Australian Government

COVID-19 VACCINATION

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

Information to help patients make informed decisions.

The AstraZeneca COVID-19 vaccine is very effective in preventing severe disease and death due to COVID-19 in adults of all ages. Millions of doses have been administered around the world to adults of all ages with very few serious side effects.

However, a very rare side effect involving blood clotting with low blood platelet count – thrombosis with thrombocytopenia syndrome (TTS) – may occur after a first dose of AstraZeneca COVID-19 vaccine. Initial experience in the first 3 months of vaccination in Europe (including the UK) suggests this occurs in approximately four to six in a million people. It appears to be less likely in older adults than younger adults – but remains very rare. This condition is serious and requires hospital treatment. About one in four people with this condition may die.

The Australian Technical Advisory Group on Immunisation (ATAGI) advises that while both the AstraZeneca and Pfizer COVID-19 vaccines are recommended in all adults, the COVID-19 Pfizer vaccine is preferred over the AstraZeneca vaccine for use in adults aged under 50 years.

The AstraZeneca vaccine can be used in adults aged under 50 where the benefits are likely to outweigh the risk and the patient has made an informed decision based on an understanding of the risks and benefits.

This recommendation is based on the increasing risk of severe outcomes from COVID-19 in older adults and their lower risk of TTS, compared with the lower risk and higher (but still very low overall) risk of TTS after AstraZeneca vaccination in adults aged under 50.

People who have had the first dose of the AstraZeneca vaccine without any serious adverse effects such as TTS or anaphylaxis, can be given the second dose, including adults aged under 50 years. No cases of this new syndrome have been reported as linked to the second dose of vaccine.

It is important to weigh up the potential benefits and risk of harm of AstraZeneca COVID-19 vaccine to ensure patients are aware of this rare but serious side effect and make a fully informed decision on vaccination with the AstraZeneca vaccine.

What would the benefit vs risk be in the event of a COVID-19 outbreak?

Currently, there may not be any transmission or local outbreaks of COVID-19 in Australia. However, this could change at any time. Even with border controls and other measures in place, there are still cases of COVID-19 occurring following virus transmission from quarantine settings into the community. Most, if not all, Australians will be exposed to the SARS-CoV-2 virus (the virus that causes COVID-19) over time. Most Australians have not yet been vaccinated and are not immune to it.

It's important to understand that the risk versus benefit of vaccination will be different, depending on how many COVID-19 cases there are in the community at a given time and the age of someone being vaccinated.

To help providers and patients make informed decisions, ATAGI have looked at two scenarios – Australia's first wave in early 2020, and Victoria's second wave later in 2020 – to illustrate how the benefits versus risk of vaccination with AstraZeneca COVID-19 vaccine would weigh up if Australia had another outbreak of COVID-19 similar to what has happened in the past (adapting the method used by Winton Centre for Risk and Evidence Communication, University of Cambridge).

In these scenarios the number of people who would be admitted to intensive care, and potentially need artificial ventilation or die from COVID-19, increases significantly with age. It is worthwhile noting that the COVID-19 incidence in the Victorian second wave, which is used to illustrate a potentially higher incidence situation in Australia, is still quite modest compared to COVID-19 disease incidence in many other countries overseas (for example, the COVID-19 incidence rate in the Victorian second wave is 8 times less than that of the low incidence scenario in the UK that was used in the risk-benefit assessment by the **Winton Centre for Risk and Evidence Communication**).

Looking at these two scenarios, and also because the risk of TTS appears to be lower at older age, the benefits of vaccination in preventing severe COVID-19 with AstraZeneca outweighs potential risks of TTS in older age groups in a low incidence scenario, and for all adults in a higher incidence scenario.

Explainer: How did ATAGI measure the potential benefits versus risk in this example?

Estimating benefits of vaccination preventing severe COVID-19

In this simplified illustration, ATAGI measures the benefits of vaccination by counting how many COVID-19 patients can be prevented from needing treatment in an intensive care unit (ICU admission) in hospitals if 100,000 people at that age have been vaccinated with this vaccine. They also assume that people vaccinated with this vaccine are 80 per cent less likely to get severe disease and need ICU treatment. 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.

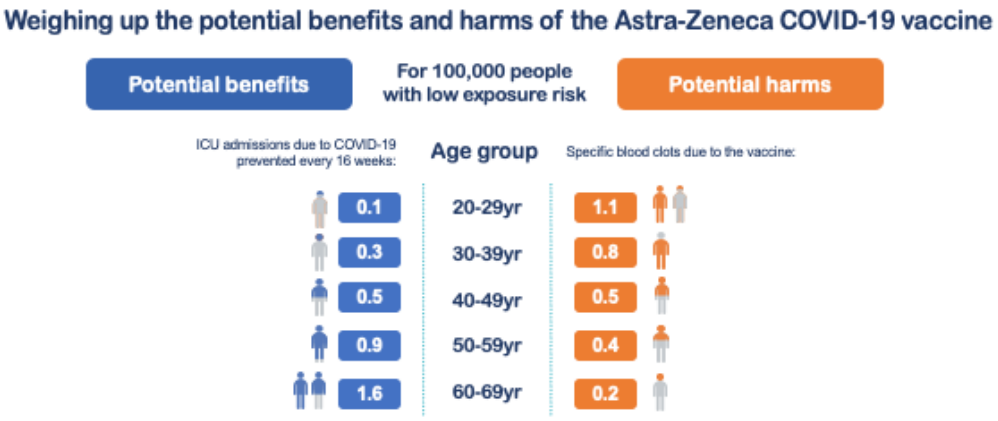
There are additional benefits that are not shown in these simplified scenarios. These include protection against overall COVID-19 and complications such as 'long COVID' and death due to COVID-19. Vaccination may also protect the unvaccinated close contacts of vaccinated individuals and the community more broadly by preventing transmission of the virus, which is supported by growing evidence. Additionally, the risk of severe disease may be higher with some variant strains of the virus, also known as variants of concern (VoC).

Note:
The exposure risk applied to each of these illustrative scenarios is an average for the whole population calculated for the 16 week period. COVID-19 disease exposure risk would vary by circumstance or setting; for example staff in direct contact with COVID-19 cases would have higher exposure risk than the average population, and during these disease waves people living in high incidence areas had a higher risk than people in regional areas. The exposure risk would be much greater across the population as a whole if international borders were opened with easing of restrictions. These illustrative scenarios are selected to reflect possible scenarios if an outbreak was to occur in coming weeks.

Estimating harm from TTS

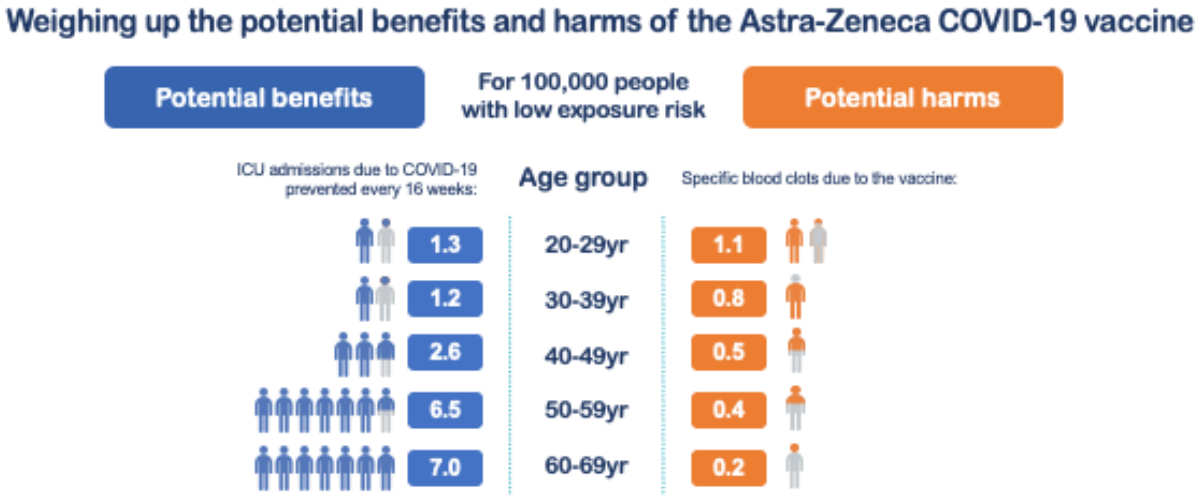
ATAGI measures the risk of harm by estimating the number of people who may get TTS if 100,000 people at that age have been vaccinated with this vaccine – assuming the likelihood is the same as seen in the UK for the same age.

Scenario 1 - Exposure risk similar to first wave of COVID-19 in Australia for severe COVID-19 disease requiring ICU admission (in a 16 week period)



In Scenario 1, the benefits of vaccination with AstraZeneca in preventing severe COVID-19 outweigh harms from TTS in people aged 50 years and over. This is based on a scenario of low level of exposure to COVID-19, at 29 people per 100,000 overall in a 16-week period.

Scenario 2 – Exposure risk similar to second wave of COVID-19 in Victoria for severe COVID-19 disease requiring ICU admission (in a 16 week period)



In Scenario 2 the potential benefits of vaccination with AstraZeneca in preventing severe COVID-19 outweigh harms from TTS even for younger adults (aged less than 50 years). This is based on a scenario of higher level of exposure to COVID-19, at 275 per 100,000 overall in a 16-week period.