Joint statement from ATAGI and THANZ on Thrombosis with Thrombocytopenia Syndrome (TTS) and the use of COVID-19 Vaccine AstraZeneca

21 May 2021

Key points

- TTS, also known as vaccine induced thrombotic thrombocytopenia (VITT), is a rare newly identified condition with a different mechanism to other causes of thrombosis. Among case reports, there are no known markers for increased risk for TTS/VITT.
- The risk of TTS is not likely to be increased in people with the following conditions, and people in these groups *can receive* COVID-19 Vaccine AstraZeneca:
 - History of blood clots in typical sites
 - Increased clotting tendency that is not immune mediated
 - o Family history of blood clots
 - History of ischaemic heart disease or stroke
 - Current or past thrombocytopenia (low platelet count)
 - Those receiving anticoagulation therapy
- The list of conditions for which Comirnaty (Pfizer) is the preferred vaccine has been expanded to also include:
 - Past history of idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis
 - o Antiphospholipid syndrome with thrombosis
- TTS can be treated effectively. Guidance on the identification and management of TTS is available from the Thrombosis and Haemostasis Society of Australia and New Zealand.

The Australian Technical Advisory Group on Immunisation (<u>ATAGI</u>) and the <u>Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ</u>) are closely monitoring local and international data on the very rare and newly identified condition associated with <u>COVID-19 Vaccine AstraZeneca</u> called <u>thrombosis</u> with <u>thrombocytopenia</u> syndrome (TTS) or vaccine induced thrombotic thrombocytopenia (VITT).

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

TTS is distinct from other clotting conditions

TTS is different from other blood clotting conditions and is triggered by the immune system's response to the COVID-19 Vaccine AstraZeneca. It results in both thrombosis *and* low platelet levels. In the majority of cases, pathological antibodies against platelet factor 4 (PF4), a protein released from platelets, are detected. Studies are ongoing to better understand the exact mechanism of TTS. TTS has been reported in patients who have received the COVID-19 Vaccine AstraZeneca and the Janssen COVID-19 Vaccine (the latter is not used in Australia).

TTS is a rare condition with a different mechanism to most other causes of thrombosis and/or thrombocytopenia. Among case reports, there are no known markers for increased risk for TTS. Based upon this, the following groups of people can receive COVID-19 Vaccine AstraZeneca:

- People with a past history of venous thromboembolism in typical sites, such as deep vein thrombosis or pulmonary embolism
- People with a predisposition to form blood clots, such as those with Factor V Leiden, or other non-immune thrombophilic disorders

- People with a family history of clots or clotting conditions
- People currently receiving anticoagulant medications
- People with a history of ischaemic heart disease or cerebrovascular accident
- People with a current or past history of thrombocytopenia.

TTS can now be treated very effectively. THANZ have developed guidance on identification and treatment of TTS.

As part of informed consent for each dose, people who are considering being vaccinated with COVID-19 Vaccine AstraZeneca should be aware that TTS is a very rare potential complication. They should be advised of the possible symptoms of TTS and when to seek medical advice.

Comirnaty (Pfizer), the alternative COVID-19 vaccine available in Australia, is the preferred vaccine brand for:

• People aged under 50 years, since the risk of TTS, albeit very low, appears to be higher in younger adults.

Comirnaty (Pfizer) is recommended for people 16 years and above with:

- A past history of cerebral venous sinus thrombosis (CVST)
- A past history of heparin-induced thrombocytopenia (HIT)
- A past history of idiopathic splanchnic (mesenteric, portal and splenic) venous thrombosis
- Anti-phospholipid syndrome with thrombosis
- People with contraindications to COVID-19 Vaccine AstraZeneca, i.e.
 - Anaphylaxis to a previous dose of COVID-19 Vaccine AstraZeneca, or to an ingredient of the vaccine
 - Thrombosis with thrombocytopenia occurring after the first dose of COVID-19 Vaccine AstraZeneca
 - Other serious adverse events attributed to the first dose of COVID-19 Vaccine AstraZeneca

The risk of TTS is lower after the second dose

<u>UK data</u> suggest that the risk of TTS is much lower with a second dose, with 15 cases reported to date out of 9.0 million second doses of COVID-19 Vaccine AstraZeneca given. This translates into an estimated rate of 1.7 case per million doses.

ATAGI reinforces that people of any age who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events can receive the second dose.

Benefits of vaccination

Vaccination against COVID-19 remains the best way to prevent severe illness and death from COVID-19. The benefits of vaccination are many and include protection against severe illness and death from COVID-19 for the individual, as well as indirect benefits for the community. The risk of potential outbreaks of COVID-19 is ever-present. The Australian population remains largely unimmunised and susceptible to COVID-19 risks.

People who choose to delay vaccination until a vaccine other than AstraZeneca COVID-19 vaccine is available should be aware they may not be protected against COVID-19 for months. ATAGI and THANZ acknowledge the challenges of decision making as information continues to emerge.

Weekly updates are provided by the Therapeutic Goods Administration (<u>TGA</u>) on TTS in Australia, and <u>ATAGI</u> on rates of TTS by age and any related updates to recommendations on COVID-19 vaccine use. To keep up to date visit: https://www.health.gov.au/news.