Clinical update regarding vaccines

Please find below a clinical update (3 December 2021) regarding advice and information relating to TTS other adverse events and COVID 19 vaccines.

Key messages:

- The COVID-19 booster dose is recommended for everyone 18 years and over, to be given ≥ 6 months following completion of the primary course, with Comirnaty (Pfizer) as the preferred vaccine, irrespective of the COVID-19 vaccine used for the first or second dose.
- ATAGI advises that in certain circumstances, the 6-month interval for a booster dose may be shortened to 5 months. For example, for patients with a greater risk of severe COVID-19 in outbreak settings, people travelling overseas who will be away when their booster dose is due, or in outreach vaccination programs where access is limited. Immunisation providers can use their clinical judgement to determine whether it is appropriate to administer a booster dose from 5 months since the second dose - here
- ATAGI advises that the highest priority groups to receive a booster dose are those with risk factors for severe COVID-19 (e.g. people aged over 50, people with underlying medical conditions or residents of aged care facilities) and/or those at increased occupational risk of COVID-19 - here
- ATAGI have released a statement on SARS-CoV-2 Omicron variant and COVID-19 booster doses - here
- Pregnant women who completed a 2-dose primary schedule can receive a booster dose 6 months or more after their second dose - here
- Pregnant women with severe immunocompromise are recommended to receive 3 primary doses of COVID-19 vaccine - here
- COVID-19 vaccines can be co-administered (i.e. on the same day) with an influenza vaccine. COVID-19 vaccines can also be co-administered with other vaccines if required - here
- Severely immunocompromised people should be prioritised to complete a three dose primary schedule, 2 to 6 months following the second dose - here
- People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer a subsequent dose of COVID-19 vaccine for at least 90 days - here
- A list of NSW Health vaccination clinics (including pop-up and rural and regional clinics) is available here

Highlights and updates:

This week's update regarding COVID-19 immunisation includes information on the updated guidance on COVID-19 booster and third dose vaccines for pregnant women, and adverse events of special interest following vaccination.

- To 24 November 2021, 95% of NSW residents aged 16 years and over have received at least one dose of COVID-19 vaccine, and 93% are fully vaccinated – here
- ATAGI statement on SARS-CoV-2 Omicron variant and COVID-19 booster doses – 3 December - here
- Booster vaccination information kit for residential aged care providers - here
- Updated COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy, v7 – here
- Guidance on pericarditis and myocarditis after mRNA COVID-19 vaccines - here
- ATAGI recommendations on the use of a booster dose of COVID-19 vaccine – 27 October - here
- Australian Immunisation Register (AIR) - immunisation medical exemption form (IM011) - here

Key resources:

- How to report a **suspected** adverse event following immunisation in NSW – here
- ATAGI provider guide to COVID-19 vaccination of people with immunocompromise - here
- ATAGI clinical guidance on use of an additional COVID-19 vaccine dose as a replacement dose for invalid primary courses of COVID-19 vaccines - here

- Guidance on myocarditis and pericarditis following mRNA vaccination - here
- PREDICT network – guideline for the assessment of possible vaccine-induced pericarditis/myocarditis in children and adolescents presenting to the ED - here
- RANCZR imaging recommendations for patients with suspected TTS - here
- How to get proof of your COVID-19 vaccination – here
- Primary care guidance on the approach to suspected TTS – here
- COVID-19 vaccine clinical considerations update – updated 4 November - here
- The Thrombosis & Haemostasis Society of Australia and New Zealand (THANZ) COVID-19 resources & TTS blood test request form - here
- ACEM guidelines for patient presenting with TTS symptoms – v2; June - here
- COVID-19 vaccination - provider resources provided by ATAGI - here

ATAGI statement on SARS-CoV-2 Omicron variant and COVID-19 booster doses - here

ATAGI notes the emergency of the new SARS-CoV-2 variant of concern, which has been named the Omicron variant. A booster dose is currently available to anyone in Australia aged 18 years and over who has completed their primary course of vaccination at least six months ago. ATAGI advises that there is no evidence to suggest that earlier booster doses of current COVID-19 vaccines will augment protection against the Omicron variant. ATAGI advises that in certain circumstances, the routine six-month interval for booster doses may be shortened to five months for logistical reasons, for example:

- For patients with a greater risk of severe COVID-19 in outbreak settings
- If an individual is travelling overseas and will be away when their booster dose is due
- In outreach vaccination programs where access is limited.

There are very limited data on benefit for boosters given prior to 20 weeks after completion of the primary course, and the duration of protection following boosters is not yet known. Providers should use their clinical judgement to determine whether it is appropriate to administer the dose early.

ATAGI recommendations on the use of a booster dose of COVID-19 vaccine for people aged 18 and over - here

Comirnaty (Pfizer) vaccine has been approved by the TGA for use as a booster dose in people aged 18 years and older, at least 6 months after the completion of a COVID-19 vaccine primary course.

Key points:
- The COVID-19 booster dose is recommended for everyone 18 years and over, to be given ≥ 6 months following completion of the primary course
- The highest priority groups to receive a booster dose are those with risk factors for severe COVID-19 and/or those at increased occupational risk of COVID-19
- Comirnaty (Pfizer) is recommended as a single booster dose, irrespective of the primary COVID-19 vaccine used. Vaxzevria (AstraZeneca) is not preferred, but may be used if an individual has experienced a significant adverse reaction after a previous mRNA vaccine which contraindicates further mRNA doses (e.g. anaphylaxis or myocarditis)
- ATAGI recommends that it is acceptable to co-administer a COVID-19 booster dose with an influenza vaccine
- A booster dose is not currently recommended for those aged less than 18 years. Spikevax (Moderna) is not currently recommend for use as a booster vaccine
- Severely immunocompromised individuals have recently been recommended to receive a third dose of a primary COVID-19 vaccine. Further information on a booster dose (i.e. a fourth dose) in this group will be provided soon
- Booster doses are available now through participating general practices, and at NSW Health vaccination clinics

TGA weekly safety report – 2 December - here

Myocarditis and pericarditis with mRNA vaccines

As of 28 November 2021, from 24. 4 million Comirnaty (Pfizer) doses given, there are **693 reports of suspected myocarditis** alone or in combination with pericarditis, with 137 of these reports in adolescents (12- 17-years-old). There are also **1471 reports of suspected pericarditis** alone, with 109 of these reports in adolescents. Of the **693 suspected myocarditis cases after Pfizer doses, 354 were likely myocarditis,** with the remaining as unlikely or having insufficient information. This assessment does not determine whether cases have been caused by vaccination.

To 28 November, the rates of myocarditis cases following Comirnaty for all ages (and all doses) is 2.1 per 100,0000 for males, and 0.8 per 100,000 for females, with a higher rate (for all doses) in adolescents of 6.8 per 100, 000 for males and 1.4 per 100, 000 for females. Of the cases classified as likely to be myocarditis, most of the patients experienced symptoms within 3 days of vaccination. Around half of the patients were admitted to hospital with 9 being treated in intensive care. Most patients treated in hospital were discharged within 4 days.

As of 28 November, from 1.2 million Spikevax doses given, there are 37 reports of suspected myocarditis, with 14 of these reports in adolescents, and 73 reports of suspected pericarditis, and 4 of these reports in adolescents.

Thrombosis with thrombocytopaenia syndrome (TTS)

From about 13.5 million vaccine doses, there have been 166 cases of TTS. Of these, 144 (82 confirmed, 62 probable) related to a first dose of Vaxzevria (AstraZeneca) and 22 to a second dose (6 confirmed, 16 probable).

Guillain-Barré Syndrome (GBS)

In Australia, GBS has been reported in about one in every 100,000 people following the Vaxzevria (AstraZeneca) vaccine. As of 28 November, the TGA has received **156 reports of suspected GBS** in people who have received the Vaxzevria (AstraZeneca) vaccine. It is expected that some suspected cases may not be related to vaccination, as GBS can also be caused by other conditions, such as a viral infection or some types of gastroenteritis. Following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and Vaxzevria (AstraZeneca) has not been established.

Immune thrombocytopenia (ITP)

As of 28 November 2021, the TGA has received **93 reports of suspected ITP** following vaccination. These patients had an extremely low platelet count, and signs of thrombocytopenia which may include unusual bruising, a nosebleed and/or blood blisters in the mouth. In many cases it is mild with up to a third of people having no symptoms at all, or only minor bruising. However, about 5% develop severe bleeding.

Reminder – reporting adverse events following immunisation (AEFI)

An adverse event following immunisation (AEFI) is a notifiable condition under the NSW Public Health Act (2010). **All uncommon, unexpected, or serious AEFIs must be notified by health professionals** to the local Public Health Unit (PHU) on 1300 066 055. This includes *suspected* cases.

Information about adverse event surveillance and reporting for COVID-19 vaccines is here.