

Chief Medical Officer

COVID-19 Vaccination Program

Dear Colleague,

On 23 May 2021 I wrote to bring to your attention the Australian Technical Advisory Group on Immunisation (ATAGI) and the Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ) joint statement on Thrombosis with Thrombocytopenia Syndrome (TTS) and the use of the AstraZeneca COVID-19 Vaccine.

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 also reiterates that the risks associated with the use of the AstraZeneca COVID-19 Vaccine and cases of TTS are rare.

The latest ATAGI weekly update (9 June 2021) shows that of 2.5 million doses of AstraZeneca COVID-19 Vaccine administered in Australia, the incidence of TTS is:

- 3.1 per 100,000 doses in those <50 years
- 1.8 per 100,000 doses in those \geq 50 years.

ATAGI noted the Therapeutic Goods Administration (TGA) have reviewed Australia's confirmed and probable TTS cases using the recently proposed Centre for Disease Control criteria, which uses the following categories:

- Tier 1: criteria are defined as clots in an unusual location such as the brain or abdomen and a low platelet count with or without a positive test for antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2: criteria are defined as only clots found in more usual locations such as the legs or lungs with a low platelet count and a positive test for anti-PF4 antibodies.

Of the 48 confirmed and probable cases of TTS identified in Australia, 15 met the Tier 1 definition with the remainder Tier 2. There have been two fatalities.

The small number of Tier 1 cases likely reflects heightened clinical awareness in Australia, with early case ascertainment and prompt diagnosis and treatment.

In light of this I draw to your attention the below possible symptoms of TTS:

- New onset of severe persistent headache which does not improve with simple analgesia
- Signs and symptoms of raised intracranial pressure or focal neurological deficits or seizures
- Signs or symptoms suggestive of thrombosis in other anatomical locations (e.g. abdominal pain suggestive of thrombosis in the splanchnic circulation, or chest pain suggestive of pulmonary embolism)
- Signs suggestive of clinically significant thrombocytopenia, such as petechial rash or bleeding, or bruising not at the vaccine injection site that cannot be explained

Blood clots such as DVT or PE occur commonly in the population in the absence of vaccination, at an annual rate of about 1 per 1000 people. Some of the blood clots that occur will coincidentally be after receiving the AstraZeneca COVID-19 Vaccine and not causally related to the vaccine. Providers should refer to clinical guidance from THANZ on investigation and management of anyone who presents with the above symptoms suggestive of thrombosis with thrombocytopenia after vaccination and seek expert haematologist input as needed. The THANZ resources are available at https://www.thanz.org.au/resources/covid-19/covid-19-related-resources.

Patients with this suspected condition should NOT receive any heparin or platelet transfusions. These treatments may potentially worsen the clinical course.

Based on case reports to date, the period of greatest risk of TTS is between 4-30 days post-vaccination. If a patient who has been vaccinated with the AstraZeneca COVID-19 Vaccine has any of the symptoms listed above, particularly between 4-30 days post-vaccination, it is important that they receive hospital treatment immediately.

I also appreciate that some of your patients may be reluctant to commence or continue a course of AstraZeneca COVID-19 Vaccine due to concerns about TTS. The Department of Health has recently published a document to assist health care providers to weigh up the benefits of vaccination against the risk of harm from the AstraZeneca COVID-19 Vaccine. This information is available at https://www.health.gov.au/resources/publications/covid-19-vaccine-astrazeneca

I thank you for your sustained effort and important role in supporting the COVID-19 vaccination program.

Yours sincerely,

PKelly

Professor Paul Kelly Chief Medical Officer

11 June 2021