

ATTACHMENT A

SCHEDULE OF DOCUMENTS – FOI 2487

Document No.	Date	Pages	Description	Decision on access ¹	Exemption/s applied
1	17 June 2021	4	ATAGI – Statement	R	
2	6 July 2021	6	ATAGI – sub-group meeting	RE	section 47C – part section 47F – part
3	16 July 2021	2	ATAGI – talking points	E	section 47C – full
4	8 July 2021	2	ATAGI/THANZ – media statement	R	
5	6 July 2021	4	SITAG – Clearance	REI	section 22 – part section 47C – part
6	2 June 2021	1	ATAGI COVID-19 WG TTS Meeting Agenda	REI	section 22 – part section 47F – part
7	2 June 2021	2	ATAGI COVID-19 WG TTS Meeting Outcomes	REI	section 22 – part section 47C – part section 47F – part
8	16 June 2021	4	ATAGI COVID-19 WG TTS Meeting Outcomes	REI	section 22 – part section 47C – part section 47E(d) – part section 47F – part
9	16 June 2021	2	ATAGI COVID-19 WG Executive meeting outcomes	REI	section 22 – part section 47C – part section 47E(d) – part section 47F – part
10	16 June 2021	12	ATAGI COVID-19 Executive Meeting Chat logs	E	section 47C – full

¹ E = Exempt, R = Release, RI = Release with irrelevant information removed, RE = Release with exempt information removed, REI = Release with irrelevant and exempt information removed.

11	23 June 2021	4	ATAGI COVID-19 Executive Meeting Agenda	REI	section 22 – part section 47E(d) – part
12	23 June 2021	2	ATAGI COVID-19 WG Meeting outcomes	REI	section 22 – part section 47C – part section 47F – part
13	17 June 2021	4	ATAGI Letter to Minister Hunt	RE	section 47C – part



08 July 2021

Coronavirus (COVID-19) health alert**Australian Government****Department of Health**

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

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THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH



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](#)[← All news](#)

ATAGI Sub-Group 1 Meeting – 6 July 2021 (11:30am – 12:30pm)

Primary Focus: s 47C

Wrap Up of Last Week

s 47C

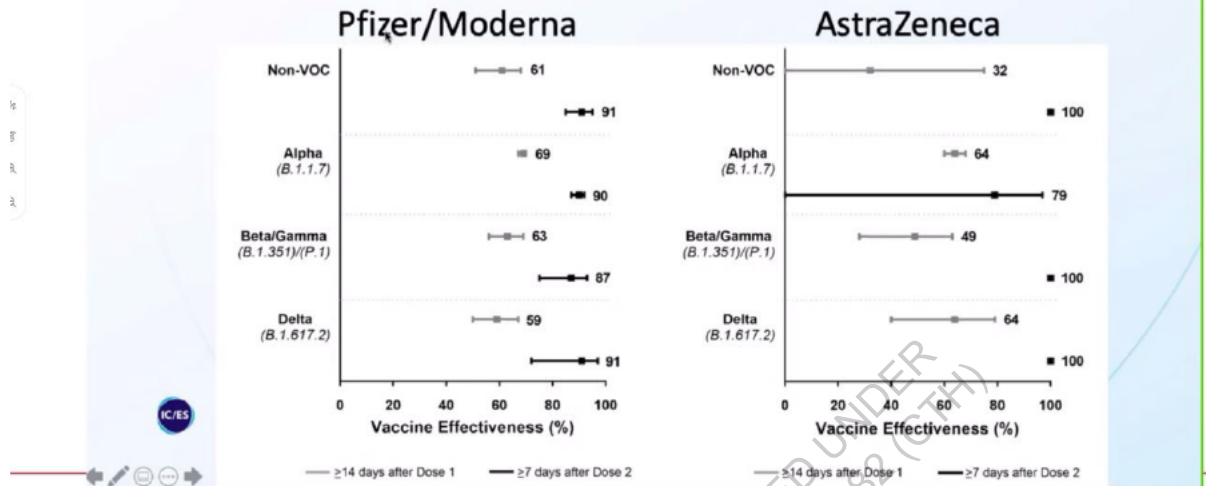
- Acceptable two-dose schedules

s 47C

Delta Variant/Variants and Vaccination (Presentation by s 47F)

- The Delta Variant has become a WHO Variant of Concern, with increasing prevalence across the world (96 countries). It became a problem in India, where it was first detected, and the UK.
- The Lambda variant has been discovered in Peru, and is becoming more prevalent in South America. We will keep an eye on this.
- The Delta variant is more transmissible.
 - Vaccine effectiveness against Delta is less than against Alpha for AstraZeneca
 - Vaccine effectiveness against Delta is similar to that against Alpha for Pfizer
 - In Scotland, after one dose of Pfizer or AstraZeneca, there was low effectiveness against the delta variant. Particularly for AZ, dose 1 effectiveness was much lower for delta than previously. Against symptomatic disease, effectiveness was a little higher.
 - Data from Public Health England has showed that hospitalisation numbers are reduced, however there is quite wide confidence intervals for the data.
 - For healthcare workers in India, vaccine effectiveness showed that after the second dose, there was increased protection against hospitalisation and ICU care.
 - The data from Canada has shown that the effectiveness after one dose of Pfizer and AstraZeneca against delta was slightly better in Canada, however they also had a larger dosing interval, of up to 16 weeks.
 - Singapore Surveillance data has seen that delta was associated with a higher odds of requiring oxygen and hospitalisation.

VE vs. symptomatic infection by VOC



s 47F

Sera neutralisation-Delta

- Pfizer reduced 1.4, 2.5, 3, and 5.8-fold reduction (vs. wild-type)
- AZ 4.5 fold reduction (2 doses). Single dose did not neutralise Delta at all.
- Similar levels to Alpha

Impacts on vaccine effectiveness

Alpha

- Pfizer – no difference in vaccine effectiveness/in T cell response & minor reduction in sera neutralisation
- AstraZeneca – no difference in vaccine effectiveness/minor reduction in sera neutralisation
- Novavax – minor reductions in vaccine effectiveness
- Janssen – no effectiveness data available

Beta

- Pfizer-BNT162 – Potential reduction in vaccine effectiveness/Marked reductions in sera neutralisation/T cell response
- AstraZeneca-ChAdOx1 – Substantial reductions in vaccine effectiveness
- Novavax-NVX-CoV2373 – Moderate reductions in vaccine effectiveness
- Janssen – Minor reductions in vaccine effectiveness

Gamma

- Pfizer-BNT162 – Marked reductions in sera neutralisation & no difference in T cell response
- AstraZeneca-ChAdOx1 – Slight reductions in sera neutralisation
- Novavax-NVX-CoV2373 – No effectiveness data available
- Janssen – Minor reductions in vaccine effectiveness

Delta

- Pfizer – Moderate reduction in effectiveness post dose 1/minor reductions in vaccine effectiveness post dose 2/Potential reduction in sera neutralisation
- AstraZeneca – Moderate reduction in effectiveness post dose 1/minor reductions in vaccine effectiveness post dose 2/Potential reduction in sera neutralisation

Delta Variant in Children

- There is much media about cases of the Delta variant being recorded in children, but this is not currently backed up with data.
- There are increasing cases in 10 – 19 year olds, and 20 – 29 year olds, but this may be related to the vaccine uptake, and the lack of vaccines delivered for these age groups.
- Comparing the current UK Delta wave to the UK Alpha wave early in 2021, there is not a big difference, although older age groups are noting less cases, which might reflect their increased vaccination numbers.

Delta with K417N

- There are two different delta variants with K417N mutations: Delta-AY.1 and Delta-AY.2

s 47F

Delta with K417N



- 2 different Delta with K417N mutations: Delta-AY.1 and Delta-AY.2
 - Note K417N also present in Beta variant
- As of 22 June 2021, 161 genomes of Delta-AY.1 have been identified on GISAID. From Canada (1), India (8), Japan (15), Nepal (3), Poland (9), Portugal (22), Russia (1), Switzerland (18), Turkey (1), USA (83).
- In addition there are 41 cases in UK
- PHE are monitoring its spread

Current Knowledge Gaps

- No data yet on vaccine effectiveness against onward transmission of the Delta variant.
- There is a potential need to adjust the duration of quarantine and isolation due to the increased time a person can transmit the virus
- There is uncertainty of the repercussions of Delta with K417N mutations.

Discussion: General

- There is not much data on how the vaccine-dosing interval impacts efficacy against variants. There is some from the UK and Canada, but Canada is still administering the second doses.
- The interval impacts and variants demonstrate the importance of second doses. The message emphasising two doses rather than one is critical.
- There is not vaccine effectiveness against the Delta variant split by age. The data is lumped together as 'variants' and age, but not the specific variants.
- In Canada, some of their data refers to point mutations, rather than genomic sequences of the variants.
- There is a trade-off for Australia whether to space out the vaccines more due to not having endemic COVID-19 circulating in Australia, or whether to keep the doses close together due to outbreaks. This interval needs to be discussed in more detail.
- Are there any existing signals to demonstrate increased transmission in children?
 - More vaccine coverage in older age groups, may be impacting whether it looks like increased transmission is happening in children.
 - The US are seeing more disease in children. They are the most unvaccinated age group. The hospitalisation rates of children from COVID-19 have not increased to date.
 - The Delta variant is twice as transmissible in all groups as the ancestral strain, which means in school there are likely to be epidemic. This age group is likely to need to be vaccinated.
- The Lambda Variant has been noted as a Variant of Interest by the WHO a few weeks back after several thousand cases through South America. There is still more focus on delta, as data on the Lambda variant has not come through yet. The WHO is forming a technical advisory group to monitor variants as they arise.

s 47C

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Next Meeting: The next meeting will either be next week or the week after.

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08 July 2021

Coronavirus (COVID-19) health alert**Australian Government****Department of Health**

ATAGI/THANZ statement provides further guidance for the AstraZeneca vaccine and narrows contraindication

The Australian Technical Advisory Group on Immunisation (ATAGI) and the Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ) have released a joint statement on Thrombosis with Thrombocytopenia Syndrome (TTS) and the use of the COVID-19 Vaccine AstraZeneca.

Date published:

23 May 2021

Type:

News

Intended audience:

General public



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

It provides greater clarity on the nature of TTS and narrows the conditions determined to be contraindications for use of the vaccine.

The Chief Medical Officer (CMO) has also written to healthcare professionals regarding the joint statement.

Read the statement

Tags:

Communicable diseases

Emergency health management

COVID-19 vaccines

← **All news**

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Meeting Outcomes

COVID-19 Vaccine and Treatments for Australia - Science and Industry Technical Advisory Group

Meeting 11: Thursday 1 July 2021, 10:30am – 12:30pm

Attendees provided at Attachment A

Agenda Item	Meeting Outcomes
1. Welcome and acknowledgement	<p>s 22</p> <ul style="list-style-type: none"> Meeting opened at 10:30am
2. Vaccine and Treatment Update	<p>s 22</p> <ul style="list-style-type: none"> The TGA is undertaking evaluation of one COVID-19 therapeutic and would welcome working collaboratively with the HTA process being developed. <p>s 47C</p> <ul style="list-style-type: none"> The Janssen vaccine has been provisionally approved by the TGA. The Moderna vaccine has been given provisional determination. Global focus is on the Delta variant, with some vaccine manufacturers assessing efficacy against and looking to target the variant. <p>s 22</p> <ul style="list-style-type: none"> Moderna has indicated supply of one million vaccine doses in September 2021, Pfizer will be ramping up supply to Australia in August/September 2021. Scale up for vaccine administration needs to occur in Q3 to be prepared for Q4 roll out. The Chair noted the PM's announcement for AstraZeneca to be made available for those under 40 in discussion with their GP. The Chair confirmed that this is not a change in position or policy. <p>s 22</p>

s 47C

3. Vaccine Supply for 2022 – 2023, including boosters

s 47C

- Moderna has 10 million doses arriving in 2021, and 15 million booster doses arriving in 2022. They have ongoing studies of multivalent vaccines. Government must opt into the booster doses by September 2021.

s 47C

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4. Other business

5. Close and next meeting

- Meeting closed at 11:50am

Attachment A – SITAG 1 July 2021 - Attendees

Member	Background and role
SITAG MEMBERS IN ATTENDANCE	
Dr Brendan Murphy	Secretary, Department of Health SITAG Chair
Prof Paul Kelly	Chief Medical Officer, Department of Health SITAG Deputy Chair
A/Prof Chris Blythe	Co-Chair, ATAGI
Mr Mark Sullivan	Managing Director, Medicines Development Ltd
Prof Andrew Wilson	Chair, PBAC
Ms Sue MacLeman	Chair, MTP Connect
Dr John Anderson	Independent Advisor
Kirsten O'Doherty	Independent Advisor
Dr Felicia Pradera	Program Manager for Medical Countermeasures Development, DMTC
Dr Cathy Foley	Australia's Chief Scientist
Ms Judi Zielke (proxy for Dr Larry Marshall)	Chief Operating Officer, CSIRO
APOLOGIES	
Prof Allen Cheng	Co-Chair, ATAGI
OTHER NON-MEMBERS IN ATTENDANCE	
Dr John Skerritt	Head, Therapeutic Goods Administration
Mr David Luchetti	Head, Vaccine Manufacturing Taskforce, Department of Industry, Science, Energy and Resources
Prof Michael Kidd	Deputy Chief Medical Officer, Department of Health
Dr Allison Jones	Assistant Secretary, Science and Investment Branch, Department of Health
SITAG Secretariat	COVID-19 Vaccine Strategy Taskforce Members

ATAGI Meeting: AstraZeneca and TTS

2 June 2021, 1:00 – 2:00pm

Members	NCIRS Technical Staff	Department of Health reps
Chris Blyth (co-chair)	s 47F	Lisa Schofield
Allen Cheng (co-chair)		Hope Peisley
Katie Flanagan		s 22
Kristine Macartney		Darius Everett
Robyn Gibbs		Mary Wood
Bette Liu		John Skerritt
Cheryl Jones		Kay Elspeth
James Wood		
Karen Bellamy		Secretariat
Katherine Gibney	s 22	
Louise Flood		
Michelle Giles		
Nicholas Silberstein		
Tom Snelling		
Tony Korman		
Madeline Hall		
Andrew Wilson		
Deb Petrys		
James Wood		
Katherine Gibney		
Nicholas Silberstein		
Tom Snelling		
Kristy Cooper		
Diane Walsh		
Agenda item	Purpose	Sponsor
1. Welcome and apologies/general committee business <ul style="list-style-type: none"> Acknowledgement to Country Apologies Declarations of interest 	Information	Chris Blyth/Allen Cheng
2. Current epidemiological situation in Australia	Update/discuss	Allen Cheng – 5 mins
3. Current TTS status and rates	Update/discuss	s 22 – 5 mins
4. TTS outcomes	Update/discuss	Nigel Crawford & Chris Blyth – 5 mins
5. Current vaccine coverage	Information	NCIRS – 5 mins
6. Onward vaccine supply and prioritisation based on current epidemiology	Information	Hope Peisley – 10 mins
7. Active policy issues <ul style="list-style-type: none"> a. Request to review age cut off for AZ vaccines 	Discuss	a. All – 10 mins s 22 s 22 s 22

8. Update of COVID-19 communication materials	Information	Chris Blyth/Secretariat
Meeting close		

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ATAGI Meeting: AstraZeneca and TTS

2 June 2021, 1:00 – 2:00pm

In attendance:

Members	NCIRS Technical Staff	Department of Health reps
Chris Blyth	s 47F	s 22
Allen Cheng		Darius Everett
Andrew Wilson		Elspeth Kay
Bette Liu		Hope Peisley
Diane Walsh		John Skerritt
Debra Petrys		s 22
James Wood		s 22
Karen Bellamy		s 22
Katherine Gibney		
Katie Flanagan		Secretariat
Kristine Macartney		s 22
Kristy Cooper		
Louise Flood		
Madeline Hall		
Nigel Crawford		
Robyn Gibbs		
Tom Snelling		
Tony Korman		
Michelle Giles		

1. Welcome and apologies / general committee business

Members:

- NOTED acknowledgement to country
- NOTED attendees and apologies (Lisa Schofield, Cheryl Jones)
- Declared no conflicts of interest

2. Current epidemiological situation in Australia

Members NOTED an update on the VIC outbreak including case numbers and vaccine coverage rates.

3. Current TTS status and rates

Members NOTED an update from the TGA on confirmed and probable TTS cases:

- 31 confirmed TTS cases
- 8 probable cases

Members DISCUSSED:

- Age median range of TTS cases
- Time to onset of TTS cases (14 days)
- Age distribution of confirmed and probable TTS cases
- Vaccine coverage rates
- AEFI reports and numbers
- Analysis of outcomes data of first 33 cases is underway

4. TTS outcomes

Members NOTED and DISCUSSED:

ATAGI Meeting: AstraZeneca and TTS

2 June 2021, 1:00 – 2:00pm

- Case summaries and clinical spectrum of TTS cases in VIC and WA
- Four “tier 1” (more severe disease) TTS cases in VIC; three “tier 1” in WA

5. Current vaccine coverage

Members NOTED and DISCUSSED:

- Vaccine coverage rates administered up to 30 May 2021 by age group
- Plateau in 70-79 years cohort
- Increase in vaccine uptake in 50-59 and 60-69 years

6. Onward vaccine supply and prioritisation based on current epidemiology

Members NOTED that vaccine supply has not changed dramatically.

s 47C

8. Update of COVID-19 communication materials

Members NOTED that updates on advice documents are underway.

Meeting closed at approximately 2:30pm.

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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
Lucas de Toca
Elspeth Kay

s 22

s 22

ATAGI COVID-19 WG Secretariat

s 22

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
- NOTED a presentation from National Centre for Immunisation Research and Surveillance (NCIRS) on vaccine coverage

- NOTED an update on estimations of COVID-19 vaccine supply from the COVID-19 Vaccine Taskforce
- NOTED supply increases would enable ramp up of GPs offering Comirnaty from July.

s 47C, s 47E(d)

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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.

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Australian Technical Advisory Group on Immunisation (ATAGI) COVID Working Group
Executive Team Meeting #36
16 June 2021, 2-3PM
Outcomes

In attendance:

Executive Members

Chris Blyth (Co-Chair)
Katie Flanagan
Robyn Gibbs
Nigel Crawford
Kristine Macartney

NCIRS support staff

s 47F

Department of Health representatives

Lisa Schofield (partial meeting)
Hope Peisley
Darius Everett

Secretariat

s 22

1. Meeting Opened

Members NOTED:

- Attendees and apologies (Allen Cheng)
- Acknowledgement of country
- No new conflicts of interest

s 22

3. Issues for discussion

Members NOTED:

s 47C, s 47E(d)

4. Documents under development

Members NOTED:

- Updates to documents related to COVID-19 vaccination and pregnancy (clinical guidance and shared decision making guide) have been updated in line with joint Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG) and ATAGI statement and published
- s 47C, s 47E(d)

- Subgroup 3 is developing guidance for s 47C, s 47E(d) with input from GP and emergency medicine experts, expected to be ready for endorsement next meeting.

5. Subgroup issues to raise

Members:

s 47C, s 47E(d)

s 47C, s 47E(d)

6. Other issues

- NOTED Immunisation branch has developed a paper on criteria in the Australian Immunisation Register (AIR) for vaccination certificates

s 47E(d)

Action item	Responsible Officer (s)	Progress
Review paper on AIR changes and provide feedback to immunisation branch by end of week	ATAGI Executive	In progress

7. Next meeting

Members NOTED the next ATAGI Executive meeting is scheduled for Wednesday 23 June 2021.

Meeting Closed: approx. 3:00PM



Australian Government
Department of Health

ATAGI COVID-19 Working Group
Videoconference Meeting #35
23 June 2021, 2.00 -3.00PM

Agenda item	Purpose	Sponsor
1. Welcome and apologies/general committee business <ul style="list-style-type: none">Acknowledgement to CountryDeclarations of InterestApologies	Information	Allen Cheng, Chris Blyth
2. Outcomes and Actions from last meeting (19 May) <ul style="list-style-type: none">Outcomes on SharePoint	Endorse/ Discuss	All
3. Documents under development		Allen Cheng, Chris Blyth
4. Issues for discussion	Endorse/ Discuss	All
5. Sub-group issues to raise (if required)	Discuss	All
6. Other issues (if required)	Information	All
7. Next meeting – Wednesday 30 June 2021 at 2-3PM (EST)	Information	All
Meeting close		



Australian Government
Department of Health

Document	Status	Notes
Shared DMG – for women who are pregnant, breast feeding, or planning pregnancy	V3 published 4 May	https://www.health.gov.au/resources/publications/covid-19-vaccination-covid-19-vaccination-decision-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy
Shared DMG for frail older people	V2 published 4 May	https://www.health.gov.au/resources/publications/covid-19-vaccination-covid-19-vaccination-decision-guide-for-frail-older-people-including-those-in-residential-aged-care-facilities
Shared DMG for immunocompromise	V2 published 4 May	https://www.health.gov.au/resources/publications/atagi-covid-19-vaccination-decision-guide-for-people-with-immunocompromise
Provider guide for people with immunocompromise	V2 published 4 May	https://www.health.gov.au/resources/publications/atagi-provider-guide-to-covid-19-vaccination-of-people-with-immunocompromise
Shared DMG for palliative care	V1 published 4 May	https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-decision-guide-for-people-receiving-palliative-care-or-end-of-life-care
Consent documents: 1) Consent form 2) Provider information 3) Patient resource – Info sheet on Pfizer 4) Patient resource – info sheet on AZ 5) Patient resource – what to do before your appointment 6) Patient resource – post vaccination – Pfizer 7) Patient resource – post vaccination – AZ	All published Update for 1, 2, 4, 7 published	Published documents: https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/information-for-covid-19-vaccination-providers

Endorse: a decision is to be made at this meeting
Discuss: a decision is to be made at a future meeting or out of session
Information: no decision points at this stage

FOI 2487

Clinical guidance v2	Published V3 update published 10 May	https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021
Flu guidance	Published	https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-advice-on-influenza-and-covid-19-vaccines
Multi-dose vials – provider resource	V2 published 4 May	https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-guidance-on-the-use-of-multi-dose-vials-for-covid-19-vaccination
Rapid ATAGI statement on storage and use of doses in syringes	Published	https://www.health.gov.au/resources/publications/covid-19-vaccine-general-questions-for-vaccine-providers
Patient information sheet on AstraZeneca and TTS	Published V2 published 4 May	https://www.health.gov.au/resources/publications/astrazeneca-vaccine-and-the-covid-19-vaccination-program-patient-information
Provider information sheet on AstraZeneca and TTS	Published 20/04 V2 published 4 May	https://www.health.gov.au/sites/default/files/documents/2021/04/covid-19-vaccination-information-for-immunisation-providers-on-thrombosis-with-thrombocytopenia-syndrome-tts-following-covid-19-vaccination.pdf
Mixed schedules advice	Endorsed and provided to the Taskforce	Taskforce considering best way to communicate

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THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH

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		s 22
Debra Petrys		John Skerritt
James Wood		s 22
Karen Bellamy		s 22
Katherine Gibney		s 22
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

s 47C

3. Vaccine Coverage

Members NOTED and DISCUSSED:

- Australian vaccine uptake data by age group and State and Territory

s 22

- Geographical areas of low coverage

s 47C

- Many are receiving their 2nd dose on time

ATAGI Meeting: AstraZeneca and TTS

23 June 2021, 1:00 – 2:00pm

s 22

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

s 47C

- Adolescent group

Other topics raised by members:

s 47C

- Myocarditis signal

Meeting closed at approximately 2:07pm.

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THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH



Australian Government
Department of Health

17th June 2021

The Hon Greg Hunt MP
Minister for Health
Parliament House
CANBERRA ACT 2600

Dear Minister Hunt,

Re: Revised recommendations on the use of COVID-19 Vaccine AstraZeneca

Following a review of the risk and benefits, the Australian Technical Advisory Group on Immunisation (ATAGI) has today revised its recommendations for use of COVID-19 Vaccine AstraZeneca in the Australian context. ATAGI now recommends:

- COVID-19 Pfizer vaccine (Comirnaty) is the preferred vaccine for those under 60 years of age. The recommendation was revised due to a higher risk and observed severity of thrombosis and thrombocytopenia syndrome (TTS) in the 50-59 year old age group than reported internationally and initially estimated in Australia.
- For those aged 60 years or above, 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. The benefit of vaccination in preventing COVID-19 with COVID-19 Vaccine AstraZeneca outweighs the risk of TTS 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 the second dose.

ATAGI reinforces that due to the ongoing risk of COVID-19, maximising vaccine coverage is a priority. ATAGI acknowledges that this recommendation and ongoing supply constraints of the COVID-19 Pfizer vaccine are likely to have an impact on the overall program, yet believes emerging data on the risks of TTS with COVID-19 Vaccine AstraZeneca vaccine warrant this important step.

s 47C

ATAGI remains committed to reviewing the emerging data on risks and benefits of COVID vaccines and, if required, providing additional technical advice to government on the safety and use of COVID vaccines.

Yours sincerely

Chris Blyth and Allen Cheng on behalf of the Australian Technical Advisory Group on Immunisation

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

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.