reliable resources are listed at the end of this report.

Latest recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI)

In light of a significant COVID-19 outbreak involving the Delta variant in Australia, ATAGI have reviewed their advice on use of COVID-19 vaccines. Their latest statement, published on 13 July 2021, states that recommendations are unchanged (about:blank) and that Pfizer's Comirnaty vaccine is preferred over the AstraZeneca vaccine for those aged 16–60 years old. The statement reinforces that the benefits of the AstraZeneca vaccine strongly outweigh the risks for people aged 60 and over and given the current outbreak vaccination is essential in this group.

Now we are in an outbreak situation and the risk of catching COVID-19 is higher, ATAGI urges younger Australians who may not be able to get vaccinated immediately with Comirnaty to re-assess whether to get the AstraZeneca vaccine. This should consider the protective benefits of vaccination to themselves and their contacts who may be more vulnerable to serious disease or death from COVID-19.

ATAGI also recommends getting the second AstraZeneca dose within 4–8 weeks after the first dose, rather than waiting 12 weeks, so full protection can be reached sooner.

More details are given in the full ATAGI statement (https://www.health.gov.au/news/atagi-statement-on-use-of-covid-19-vaccines-in-an-outbreak-setting).

AstraZeneca COVID-19 vaccine

Reports of side effects to the AstraZeneca vaccine continue to be generally consistent with what is being observed internationally. Most are expected side effects that we know occur after vaccination and resolve within a few days. To 11 July 2021, approximately 5.4 million doses of the AstraZeneca COVID-19 vaccine have been administered.

Thrombosis with thrombocytopenia syndrome (TTS)

The TGA and other international medicines regulators continue to closely monitor and investigate TTS. This is a rare event involving serious blood clots with a low blood platelet count. It is triggered by the immune system's response to the AstraZeneca vaccine and is different from other clotting conditions.

The latest reporting rates of TTS in Australia were published in a statement from ATAGI on 8 July 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-7-july-2021).

While TTS is very rare, some people may have concerns that they can discuss with their doctor. This is essential to allow people to make an informed choice about vaccination.

People should seek immediate medical attention if they develop any of the following symptoms after vaccination:

- severe or persistent headache, blurred vision, confusion or seizures
- shortness of breath, chest pain, leg swelling or persistent abdominal pain
- unusual skin bruising and/or pinpoint round spots beyond the site of vaccination.

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

Early detection of TTS can prevent more serious complications developing. Guidance for health professionals is available (https://www.health.gov.au/resources/publications/covid-19-vaccination-primary-care-approach-to-thrombosis-with-thrombocytopenia-syndrome-after-covid-19-astrazeneca-vaccine) which outlines when to suspect TTS, initial tests that can be performed in primary care and when to refer people for emergency care.

Death related to TTS

A 72-year-old woman from South Australia has sadly died after developing TTS following vaccination with her first dose of the AstraZeneca vaccine. The TGA extends its sincerest condolences to her family and loved ones. The woman was previously confirmed (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-08-07-2021) as having TTS related to vaccination. This was a very severe case of TTS involving blood clots in the brain and a very low platelet count. Her death was announced by the South Australian Deputy Chief Public Health Officer on Monday 12 July 2021.

TTS cases to date

Since last week's report, a further seven reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS likely to be linked to the AstraZeneca vaccine (Table 1). One of the cases reported this week is critically unwell in intensive care.

Table 1: Newly confirmed and probable TTS cases for the week of 9-15 July 2021‡

New confirmed TTS	New probable TTS

New confirmed TTS	New probable TTS
Four new cases: • 67-year-old man from NSW • 67 and 70-year old women from Victoria • 71-year-old man from Western Australia	Three new cases: • 48-year-old woman from Victoria • 61-year-old woman from Western Australia • 66-year-old woman from the ACT

‡As previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021), the TGA determines whether a report is likely to represent TTS by assessing cases against a consistent set of criteria, based on the case definitions established by the UK's Medicines and Healthcare products Regulatory Agency.

In addition to the new cases identified above, two cases previously reported as probable were reclassified to confirmed. This takes the total Australian reports assessed as TTS following the AstraZeneca vaccine to 51 confirmed cases and 32 probable cases, with a total of 83 cases overall from approximately 5.4 million doses of the AstraZeneca vaccine.

Further information on one of the probable cases reported last week indicates it occurred after the second vaccine dose. The case appeared relatively mild and remains under investigation to determine whether or not it is linked to the vaccine. Based on UK data, the risk of TTS after the second dose is extremely low (1.7 cases per million second doses (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting)).

When assessed against the criteria used by the US Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf), fewer than half of the cases reported to TGA are classified as Tier 1 cases which tend to have more serious outcomes. Tier 1 cases involve clots in an unusual location, such as the brain or abdomen (Table 2). The Tier 2 and unclassified TTS cases had only the more common clots like deep vein thrombosis or pulmonary embolism.

In Australia, severe cases of TTS appear to be more common in women, with nearly half of women with TTS receiving treatment in intensive care. In comparison, only 10% of men with TTS were treated in intensive care. Also, cases meeting the criteria for Tier 1 were twice as likely to occur in women compared to men.

Table 2: Total confirmed and probable TTS cases to date by age and CDC classification

Age	Total cases	CDC classification†		
		Tier 1	Tier 2	Not classified
<30 years	1	-	1	-
30-39	1	1	-	-
40-49	5	5	-	-
50-59	22	10	7	5
60-69	19	6	6	7
70-79	23	7	7	9
80+	12	3	4	5
All ages	**83** **(38 men, 45 women)**	**32**	**25**	**26**

† The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) and a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) and a low platelet count and anti-PF4 antibodies
- Not classified = case does not meet the criteria for Tier 1 or Tier 2 (for example clots in common locations with low platelet count but no evidence of anti-PF4 antibodies).

Cases have most often occurred about two weeks after vaccination, although the time to onset (or diagnosis) has ranged from one to 54 days (Table 3) In some cases with a longer time to diagnosis, patients had experienced symptoms at an earlier stage but complicating factors, including symptoms from comorbidities, may have delayed a clear diagnosis.

Table 3: Time to onset, treatment and outcomes for TTS cases*

Time to onset/ diagnosis (days)	Median (range)	12 (1-54)
Treated in ICU	At any point	24
	Currently	6
Outcome	Discharged	55
	In hospital	25
	Fatal	3

*Data is based on the most recent medical information available to the TGA

The Product Information now includes updated advice about the risk window for suspecting TTS. Specifically, people diagnosed with thrombocytopenia within 21 days of vaccination should be investigated for signs of a blood clot. Similarly, patients diagnosed with a blood clot within 21 days of vaccination should be tested for thrombocytopenia.

In addition, the Product Information lists autoimmune disorders, including immune thrombocytopenia, as risk factors for TTS.

Immune thrombocytopenia (ITP)

The TGA is closely monitoring reports of ITP in light of a previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-08-07-2021) fatal case in a 61-year-old woman after receiving her first dose of the AstraZeneca vaccine. An external Vaccine Safety Investigation Group (VSIG) of clinical experts concluded that the woman's death was likely linked to the vaccine.

ITP is a rare bleeding disorder that occurs when the immune system mistakenly destroys platelets, which help blood to clot. It can occur after the immune system is activated, for example by a viral infection or vaccination, and has been reported with other vaccines for hepatitis B, measles, mumps, rubella and influenza. In many cases the condition is mild with up to a third of people with ITP having no symptoms at all, or only minor bruising. However, about 5% develop severe bleeding.

The risk of ITP associated with the AstraZeneca vaccine is still being investigated and characterised internationally. This follows an observation from a recent Scottish study (https://www.nature.com/articles/s41591-021-01408-4#article-info) which found that the first dose of the AstraZeneca COVID-19 vaccine was associated with a small increased risk of ITP of about 1 case per 100,000 people.

The TGA continues to evaluate reports of suspected ITP following vaccination and will report further information when it is known. To 11 July 2021, the TGA has received 31 reports of suspected ITP. These patients had an extremely low platelet count, signs of thrombocytopenia including unusual bruising, a nosebleed and/or blood blisters in the mouth. These symptoms occurred in a timeframe that suggested they could be linked to vaccination.

We encourage people to seek medical attention if they experience signs and symptoms that could suggest ITP, such as unusual skin bruising or clusters of small red or purple spots that do not lose their colour when pressed. Unusual bleeding is another sign, for example bleeding from the nose or mouth that is hard to stop, or blood in the urine or stools.

The Product Information has been updated to provide health professionals with further information about the risk of thrombocytopenia based on post-marketing experience.

Guillain-Barre Syndrome (GBS)

The TGA has been closely monitoring reports of GBS since the beginning of the COVID-19 vaccine rollout as it has been associated with other types immunisations such as influenza vaccines (https://academic.oup.com/cid/article/58/8/1149/355966).

A review by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (EMA PRAC) on 5-8 July 2021 (https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-5-8-july-2021) was unable to confirm or rule out a possible association with the vaccine. However, the committee recommended that a warning about GBS be added to the Product Information to raise awareness amongst health professionals and consumers.

GBS is a rare immune disorder in which the body's immune system attacks nerve cells. What causes it is not fully understood, but it often follows a viral infection or a bacterial type of gastroenteritis. GBS causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking. In many cases it resolves within months but can sometimes take up to two years.

To 11 July 2021, the TGA has received 52 reports of suspected GBS in people who have received the AstraZeneca vaccine. A possible link between GBS and the AstraZeneca vaccine remains under investigation by the TGA and involves looking more closely at whether these suspected cases meet the clinical criteria for GBS. This is a complex process requiring detailed patient information to exclude alternative causes and be certain of a diagnosis. The TGA is currently following up cases for this information and will report more on this issue as it becomes available.

We encourage people to seek medical attention if they experience symptoms that could suggest GBS. This includes weakness and paralysis in the hands or feet that can progress to the chest and face over a few days or weeks.

Capillary leak syndrome

Cases of capillary leak syndrome following immunisation with the AstraZeneca vaccine have been reported overseas (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting). Two of these eight cases had a history of capillary leak syndrome. This is an extremely rare but severe relapsing-remitting condition where fluid from small blood vessels (capillaries) leaks into surrounding tissues. It is not well understood what triggers a relapse.

The TGA received one case of a patient who died from multi-organ failure but had signs of capillary leakage (reported previously (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021)). Although there was a temporal link with the vaccine, an expert Vaccine Safety Investigation Group was unable to establish a causal link as other causes could not be ruled out.

As a precautionary measure, the sponsor of the AstraZeneca vaccine has included a warning in the Product Information about capillary leak syndrome and specifically advise that the vaccine should not be used in people who have a history of this condition.

Up-to-date information about the expected side effects of the AstraZeneca COVID-19 vaccine can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=COVID-19%20Vaccine%20AstraZeneca) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=COVID-19%20Vaccine%20AstraZeneca&r=/) (for health professionals).

Comirnaty (Pfizer) vaccine

Reports of side effects to the Comirnaty vaccine continue to be consistent with what has been observed in the clinical trials and by other medicine regulators overseas. To 11 July 2021, approximately 3.7 million doses of the Comirnaty vaccine have been administered.

Myocarditis and pericarditis

The TGA continues to monitor reports of myocarditis (inflammation of the heart) and pericarditis (inflammation of the membrane around the heart) following a safety concern in the US (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html) and Israel (https://www.gov.il/en/departments/news/01062021-03).

To 11 July 2021, the TGA has received 50 cases of suspected myocarditis and/or pericarditis. We are evaluating these cases in line with international regulatory criteria to confirm whether or not they are myocarditis and pericarditis.

At a recent meeting on 5-8 July, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee concluded that myocarditis and pericarditis can occur after vaccination but cases are very rare (https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-5-8-july-2021). This is consistent with previous advice from the US CDC's Advisory Committee on Immunization Practices (https://www.hhs.gov/about/news/2021/06/23/statement-following-cdc-acip-meeting-nations-leading-doctors-nurses-public-health-leaders-benefits-vaccination.html).

The TGA is currently working with Pfizer to add a warning statement to the Product Information and include myocarditis and pericarditis as an adverse event identified through post-marketing experience.

We know that myocarditis and pericarditis are much more common with COVID-19 infection and the risks to the heart can be more severe in this context. The benefits of protection against COVID-19 far outweigh these rare and generally mild side effects.

We encourage people to seek medical attention if they experience symptoms that could suggest myocarditis or pericarditis such as of chest pain, shortness of breath and palpitations. Typically, these have occurred within seven days of vaccination, and more commonly after the second dose of Comirnaty.

Up-to-date information about Pfizer Comirnaty can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=Comirnaty) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=comirnaty) (for health professionals).

Useful links

COVID vaccines – is it true? (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true)

Top 3 COVID-19 vaccine questions – COVID-19 testing with mild symptoms, quarantine and COVIDSafe behaviours – 13 July 2021 (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-covid-19-testing-with-mild-symptoms-quarantine-and-covidsafe-behaviours)

ATAGI statement on use of COVID-19 vaccines in an outbreak setting – published 13 July 2021 (https://www.health.gov.au/news/atagi-statement-on-use-of-covid-19-vaccines-in-an-outbreak-setting)

TGA COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines)

Australian Government Department of Health COVID-19 vaccines (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines) hub

AusVaxSafety (http://www.ausvaxsafety.org.au) (active surveillance activities and information)

COVID-19 vaccine symptom checker (https://www.healthdirect.gov.au/symptom-checker/tool/basic-details)

Database of Adverse Event Notifications (DAEN) (https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx)

Advice on COVID-19 vaccination during pregnancy – 9 June 2021 (https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women)

Comirnaty vaccine – phase III clinical trial (https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_home)

AstraZeneca vaccine – phase III clinical trial (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext)

URL: https://www.tga.gov.au/node/938707 (https://www.tga.gov.au/node/938707)

Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine weekly safety report - 22-07-2021

Release date Thursday, 22 July 2021 Previous reports

Vaccination against COVID-19 is the single most effective way to reduce severe illness and death from infection. Two COVID-19 vaccines (//www.tga.gov.au/covid-19-vaccines) are currently in use in Australia – AstraZeneca and Pfizer (Comirnaty). Like all medicines, the vaccines can have side effects (also known as adverse events). The overwhelming majority of these are mild and resolve within a few days. The Therapeutic Goods Administration (TGA) closely monitors suspected side effects. Importantly, adverse events reported to the TGA are often not caused by the vaccine itself. Learn more about causality (//www.tga.gov.au/about-daen-medicines#causality).

Learn about the TGA's COVID-19 vaccine safety monitoring and reporting (//www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting) activities or report a suspected side effect (//www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine).

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with many vaccines.
- Over the last week, four additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. When assessed using the UK case definition, one was confirmed and three were deemed probable TTS. This brings the total number of cases of TTS to 87 from 6.1 million doses of the AstraZeneca vaccine administered to date.
- Sadly two people with confirmed TTS following the first dose of the AstraZeneca vaccine died in the last week. One was a 44-year-old man from Tasmania and the other was a 48-year-old woman from Victoria. We extend our sincere condolences to their families and loved ones.
- In particular, we continue to closely monitor reports of immune thrombocytopenia (ITP) and Guillain-Barre Syndrome (GBS) following vaccination with the AstraZeneca vaccine, and myocarditis and pericarditis with the Pfizer (Comirnaty) vaccine.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues (//www.tga.gov.au/tga-safety-monitoring-medicines#steps).

In the week of 12-18 July 2021 we received 1,177 AEFI reports for COVID-19 vaccines.

Large scale vaccination means that coincidentally some people will experience a new illness or die shortly after vaccination. The TGA reviews all deaths reported in people who have received the vaccination. We also monitor signals that may relate to vaccine safety to distinguish between coincidental events and possible side effects of the vaccine. Part of our analysis includes comparing natural expected death rates with observed death rates following immunisation. So far, the observed number of deaths reported after vaccination remains less than the expected number of deaths that would occur naturally, or from other causes, for that proportion of the population.

Since the beginning of the vaccine rollout to 18 July 2021, over 10.1 million doses of COVID-19 vaccines have been given. The TGA has received and reviewed 399 reports of deaths in people who have recently been vaccinated and found six that were linked to immunisation. These deaths were all related to the first dose of the AstraZeneca vaccine – five were TTS cases and one was a case of immune thrombocytopenia (ITP).

Total adverse event reports to 18 July 2021

4.1	41,406	10,125,533
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
27,451	13,672	291

Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	3.4	New South Wales	2.9
Northern Territory	3.6	Queensland	3.8
South Australia	3.7	Tasmania	6.2
Victoria	5.5	Western Australia	3.7

Most commonly reported vaccine side effects

The most common adverse effects following immunisation reported to the TGA are predictable and have been observed with many other vaccines. They include headache, muscle pain, fever, chills and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 12-18 July 2021 were headache, fever, muscle pain, fatigue and chills.

The most common reactions reported for the Pfizer (Comirnaty) COVID-19 vaccine in the week of 12-18 July 2021 were headache, muscle pain, fatigue, dizziness and nausea.

Interpreting information on vaccine adverse event reports

We are aware that false claims are circulating based on misinterpretation of adverse event information published by the TGA and medicine regulators overseas. To improve transparency, the TGA makes adverse event reports publicly available 90 days after they are received in the Database of Adverse Event Notifications (DAEN (//www.tga.gov.au/database-adverse-event-notifications-daen)). When interpreting this information, it is important to understand that many of these events may not be caused by the vaccine.

The TGA encourages reporting of adverse events even if people are uncertain or only suspicious that it is related to a vaccine or medicine. This supports our scientists and health professionals to use the data to look for new safety signals. Reporting of adverse events, such as the death of anyone who has received a vaccine, is mandatory for health professionals in some states. It is therefore important to remember that the number of adverse events and deaths is not an indicator of the safety of the vaccines. Detailed investigation and expert review of individual case reports and the data are required to assess whether there is a link between an event and the vaccine.

It is important when looking for information about COVID-19 vaccines to consider whether the source of the information is credible. Useful websites such as 'COVID vaccines – is it true? (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true)' can address false claims and misleading rumours. Other reliable resources are listed at the end of this report.

Latest immunisation recommendations

COVID-19 outbreak

In light of a significant COVID-19 outbreak involving the Delta variant, the Australian Technical Advisory Group on Immunisation (ATAGI) continues to recommend that Pfizer's Comirnaty vaccine is preferred over the AstraZeneca vaccine for those aged 16–60 years old (https://www.health.gov.au/news/atagi-statement-on-use-of-covid-19-vaccines-in-an-outbreak-setting). ATAGI reinforces that the benefits of the AstraZeneca vaccine strongly outweigh the risks for people aged 60 and over and vaccination is very important in this group, particularly given the current outbreak.

With the current COVID-19 outbreaks, ATAGI has recommended that younger Australians who may not be able to get vaccinated immediately with Comirnaty assess whether to get the AstraZeneca vaccine. This should consider the protective benefits of vaccination to themselves and their contacts, who may be more vulnerable to serious disease or death from COVID-19, against the rare risk of a serious vaccine side effect.

Where there is a higher risk of contracting COVID-19, ATAGI also recommends getting the second AstraZeneca dose within 4–8 weeks after the first dose, rather than waiting 12 weeks, so full protection can be reached sooner.

Vaccination during pregnancy

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and ATAGI recommend immunisation with the Comirnaty vaccine at all stages of pregnancy (https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women). This is due to the risk of complications from COVID disease for pregnant women and their unborn baby.

To date, no serious pregnancy-related safety concerns with the Comirnaty vaccine have been identified based on data from large numbers women overseas who have been vaccinated. After immunisation, protective antibodies have been found in cord blood and breastmilk. This suggests that vaccinating pregnant women may also offer protection to their infants after birth.

Women planning to become pregnant do not need to delay vaccination or avoid becoming pregnant after they have received the vaccination. Pregnant women are encouraged to discuss the timing of vaccination with their health professional. More details are given on the RANZCOG website (https://ranzcog.edu.au/statements-guidelines/covid-19-statement/covid-19-vaccination-information).

AstraZeneca COVID-19 vaccine

We continue to receive reports of side effects to the AstraZeneca vaccine. The reports are generally consistent with what is being observed internationally and most are expected side effects that we know occur after vaccination and resolve within a few days. To 18 July 2021, approximately 6.1 million doses of the AstraZeneca have been administered in Australia.

Thrombosis with thrombocytopenia syndrome (TTS)

> Early detection of TTS may help to prevent more serious complications developing. Guidance for health professionals is now available (https://www.health.gov.au/resources/publications/covid-19-vaccination-primary-care-approach-to-thrombosis-with-thrombocytopenia-syndrome-after-covid-19-astrazeneca-vaccine) which outlines when to suspect TTS, initial tests that can be performed in primary care and when to refer people for emergency care.
>
> People should seek immediate medical attention if they develop any of the following symptoms after vaccination:
>
> - severe or persistent headache, blurred vision, confusion or seizures
> - shortness of breath, chest pain, leg swelling or persistent abdominal pain
> - unusual skin bruising and/or pinpoint round spots beyond the site of vaccination.
>
> The most common time period for onset of TTS symptoms is 4–30 days after vaccination.

TTS is a rare event involving serious blood clots with a low blood platelet count. It is triggered by the immune system's response to the AstraZeneca vaccine and is different from other clotting conditions.

The latest rates of TTS in Australia were published in a statement from ATAGI on 15 July 2021. (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-14-july-2021)

While TTS is very rare, some people may have concerns that they can discuss with their doctor. 'Weighing up the potential benefits against risk of harm from COVID-19 Vaccine AstraZeneca' (https://www.health.gov.au/resources/publications/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca) includes information to help people make informed decisions about vaccination.

Deaths related to TTS

Sadly, this week we were notified that two confirmed cases of TTS after the first dose of the AstraZeneca vaccine were fatal. One was in a 44-year-old man from Tasmania and the other was in a 48-year-old women from Victoria (this case was reported as probable TTS in last week's report (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-15-07-2021)). The TGA extends its sincerest condolences to their families and loved ones.

Since the beginning of the vaccine rollout in Australia, a total of five deaths from TTS have been reported out of 6.1 million doses of the AstraZeneca vaccine. All of them were related to a first dose of the vaccine.

TTS cases to date

Since last week's report, a further four reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS likely to be linked to the AstraZeneca vaccine (Table 1).

Table 1: Newly confirmed and probable TTS cases for the week of 16-22 July 2021ǂ

New confirmed TTS	New probable TTS
One new case: • 44-year-old man from Tasmania	Three new cases: • 76 and 77-year-old men and a 79-year-old woman from NSW

‡As previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021), the TGA determines whether a report is likely to represent TTS by assessing cases against accepted criteria established by the UK's Medicines and Healthcare products Regulatory Agency.

One case reported last week as probable was reclassified to confirmed. This takes the total Australian reports assessed as TTS following the AstraZeneca vaccine to 87 cases (53 confirmed, 34 probable) from approximately 6.1 million vaccine doses.

We continue to investigate three probable TTS cases which appear to be related to the second dose. These cases, which have presented with less serious symptoms will be considered by an external panel of experts in the coming week to determine whether they are related to vaccination or not. UK data indicates that the risk of TTS after the second dose is extremely low (1.8 cases per million second doses (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting)).

When assessed against the criteria used by the US Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf), fewer than half of the cases reported to TGA are classified as Tier 1 cases which tend to have more serious outcomes. Tier 1 cases involve clots in an unusual location, such as the brain or abdomen (Table 2).

In Australia, severe cases of TTS appear to be more common in women in younger age groups. Nearly half of the TTS cases in women required treatment in intensive care. Cases meeting the criteria for Tier 1 were also twice as likely to occur in women compared to men. Four of the five deaths occurred in women aged 48 (two cases), 52 and 72-years-old. The other death was in a 44-year-old man, as reported above.

Table 2: Total confirmed and probable TTS cases to date by age and CDC classification

Age	Total cases	CDC classification†		
		Tier 1	Tier 2	Not classified
<30 years	1	-	1	-
30-39	1	1	-	-
40-49	6	6	-	-
50-59	22	10	7	5
60-69	19	6	6	7
70-79	26	7	7	12
80+	12	3	4	5
All ages	87 (41 men, 46 women)	33	25	29

† The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) and a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) and a low platelet count and anti-PF4 antibodies
- Not classified = case does not meet the criteria for Tier 1 or Tier 2 (for example clots in common locations with low platelet count but no evidence of anti-PF4 antibodies).

Cases have most often occurred about two weeks after vaccination, although the time to onset (or diagnosis) has ranged from one to 54 days (Table 3).

Table 3: Time to onset, treatment and outcomes for TTS cases*

Time to onset/ diagnosis (days)	Median (range)	12 (1-54)
Treated in ICU	At any point	26
	Currently	6
Outcome	Discharged	57
	In hospital	25

	Fatal	5

*Data is based on the most recent medical information available to the TGA

Immune thrombocytopenia (ITP)

The TGA is continuing to monitor reports of ITP. It is a type of thrombocytopenia or low platelet count. Thrombocytopenia has been included as a very rare adverse event in the Product Information for the AstraZeneca vaccine.

ITP occurs when the immune system mistakenly destroys platelets, which help blood to clot. It can occur after the immune system is activated, for example by a viral infection or vaccination, and has been reported with other vaccines. In many cases ITP is mild with up to a third of people having no symptoms at all, or only minor bruising. However, about 5% develop severe bleeding.

The risk of ITP associated with the AstraZeneca vaccine is still being investigated and characterised internationally (https://www.nature.com/articles/s41591-021-01419-1#:~:text=A%20prospective%20cohort%20analysis%20finds,is%20yet%20to%20be%20established.) and the TGA will report more information when it is known. ITP is difficult to diagnose because, unlike TTS, it does not have unique identifying features if it occurs after vaccination. There is no specific test that confirms ITP, so doctors rely on excluding other causes of thrombocytopenia. An alternative diagnosis often only becomes clear once more detailed patient information becomes available.

To 18 July 2021, the TGA has received 34 reports of suspected ITP following vaccination. These patients had an extremely low platelet count, and signs of thrombocytopenia including unusual bruising, a nosebleed and/or blood blisters in the mouth. These symptoms occurred in a timeframe that suggested they could be linked to vaccination and no other obvious cause was identified based on the information provided to TGA.

We encourage people to seek medical attention if they experience signs and symptoms that could suggest ITP, such as unusual skin bruising or clusters of small red or purple spots that do not lose their colour when pressed. Unusual bleeding is another sign, for example bleeding from the nose or mouth that is hard to stop, or blood in the urine or stools.

Guillain-Barre Syndrome (GBS)

The TGA has been closely monitoring reports of GBS since the beginning of the COVID-19 vaccine rollout as it has been associated with other types of immunisations such as influenza vaccines (https://academic.oup.com/cid/article/58/8/1149/355966).

A review by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (EMA PRAC) on 5-8 July 2021 (https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-5-8-july-2021) was unable to either confirm or rule out a possible association with the vaccine. However, a warning has been added to the European Product Information (https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca#product-information-section) alerting health professionals to the signs and symptoms of GBS to ensure correct diagnosis and treatment.

GBS is a rare immune disorder in which the body's immune system attacks nerve cells. What causes it is not fully understood, but it often follows a viral infection or a bacterial type of gastroenteritis. GBS causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking. In many cases it resolves within months but can sometimes take up to two years.

To 18 July 2021, the TGA has received 61 reports of suspected GBS in people who have received the AstraZeneca vaccine. A possible link between GBS and the AstraZeneca vaccine remains under investigation and we are seeking expert advice on the results of a detailed evaluation.

We encourage people to seek medical attention if they experience symptoms that could suggest GBS. This includes weakness and paralysis in the hands or feet that can progress to the chest and face over a few days or weeks.

Up-to-date information about the expected side effects of the AstraZeneca COVID-19 vaccine can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=COVID-19%20Vaccine%20AstraZeneca) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=COVID-19%20Vaccine%20AstraZeneca&r=/) (for health professionals).

Comirnaty (Pfizer) vaccine

Reports of side effects to the Comirnaty vaccine continue to be reported to the TGA and are consistent with what has been observed in the clinical trials and by other medicine regulators overseas. To 18 July 2021, approximately four million doses of the Comirnaty vaccine have been administered in Australia.

Myocarditis and pericarditis

A causal relationship of myocarditis (inflammation of the heart) and pericarditis (inflammation of the membrane around the heart) to the vaccine has not yet been established but is suspected. The TGA has worked with Pfizer to add a warning statement about these adverse events to the Consumer Medicine and Product Information for Comirnaty. This is in response to rare cases following vaccination in Australia and internationally.

These rare effects on the heart typically occur within 14 days of vaccination, particularly after the second dose of Comirnaty and more often in younger men. While cases are usually transient and resolve following rest, some patients require treatment in hospital.

The TGA continues to monitor myocarditis and pericarditis by analysing adverse event reports, working with international regulators and reviewing the medical literature. To 18 July 2021, we have received 66 cases of suspected myocarditis and/or pericarditis. We are evaluating these cases in line with internationally accepted criteria to assess whether or not they are myocarditis and/or pericarditis that is likely to be related to vaccination.

We know that myocarditis and pericarditis are much more common with COVID-19 infection and damage to the heart is frequently severe after infection. The benefits of protection against COVID-19 far outweigh the risks from these rare and transient side effects.

We encourage people to seek medical attention if they experience symptoms that could suggest myocarditis or pericarditis such as of chest pain, shortness of breath and palpitations.

Up-to-date information about Pfizer Comirnaty can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=Comirnaty) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=comirnaty) (for health professionals).

Useful links

Top 3 COVID-19 vaccine questions – Rapid COVID-19 tests, herd immunity and what causes the virus to change (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-rapid-covid-19-tests-herd-immunity-and-what-causes-the-virus-to-change)

Top 3 COVID-19 vaccine questions – COVID-19 vaccines and variants, and recent ATAGI advice about AstraZeneca doses – 16 July 2021 (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-covid-19-vaccines-and-variants-and-recent-atagi-advice-about-astrazeneca-doses)

COVID-19 vaccines: Frequently asked questions – 15 July 2021 (https://www.ncirs.org.au/covid-19/covid-19-vaccines-frequently-asked-questions)

COVID vaccines – is it true? 14 July 2021 (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true)

Latest recommendations from ATAGI on the use of COVID-19 vaccines during an outbreak – 13 July 2021 (https://www.health.gov.au/news/atagi-statement-on-use-of-covid-19-vaccines-in-an-outbreak-setting)

TGA COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines)

Australian Government Department of Health COVID-19 vaccines (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines) hub

AusVaxSafety (http://www.ausvaxsafety.org.au) (active surveillance activities and information)

COVID-19 vaccine symptom checker (https://www.healthdirect.gov.au/symptom-checker/tool/basic-details)

Database of Adverse Event Notifications (DAEN) (https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx)

Advice on COVID-19 vaccination during pregnancy – 9 June 2021 (https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women)

Comirnaty vaccine – phase III clinical trial (https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_home)

AstraZeneca vaccine – phase III clinical trial (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext)

URL: https://www.tga.gov.au/node/938717 (https://www.tga.gov.au/node/938717)

Australian Technical Advisory Group on Immunisation (ATAGI)
Weekly meeting on Thrombosis with Thrombocytopenia Syndrome (TTS)
16 June 2021, 1-2PM

Attendees

ATAGI

Allen Cheng
Chris Blyth
Katie Flanagan
Robyn Gibbs
Nigel Crawford
Michelle Giles
Kristine Macartney
Bette Liu
James Wood
Debra Petrys
Nicholas Silberstein
Diane Walsh
Andrew Wilson
Karen Bellamy
Katherine Gibney
Tony Korman
Madeline Hall
Cheryl Jones
Louise Flood

NCIRS

s 47F

Department of Health

Lisa Schofield
Hope Peisley
Darius Everett
John Skerritt

s 22

Lucas de Toca
Elspeth Kay

s 22

ATAGI COVID-19 WG Secretariat

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1. Welcome

Attendees NOTED:

- Welcome and apologies (Tom Snelling, Kristy Cooper)
- Acknowledgment of country
- No new declarations of interest.

2. Presentation on Australian TTS Cases

Attendees:

- NOTED a presentation on Australian Thrombosis with Thrombocytopenia Syndrome (TTS) cases from the Therapeutic Goods Administration (TGA)
- DISCUSSED TTS outcome including risk of death and morbidity
- DISCUSSED classification and tiers including a need to simply explain to consumers the potential outcomes of TTS

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s 47C, 47E(d)

4. Next steps

ATAGI members:

- AGREED to change the age recommendation for COVID-19 Vaccine AstraZeneca to indicate that Pfizer is the preferred vaccine for people under 60 years of age (Attachment A).
- NOTED ATAGI's recommendations would be refined and confirmed at ATAGI Meeting #81 (17 June 2021) as the first agenda item and provided to Government following endorsement.
- This change would be rapidly communicated by the Government.

s 47C, 47E(d)

ATAGI Meeting: AstraZeneca and TTS

23 June 2021, 1:00 – 2:00pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Chris Blyth	s 47F	Lisa Schofield
Diane Walsh		Darius Everett
Andrew Wilson		Elspeth Kay
Bette Liu		Susan Trainor
Debra Petrys		John Skerritt
James Wood		Megan Mcstea
Karen Bellamy		s 22
Katherine Gibney		Kaylene Raynes
Katie Flanagan		
Kristine Macartney		
Louise Flood		**Secretariat**
Nigel Crawford		s 22
Tony Korman		
Cheryl Jones		
Robyn Gibbs		
Tom Snelling		
Michelle Giles		

1. **Welcome and apologies / general committee business**

   Members:
   - NOTED acknowledgement to country
   - Declared no conflicts of interest

2. **TGA update**

   Members NOTED and DISCUSSED:
   - 37 confirmed TTS cases
   - 25 probable TTS cases
   - Slight change to time to TTS onset to 10 days (from median of 14 days)
   - Tier 1 cases in minority compared to tier 2 or unclassified cases
   - TTS rates by State and Territory

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ATAGI Meeting: AstraZeneca and TTS

23 June 2021, 1:00 – 2:00pm

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ATAGI Co-chair summary:

- no change in data that will warrant adjustment of last week's ATAGI advice but will closely monitor second dose coverage data
- AstraZeneca coverage data should be monitored

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Meeting closed at approximately 2:07pm.

ATAGI Meeting: AstraZeneca and TTS

30 June 2021, 1:00 – 2:00pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Chris Blyth	s 47F	s 22
Diane Walsh		Darius Everett
Andrew Wilson		Elspeth Kay
Bette Liu		s 22
James Wood		John Skerritt
Karen Bellamy		Megan Mcstea
Katherine Gibney		Paul Kelly
Katie Flanagan		Paul McBride
Kristine Macartney		s 22
Nigel Crawford		Brendan Murphy
Tony Korman		Catherine Brogan
Robyn Gibbs		Lucas de Toca
Tom Snelling		John Frewen
Kristy Cooper		**Secretariat**
Michelle Giles		s 22

1. **Welcome and apologies / general committee business**

   Members:
   - NOTED acknowledgement to country
   - Declared no conflicts of interest

s 22

3. **TGA update**

   Members NOTED and DISCUSSED:
   - 40 confirmed TTS cases
   - 28 probable TTS cases
   - Gradual steadying out of TTS cases except 80+ years old cohort which is gradually increasing

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ATAGI Co-chair summary:

- no change to AstraZeneca recommendations

Meeting closed at approximately 2:35pm.

ATAGI Meeting: AstraZeneca and TTS

7 July 2021, 1:00 – 2:00pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Chris Blyth	s 47F	Hope Peisley
Allen Cheng		s 22
Diane Walsh		
Katherine Gibney		
Karen Bellamy		Jane Cook
Tony Korman		
James Wood		**Secretariat**
Nigel Crawford		s 22
Robyn Gibbs		
Michelle Giles		
Katie Flanagan		
Kristine Macartney		
Cheryl Jones		

1. **Welcome and apologies / general committee business**

   Members:
   - NOTED acknowledgement to country
   - Declared no conflicts of interest

2. **TGA update**

   <u>TTS</u>

   Members NOTED and DISCUSSED:
   - 43 confirmed TTS cases
   - 31 probable TTS cases
   - Predominantly female in confirmed cases
   - Predominantly male in probable cases
   - Increasing in 70-79 and 50-59 years old; other age cohorts stable
   - CVST cases stabilised
   - Bulk of cases are tier 2/unclassified

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ATAGI Meeting: AstraZeneca and TTS

7 July 2021, 1:00 – 2:00pm

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ATAGI co-chair summary:

- no change to AstraZeneca recommendations
- risk rates from 50 to below and over 60 years
- watching myocarditis and ITP safety signal
- no TTS cases following dose 2 of COVID-19 Vaccine AstraZeneca
- Include risk-benefit document in weekly update.

Meeting closed at approximately 2:05pm.

ATAGI Meeting: AstraZeneca and TTS

14 July 2021, 1:00 – 2:00pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Chris Blyth	s 47F	Elspeth Kay
Allen Cheng		s 22
Andrew Wilson		Hope Peisley
Bette Liu		Jane Cook
Cheryl Jones		s 22
Diane Walsh		Lisa Schofield
James Wood		**Secretariat**
Karen Bellamy		s 22
Katherine Gibney		
Kristine Macartney		
Kirsty Cooper		
Michelle Giles		
Nigel Crawford		
Robyn Gibbs		
Tom Snelling		
Tony Korman		
Nick Silberstein		

1. **Welcome and apologies / general committee business**

   Members:
   - NOTED acknowledgement to country
   - Declared no conflicts of interest
   - DISCUSSED ATAGI terms of reference and role of ATAGI, in light of recent media about ATAGI; ATAGI provides advice to Government and the Government makes decisions
   - AGREED to not make ATAGI statement/response to media

2. **TGA update**

   <u>TTS</u>

   Members NOTED and DISCUSSED:
   - 47 confirmed TTS cases
   - 31 probable TTS cases
   - Slight female dominance in confirmed cases
   - May need work on gender difference in severity
   - Tier 1 cases remain in minority
   - Watching 50-59 and 70-79 age cohorts
   - Reports of GPs dismissing headaches as potential sign of TTS
   - Is there a delay in patient presentation due to lack of awareness of TTS signs and symptoms or clinicians not recognising this symptom?
   - Reiterated importance of early presentation and recognition of TTS signs and symptoms
   - Important messaging for patients and health care providers and providing this information at point of vaccination
   - TTS is a challenging condition and inherent difficulties in diagnosis
   - Fatality rates in Australia are much lower than Europe
   - WHO clinical guidance out this week

ATAGI Meeting: AstraZeneca and TTS

14 July 2021, 1:00 – 2:00pm

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s 47C, 47G

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ATAGI co-chair summary:

- no change to AstraZeneca recommendations
- reinforce TTS primary care guide in weekly update
- ATAGI continue to review data

Meeting closed at approximately 2:10pm.

ATAGI Meeting: AstraZeneca and TTS

21 July 2021, 1:00 – 2:00pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Chris Blyth	s 47F	s 22
Allen Cheng		Elspeth Kay
Andrew Wilson		John Skerritt
Bette Liu		s 22
Cheryl Jones		
Diane Walsh		
James Wood		Hope Peisley
Karen Bellamy		Minister Hunt
Katherine Gibney		
Katie Flanagan		
Kristine Macartney		
Kirsty Cooper		**Secretariat**
Michelle Giles		s 22
Madeline Hall		
Nigel Crawford		
Penny Burns		
Robyn Gibbs		
Tom Snelling		
Tony Korman		
Vanessa Johnston		

1. **Welcome and apologies / general committee business**

Members:

- NOTED acknowledgement to country
- Declared no conflicts of interest
- WELCOMED Vanessa Johnston (CDNA representative) and Penny Burns as new members of ATAGI
- CONGRATULATED Nigel Crawford as the new Chair of ATAGI and Michelle Giles as Deputy Chair
- THANKED Allen Cheng and Chris Blyth for their service to ATAGI.

2. **TGA update**

<u>TTS</u>

Members NOTED:

- 52 confirmed TTS cases
- 32 probable TTS cases
- Slight female dominance in confirmed cases
- Predominance of females in tier 1
- ICU admission heavily weighted in female presentation
- Predominance of tier 1 cases in NSW compared to the rest of the country
- Rates per 100,000 doses relatively stable except for 40-49 year old cohort, although wide confidence interval
- Three potential TTS cases following second dose AZ for VSIG assessment next week
- TTS case rates following second dose AZ in the UK
- Canada claimed no confirmed second dose AZ TTS cases

- MHRA report that majority of second dose AZ TTS cases are older cohort with significant comorbidities

DISCUSSED:

- Reassuring data on Dose 2 AZ reflecting minimal numbers of potential TTS case; continue to monitor
- Gender difference in risk and severity of TTS cases and how to describe in the weekly update

s 22

ATAGI co-chair summary:

- no change to AstraZeneca recommendations
- add details of the severity of myocarditis in the update
- revisit work streams/work plan

Meeting closed at approximately 2:10pm.

ATAGI COVID Working Group
Subgroup 3, Meeting No. 21
10 June 2021, 11:30 – 12:30pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Nigel Crawford - lead	s 47F	s 22
Tony Korman		Darius Everett
John Kaldor		s 22
Paul Effler		Leanne Ringwood
Katie Attwell		s 22
Chris Blyth		
Debra Petrys		
Kristy Cooper		**Secretariat**
Margie Danchin	**Invited Representatives**	s 22
Cheryl Jones	s 47F	
Kristine Macartney		

1. **Welcome and apologies / general committee business**
   Members:
   - NOTED acknowledgement to country
   - NOTED attendees and apologies (Catherine King, Christine Selvey, Alan Leeb)

s 47F

   - Declared no conflicts of interest.

2. **Outcomes from previous meeting**
   Members ENDORSED outcomes and actions from previous meeting with no amendments.

3. **TTS information for primary care**
   Members NOTED and DISCUSSED:
   - How ATAGI can provide guidance in identification, referral and management of suspected TTS cases after AstraZeneca COVID-19 vaccine in primary care (GP, Emergency)
   - Importance of patient and healthcare provider awareness of TTS symptoms
   - Emergency waiting times and how suspected TTS cases can be flagged and escalated quickly
   - Cues to support nurses who are not immunisers (e.g. AstraZeneca vaccine as screening question)
   - Jurisdictions are collecting TTS mortality and morbidity information
   - Importance of including full TTS cases in risk-benefit document, as estimated rates/ratio may be difficult for the public to interpret
     - Risk-benefit document is currently being updated.

Action	Responsible officer/s	Progress
3.1 Draft 1-2 pager guidance on TTS management in primary care • Draft guidance for ACEM review • RACGP to disseminate to members	NCIRS/SG3	To progress

4. **TGA update**
   Nil.

s 22

Meeting closed at 12:35pm.

ATAGI COVID Working Group
Subgroup 3, Meeting No. 22
1 July 2021, 11:30 – 12:30pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Nigel Crawford - lead	s 47F	s 22
Tony Korman		Elspeth Kay
John Kaldor		s 22
Paul Effler		
Alan Leeb		
Kristine Macartney		
Christine Selvey		
Diane Walsh		**Secretariat**
Margie Danchin		s 22
Lena Sanci		
Katie Attwell	**Invited Representatives**	
	s 47F	

1. **Welcome and apologies / general committee business**
   Members:
   - NOTED acknowledgement to country
   - NOTED attendees and apologies (Chris Blyth, Allen Cheng, Cheryl Jones, Kristy Cooper)

s 47F

   - Declared no conflicts of interest.

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Members DISCUSSED:

- Important to keep an open mind of potential of AstraZeneca also causing myocarditis

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Meeting closed at 12:37pm.

ATAGI COVID Working Group
Subgroup 3, Meeting No. 23
15 July 2021, 11:30 – 12:30pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Nigel Crawford - lead	s 47F	s 22
Alan Leeb		
Cheryl Jones		
Chris Blyth		
Diane Walsh		
John Kaldor		Secretariat
Katie Attwell		s 22
Kristine Macartney		
Kristy Cooper		
Margie Danchin		
Paul Effler	Invited Representatives	
Tony Korman	s 47F	

1. **Welcome and apologies / general committee business**
   Members:
   - NOTED acknowledgement to country
   - NOTED attendees and apologies (Christine Selvey)

s 47F

- Declared no conflicts of interest
- NOTED TTS primary care guide now published
- NOTED subgroup lead's thanks and acknowledgement of everyone's contribution

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3. Myocarditis - TGA update

Members NOTED:

- Myocarditis probable and possible case rates (nil confirmed cases)
- Most cases in males
- Time to symptoms onset not available in majority of reported cases
- Comirnaty Product Information update expected to be finalised within next week or so
- TGA meeting with international regulators next week
- No mention of strenuous exercise in case narratives
- Next steps: deep dive of cases

Meeting closed at 12:34pm.