



# Weighing up the potential benefits against risk of harm from COVID-19 Vaccine AstraZeneca

Information for health care providers to help consumers make informed decisions

29 June 2021

### Why vaccinate?

Over time, all people in Australia will be exposed to the SARS-CoV-2 virus (the virus that causes COVID-19). Vaccination is the best way to develop immunity and prevent COVID-19 disease. Protection through vaccination will mean that, in time, we would not need measures like strict lockdowns with travel restrictions. These measures have considerable personal, community and economic impact.

Some people may choose to delay vaccination because there are low numbers of COVID-19 cases in Australia and little or no community transmission. But this could change at any time, and vaccination protects the community before the disease spreads. Even with border controls and other measures in place, cases of COVID-19 are happening because of virus transmission from quarantine settings into the community.

#### **COVID-19 Vaccine AstraZeneca prevents disease**

COVID-19 Vaccine AstraZeneca is very effective in preventing severe disease and death due to COVID-19 in adults of all ages. By early June 2021, millions of doses of this vaccine have been given worldwide.

To help providers and consumers make informed decisions, the Australian Technical Advisory Group on Immunisation (ATAGI) has looked at three scenarios that show the benefits and risks of vaccination with COVID-19 Vaccine AstraZeneca. The benefits and risks vary depending on how many COVID-19 cases there are in the community, and the age of the person being vaccinated.

### Individual and societal benefits of COVID-19 Vaccine AstraZeneca

In these 3 scenarios, the benefits of vaccination with COVID-19 Vaccine AstraZeneca in preventing severe COVID-19 outweigh the potential risks in:

- older adults in the low exposure risk scenario
- all adults in the medium and high exposure risk scenarios.

Broader benefits of vaccination that are not shown in these simplified scenarios include:

- protection against non-severe COVID-19 and complications such as 'long COVID'
- protection of unvaccinated close contacts of vaccinated individuals
- protection of family and community from preventing transmission of the virus
- potential ability to ease and/or avoid imposing other COVID-19 mitigations.

Some of these benefits may be strong motivators to be vaccinated even while COVID-19 disease rates remain low in Australia. Also, the virus that causes COVID-19 may circulate around the world for decades. Being vaccinated is a critical step to move beyond the current pandemic situation.

### **Risks of COVID-19 Vaccine AstraZeneca**

Common side effects of vaccination include fatigue, headache, body aches and fever. More severe side effects of anaphylaxis and a condition called thrombosis with thrombocytopenia syndrome (TTS) have been reported after COVID-19 Vaccine AstraZeneca.

TTS involves blood clotting with low platelet count. Current data indicates that TTS occurs in around 2 out of every 100,000 people who receive the first dose of COVID-19 Vaccine AstraZeneca. TTS appears to be far more rare following second doses, with **data from the United Kingdom** indicating a rate of 1.5 per million second doses.

The severity of illness due to TTS ranges from fatal cases and those with significant morbidity, to relatively milder cases. TTS appears to be more severe in younger people. In Australia, the overall case fatality rate is 3%. Of the TTS cases that have been classified by the **Therapeutic Goods Administration** as confirmed or probable, over half have been discharged from hospital. Around a quarter of the Australian cases so far have been more serious and have required treatment in intensive care, and tragically two people have died.

TTS is different from generalised clotting disorders. The mechanism of action is most likely immune-mediated. It is not currently possible to predict who will develop TTS. The only risk factor for TTS identified right now is age. TTS is less likely in older adults than younger adults.

People who have a personal history or family history of blood clots, have risk factors for blood clots or take anticoagulant medication can have COVID-19 Vaccine AstraZeneca. As a precaution there is a very small group of people with clotting disorders who should get an alternative COVID-19 vaccine. More information can be found in a joint statement from ATAGI and the Thrombosis & Haemostasis society of Australia and New Zealand.

#### Discussing risks and benefits with consumers

It is important that consumers weigh up the potential benefits and risk of harm from COVID-19 Vaccine AstraZeneca to ensure that they make a fully informed decision about receiving the vaccine. Consumers should be aware of the broader benefits of being vaccinated, as well as the benefits in preventing severe disease. Consumers should be made aware of the symptoms and signs of TTS, in the very rare event that it occurs.

#### Who should get COVID-19 Vaccine AstraZeneca?

ATAGI advises that, for people aged under 60 years, the COVID-19 vaccine Comirnaty (Pfizer) is preferred over COVID-19 Vaccine AstraZeneca. For people aged 60 years and over, COVID-19 Vaccine AstraZeneca is available for use. This recommendation is based on older adults having a lower risk of TTS and a higher risk of severe outcomes from COVID-19.

COVID-19 Vaccine AstraZeneca can be used in adults aged under 60 years where the benefits are likely to outweigh the risk and the consumer 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 a second dose of the same vaccine.

## Low exposure risk in the Australian context

Scenario 1: Infection rate similar to first wave of COVID-19 in Australia (29 infections per 100,000 people in a 16-week period)

## For every 100,000 AstraZeneca vaccinations

Age	<b>Potential harms</b> Australian data as at 16 June 2021	Potential benefits
18-29	1.9 blood clots (TTS) <sup>a</sup>	<ul> <li>0.0 deaths prevented</li> <li>0.1 ICU admissions prevented</li> <li>1.0 hospitalisations prevented</li> </ul>
30-39	1.6 blood clots (TTS) <sup>a</sup>	<ul><li>0.0 deaths prevented</li><li>0.5 ICU admissions prevented</li><li>1.9 hospitalisations prevented</li></ul>
40-49	5.0 blood clots (TTS) <sup>a</sup>	<ul><li>0.0 deaths prevented</li><li>0.8 ICU admissions prevented</li><li>2.6 hospitalisations prevented</li></ul>
50-59	2.7 blood clots (TTS)	0.1 deaths prevented 1.4 ICU admissions prevented 4.6 hospitalisations prevented
60-69	1.4 blood clots (TTS)	<ul> <li>0.4 deaths prevented</li> <li>2.1 ICU admissions prevented</li> <li>7.2 hospitalisations prevented</li> </ul>
70-79	1.8 blood clots (TTS)	<ul> <li>1.5 deaths prevented</li> <li>3.4 ICU admissions prevented</li> <li>8.8 hospitalisations prevented</li> </ul>
80+	1.9 blood clots (TTS)	6.2 deaths prevented 1.6 ICU admissions prevented 11.5 hospitalisations prevented

TTS = thrombosis with thrombocytopenia syndrome. Includes probable and confirmed cases, and a range of health care presentations (including hospitalisations, ICU admissions and deaths).

a Estimates of risk are uncertain as rates are based on small numbers of vaccinations in people under 50 in Australia

## Medium exposure risk in the Australian context

Scenario 2: Infection rate similar to second wave of COVID-19 in Victoria (275 infections per 100,000 people in a 16-week period)

## For every 100,000 AstraZeneca vaccinations

Age	<b>Potential harms</b> Australian data as at 16 June 2021	Potential benefits
18-29	1.9 blood clots (TTS) <sup>a</sup>	<ul> <li>O.1 deaths prevented</li> <li>1.3 ICU admissions prevented</li> <li>10.6 hospitalisations prevented</li> </ul>
30-39	1.6 blood clots (TTS) <sup>a</sup>	<ul> <li>0.2 deaths prevented</li> <li>1.2 ICU admissions prevented</li> <li>10.7 hospitalisations prevented</li> </ul>
40-49	5.0 blood clots (TTS) <sup>a</sup>	<ul> <li>0.1 deaths prevented</li> <li>2.6 ICU admissions prevented</li> <li>16.7 hospitalisations prevented</li> </ul>
50-59	2.7 blood clots (TTS)	1.3 deaths prevented 6.6 ICU admissions prevented 24.3 hospitalisations prevented
60-69	1.4 blood clots (TTS)	3.0 deaths prevented 7.0 ICU admissions prevented 30.4 hospitalisations prevented
70-79	1.8 blood clots (TTS)	21.4 deaths prevented 8.6 ICU admissions prevented 63.1 hospitalisations prevented
80+	1.9 blood clots (TTS)	183.6 deaths prevented
		5.2 ICU admissions prevented

TTS = thrombosis with thrombocytopenia syndrome. Includes probable and confirmed cases, and a range of health care presentations (including hospitalisations, ICU admissions and deaths).

a Estimates of risk are uncertain as rates are based on small numbers of vaccinations in people under 50 in Australia

## High exposure risk in the Australian context

Scenario 3: Infection rate based on data from Europe in January 2021 (3,544 infections per 100,000 people in a 16-week period)

## For every 100,000 AstraZeneca vaccinations

Age	Potential harms Australian data as at 16 June 2021	Potential benefits
18-29	1.9 blood clots (TTS) <sup>a</sup>	O deaths prevented 6 ICU admissions prevented 64 hospitalisations prevented
30-39	1.6 blood clots (TTS) <sup>a</sup>	3 deaths prevented 8 ICU admissions prevented 81 hospitalisations prevented
40-49	5.0 blood clots (TTS) <sup>a</sup>	10 deaths prevented 15 ICU admissions prevented 12 hospitalisations prevented
50-59	2.7 blood clots (TTS)	14 deaths prevented 28 ICU admissions prevented 208 hospitalisations prevented
60-69	1.4 blood clots (TTS)	45 deaths prevented   50 ICU admissions prevented   324 hospitalisations prevented

## High exposure risk in the Australian context continued

Age	<b>Potential harms</b> Australian data as at 16 June 2021	Potential benefits
70-79	1.8 blood clots (TTS)	172 deaths prevented
		78 ICU admissions prevented
		547 hospitalisations prevented
80+	1.9 blood clots (TTS)	733 deaths prevented

### High exposure risk in the Australian context continued

Age	Potential harms Australian data as at 16 June 2021	Potential benefits	
Age 80+		Potential benefits	110 ICU admissions prevented 1239 hospitalisations prevented

TTS = thrombosis with thrombocytopenia syndrome. Includes probable and confirmed cases, and a range of health care presentations (including hospitalisations, ICU admissions and deaths).

a Estimates of risk are uncertain as rates are based on small numbers of vaccinations in people under 50 in Australia

#### Potential benefits and harms of COVID-19 Vaccine AstraZeneca

Rates of blood clots (TTS) are based on Australian data as at 16 June 2021.

## Scenario 1: Low exposure risk – infection rate similar to first wave of COVID-19 in Australia (29 infections per 100,000 people in a 16-week period)

For every 100,000 people vaccinated				
Age group	Cases of TTS due to COVID-19	Hospitalisations	ICU admissions	Deaths
	Vaccine AstraZeneca	prevented	prevented	prevented
18–29 years	1.9ª	1.0	0.1	0.0
30–39 years	1.6ª	1.9	0.5	0.0
40–49 years	5.0ª	2.6	0.8	0.0
50–59 years	2.7	4.6	1.4	0.1
60–69 years	1.4	7.2	2.1	0.4
70–79 years	1.8	8.8	3.4	1.5
≥80 years	1.9	11.5	1.6	6.2

TTS = thrombosis with thrombocytopenia syndrome

a Estimates of risk are uncertain as rates are based on small numbers of vaccinations in people under 50 in Australia. Note: Potential benefits calculated from confirmed data from ACT, NSW, Tasmania and Victoria.

## Scenario 2: Medium exposure risk – infection rate similar to second wave of COVID-19 in Victoria (275 per 100,000 people in a 16-week period)

For every 100,000 people vaccinated				
Age group	Cases of TTS due to COVID-19	Hospitalisations	ICU admissions	Deaths
	Vaccine AstraZeneca	prevented	prevented	prevented
18–29 years	1.9ª	10.6	1.3	0.1
30–39 years	1.6ª	10.7	1.2	0.2
40–49 years	5.0ª	16.7	2.6	0.1
50–59 years	2.7	24.3	6.5	1.3
60–69 years	1.4	30.4	7.0	3.0
70–79 years	1.8	63.1	8.6	21.4
≥80 years	1.9	260.5	5.2	183.6

TTS = thrombosis with thrombocytopenia syndrome

a Estimates of risk are uncertain as rates are based on small numbers of vaccinations in people under 50 in Australia. Note: Potential benefits calculated from confirmed data from Victoria.

## Scenario 3: High exposure risk – infection rate based on data from Europe in January 2021 (3,544 infections per 100,000 people in a 16-week period)

For every 100,000 people vaccinated					
Age group	Cases of TTS due to COVID-19	Hospitalisations	ICU admissions	Deaths	
	Vaccine AstraZeneca	prevented	prevented	prevented	
18–29 years	1.9ª	64	6	0	
30–39 years	1.6ª	81	8	3	
40–49 years	5.0ª	122	15	10	
50–59 years	2.7	208	28	14	
60–69 years	1.4	324	50	45	
70–79 years	1.8	547	78	172	
≥80 years	1.9	1239	110	733	

TTS = thrombosis with thrombocytopenia syndrome

a Estimates of risk are uncertain as rates are based on small numbers of vaccinations in people under 50 in Australia.

Note: Potential benefits calculated from confirmed data from Europe.

#### Notes on the data

#### Estimating benefits of vaccination in preventing severe COVID-19

In these simplified scenarios, the benefits of vaccination are measured by counting how many hospitalisations, ICU admissions and deaths from COVID-19 can be prevented for every 100,000 people at that age vaccinated with COVID-19 Vaccine AstraZeneca. It assumes that people vaccinated are 80% less likely to get severe disease, need ICU treatment or die. This is calculated for a period of 16 weeks, based on previous experience that this was the approximate time taken to suppress the disease outbreaks in Australia.

It is difficult to separate the numbers for hospitalisations, ICU admissions and deaths from COVID-19. Some numbers may have been included in more than one category. For example, some people may have been counted as a hospitalisation and an ICU admission, or as an ICU admission and a death.

The risk of severe disease may be higher from some variant strains of the virus, also known as variants of concern.

#### **Estimating harm from TTS**

The risk of harm is measured by estimating the number of people who may get TTS if 100,000 people at that age are vaccinated with COVID-19 Vaccine AstraZeneca. This is based on Australian data as at 16 June 2021.

While the estimates of risk in Australia are similar to overseas estimates, they are less certain for people aged under 50 years. This is because people in this age group are no longer vaccinated with COVID-19 Vaccine AstraZeneca in Australia.

Australia has a strong health system and highly effective vaccine safety surveillance. This means that more cases of TTS may be identified in older age groups in Australia compared with other countries. The benefit of identifying more cases of TTS is that more people are able to be treated effectively.

This guide has been made using a method adapted from the Winton Centre for Risk and Evidence Communication, **University of Cambridge for the United Kingdom**.