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Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine weekly safety report - 17-06-2021

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The Therapeutic Goods Administration (TGA) closely monitors suspected side effects (also known as adverse events) from the use of COVID-19 vaccines. Importantly, adverse events reported to the TGA are often not caused by the vaccine itself. Learn more about causality (//www.tga.gov.au/about-daen-medicines#causality).

Learn about the TGA's COVID-19 vaccine safety monitoring and reporting (//www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting) activities or report a suspected side effect (//www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine).

Summary

- The most frequently reported suspected side effects associated with Comirnaty (Pfizer) and AstraZeneca COVID-19 vaccines continue to be events that were seen in the clinical trials, and are commonly experienced with vaccines generally.
- Twelve additional cases of blood clots with low blood platelets have been assessed as thrombosis with thrombocytopenia syndrome (TTS) likely to be linked to the AstraZeneca vaccine. The increase in the number of cases correlates with an increase in the number of doses of AstraZeneca vaccine administered during the reporting period.
- This brings the total number of confirmed and probable TTS cases in Australia to 60. Seven of the 12 new cases occurred in individuals in aged between 50 and 59 years. When assessed using the United Kingdom (UK) case definition, three cases were confirmed and nine were deemed probable TTS.

Reported side effects for COVID-19 vaccines

Gathering reports of adverse events following immunisation (AEFI) is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues (//www.tga.gov.au/tga-safety-monitoring-medicines#steps).

In the week of 7-13 June 2021, we received 2106 AEFI reports for COVID-19 vaccines.

To 13 June 2021, we received 303 reports of death following vaccination for COVID-19 vaccines.

By chance, some people will experience new illnesses or die from a pre-existing condition shortly after vaccination, especially if they are elderly. We review all deaths reported after vaccination and compare the expected natural death rates in a similar case group to observed death rates following immunisation to distinguish between possible side effects of the vaccines and coincidental events.

For reports of death other than TTS, our review of cases and analysis of reporting patterns does not suggest that the vaccine caused these deaths.

Total adverse event reports to 13 June 2021

5.0 Reporting rate per 1000 doses	29,436 Total AEFI reports received	5,867,299 Total doses administered
20,418 Total reports for AZ vaccine	8,774 Total reports for Comirnaty	247 Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	4.4	New South Wales	3.7
Northern Territory	4.8	Queensland	5.1
South Australia	4.6	Tasmania	6.8
Victoria	6.3	Western Australia	4.2

Most commonly reported vaccine side effects

The AEFI most commonly reported to the TGA following COVID-19 vaccines are side effects that are observed with vaccines generally. They include headache, muscle and joint pain, fever and injection site reactions.

The most common reactions reported for the AstraZeneca COVID-19 vaccine in the week of 7-13 June 2021 were headache, fever, muscle pain, chills and nausea.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 7-13 June 2021 were headache, muscle pain, injection site reactions, nausea and lethargy.

AstraZeneca COVID-19 vaccine

We continue to receive reports of side effects to the AstraZeneca vaccine as it becomes more widely available in Australia. The reports are generally consistent with what is being observed internationally and most are expected side effects that we know occur after vaccination and resolve within a few days.

Thrombosis with thrombocytopenia syndrome (TTS)

The TGA and other medicines regulators around the world continue to closely monitor and investigate thrombosis with thrombocytopenia syndrome (TTS). This is a rare event involving serious blood clots with a low blood platelet count. TTS is triggered by the immune system's response to the AstraZeneca vaccine and is different from other clotting conditions.

As previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021), the TGA determines whether a report is likely to represent TTS by assessing cases against a consistent set of criteria, based on the case definitions established by the UK's Medicines and Healthcare products Regulatory Agency.

Since last week's report, a further 12 reports of blood clots and low blood platelets have been assessed as confirmed or probable TTS likely to be linked to the AstraZeneca vaccine (Table 1).

Table 1: Newly confirmed and probable TTS cases for the week of 11-17 June 2021

New confirmed TTS	New probable TTS
Three new cases: • 55 and 65-year-old women from Victoria • 53-year-old woman from NSW	Nine new cases: • 54-year-old man from Northern Territory • 65-year-old woman from Tasmania • 50 and 56-year-old men and a 69-year-old woman from Victoria • 58-year-old woman from South Australia • 59 and 80-year-old men from Queensland • 67-year-old woman from NSW

This takes the total Australian reports assessed as TTS following the AstraZeneca vaccine to 37 confirmed cases and 23 probable cases.

Most cases have occurred in people aged over 50 years because the AstraZeneca vaccine has been used almost exclusively in this age group since the recommendation from ATAGI on 8 April 2021 that the Comirnaty vaccine is preferred in people under 50.

The TGA's adjudication committee, which met to review these cases on 16 June 2021, confirmed that seven of the 12 new cases this week were in individuals aged 50–59 years old.

When assessed against the criteria used by the US Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf), fewer than half of them are classified as Tier 1 cases, which involve clots in an unusual location, such as the brain or abdomen (Table 2). Of note, Tier 1 cases tend to have more serious outcomes than Tier 2 cases.

Table 2: Confirmed and probable TTS cases by age and CDC classification

Age	Total cases	CDC classification†		
		Tier 1	Tier 2	Not classified
<30 years	1	-	-	1
30-39	1	1	-	-
40-49	4	4	-	-
50-59	15	6	4	5
60-69	11	4	3	4
70-79	19	6	6	7
80+	9	2	4	3
All ages	**60 (29 men, 31 women)**	23	17	20

†The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) and a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) **and** a low platelet count **and** anti-PF4 antibodies
- Not classified = case does not meet the criteria for Tier 1 or Tier 2 (for example clots in common locations with low platelet count but no evidence of anti-PF4 antibodies).

Cases have most often occurred about two weeks after vaccination, although the time to onset (or diagnosis) has ranged from two days to 52 days (Table 3). In some cases with a longer time to diagnosis, patients had experienced symptoms at an earlier stage but complicating factors, including symptoms from comorbidities, may have delayed a clear diagnosis. Approximately one in four TTS cases has required Intensive Care Unit (ICU) treatment, although all but four patients have since been released from ICU.

Table 3: Time to onset, treatment and outcomes for TTS cases*

Time to onset/ diagnosis (days)	Median (range)	13 (2-52)
Treated in ICU	At any point	13
	Currently	4

Outcome	Discharged	36
	In hospital	22
	Fatal	2

*Data is based on the most recent medical information available to the TGA

Updated reporting rates of TTS in Australia were published in last weeks' statement from ATAGI published 10 June 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-9-june-2021). The rates remain consistent with what is being seen internationally, including in Europe, the UK, the Middle East and Canada.

While TTS is very rare, it is appreciated that some people will may have concerns that they can discuss with their doctor. This is essential to allow people to make an informed choice.

There have only been a limited number of second doses of AstraZeneca vaccine administered so far in Australia. Data from the UK indicates that TTS is much less common after second doses, with an overall incidence of 1.5 cases per million doses.

Anyone who has been vaccinated should seek immediate medical attention if they develop any of the following symptoms after vaccination:

- severe or persistent headache or blurred vision
- shortness of breath, chest pain, leg swelling or persistent abdominal pain
- unusual skin bruising and/or pinpoint round spots beyond the site of vaccination.

The most common time period for onset of TTS symptoms is 4-30 days after vaccination.

Capillary leak syndrome

Capillary leak syndrome following immunisation with the AstraZeneca vaccine has been observed overseas (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting). The TGA continues to monitor for this following vaccination. A causal link between capillary leak syndrome and the vaccine has not been established.

Capillary leak syndrome is a very rare but severe condition where fluid from small blood vessels (capillaries) leaks into surrounding tissues. This causes swelling, usually in the arms or legs, and a drop in blood pressure. The blood also becomes thicker and has reduced amounts of a protein called albumin.

The TGA has received one case of a patient who died from multi-organ failure but had signs of capillary leakage. Although there was a temporal link with the vaccine, an expert Vaccine Safety Investigation Group was unable to establish a causal link (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-10-06-2021)as other causes could not be ruled out.

Capillary leak syndrome has been under investigation by the Pharmacovigilance Risk Assessment Committee in Europe since April this year. The Committee analysed six cases in the context of 78 million vaccine doses given in Europe. One of the individuals died. Most of the cases were in women and occurred within four days of receiving the vaccine. Three of the patients had had capillary leak syndrome previously. At a meeting on 7–10 June 2021 (https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7-10-june-2021), the Committee concluded that the AstraZeneca vaccine should not be given to people who have a history of capillary leak syndrome and that the product information for the vaccine should contain a warning about this.

The TGA continues to work with international regulators to learn more about the possible relationship between the AstraZeneca vaccine and this syndrome. We are also communicating with the sponsor on this issue and will report more information when it becomes available.

Immune thrombocytopenic purpura

A recent article (https://www.nature.com/articles/s41591-021-01408-4) based on data from Scotland's COVID-19 vaccination program suggests there may be a small increase in the risk of a bleeding disorder called immune thrombocytopenic purpura (ITP) following immunisation with the AstraZeneca vaccine. The incidence of ITP in the study was very rare at around one case in 100,000 vaccinated people. This is comparable to what has been found with other vaccines for hepatitis B, measles, mumps, rubella and influenza.

ITP is characterised by a decrease in platelets (which help blood to clot). It causes minor bruising in some people whereas others may develop excessive bleeding and long-term disability.

The TGA is closely monitoring this issue and will collaborate with counterparts overseas to learn more about a possible link with the AstraZeneca vaccine.

Up-to-date information about the expected side effects of the AstraZeneca COVID-19 vaccine can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=COVID-19%20Vaccine%20AstraZeneca) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=COVID-19%20Vaccine%20AstraZeneca&r=/) (for health professionals).

Comirnaty (Pfizer) vaccine

Side effects to the Comirnaty vaccine continue to be reported to the TGA and are consistent with what has been observed internationally. Most are expected side effects that we know occur after vaccination and resolve within a few days.

Myocarditis and pericarditis

The TGA continues to monitor reports of myocarditis (inflammation of the heart) and pericarditis (inflammation of the membrane around the heart) following reports of a signal for a possible safety concern in the US and Israel. These conditions often occur following a viral infection and most cases are mild with no long-term effects. Severe cases may cause damage to the heart muscle although this is very rare.

The Centre for Disease Control and Prevention in the US has reported a higher than usual number of cases of myocarditis and pericarditis after vaccination with Comirnaty (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html). These cases were mainly in teenage boys after the second vaccine dose and symptoms typically started within a week of vaccination. Most individuals responded to treatment and rest. A similar pattern of cases has also been reported in Israel (https://www.gov.il/en/departments/news/01062021-03). Almost all were considered mild and resolved within a few days. A causal link to the vaccine has not yet been established but international regulators are investigating this.

Since the beginning of the vaccine rollout in Australia (to 13 June 2021), the TGA has received one report of myocarditis and 14 reports of pericarditis following immunisation with the Comirnaty vaccine. Approximately two million doses of the vaccine have been given during this time. Three cases were in men (aged 18, 23 and 72 years) and 11 were in women (aged 26-44 years). Most cases appeared to be mild with individuals reported to be recovered or recovering. There is no indication at present that these cases are due

to the vaccine but the TGA is continuing to monitor this issue and is collaborating with international medicine regulators. We encourage people to report symptoms that could suggest myocarditis or pericarditis such as of chest pain, shortness of breath and palpitations, particularly after the second dose of Comirnaty.

Up-to-date information about Pfizer Comirnaty can be found in the Consumer Medicine Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=Comirnaty) (for consumers) and Product Information (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=comirnaty) (for health professionals).

Useful links

TGA COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines)

Australian Government Department of Health COVID-19 vaccines (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines) hub

AusVaxSafety (http://www.ausvaxsafety.org.au/) (active surveillance activities and information)

COVID-19 vaccine symptom checker (https://www.healthdirect.gov.au/symptom-checker/tool)

Database of Adverse Event Notifications (DAEN) (https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx)

The latest from ATAGI – published 10 June 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-9-june-2021)

Updated advice on COVID-19 vaccination during pregnancy (https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women)

Timing of the flu vaccine with COVID-19 vaccination (https://www.health.gov.au/news/updated-atagi-advice-on-administering-seasonal-influenza-vaccines-in-2021)

Top 3 COVID-19 vaccine questions – Vaccine wait times, eligibility, and new variant susceptibility (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-lockdown-and-transmission-after-covid-19-vaccines-and-new-covid-19-strains)

Top 3 COVID-19 vaccine questions – Vaccine eligibility changes, accessing the vaccine and why getting vaccinated is important (about:blank)

URL: https://www.tga.gov.au/node/938285 (https://www.tga.gov.au/node/938285)