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Subject: ATAGI Statement on TTS - 17 June 2021 [SEC=OFFICIAL]
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Dear s 22

As you're aware, the Australian Government has asked that the Australian Technical Advisory Group on Immunisation (ATAGI) monitor the rates of TTS cases in the Australian context and update its recommendations should it be required on the basis of this data.

To this end, ATAGI has met today and provides the updated advice to Government from its deliberations.

Kind regards,

ATAGI COVID-19 WG Secretariat

Vaccine Policy Branch | COVID-19 Vaccine Taskforce Division

Australian Government Department of Health

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The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

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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.

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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.