Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccine weekly safety report - 27-05-2021

Release date Thursday, 27 May 2021 Previous reports

The Therapeutic Goods Administration (TGA) closely monitors suspected side effects (also known as adverse events) from the use of COVID-19 vaccines. Most of the adverse events reported to the TGA are expected side effects seen with vaccines generally.

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.
- Nine 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. When assessed using the United Kingdom (UK) case definition, six cases are confirmed TTS and three are probable.

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 17-23 May 2021 we received 1609 AEFI reports for COVID-19 vaccines.

Total adverse event reports to 23 May 2021

6.1	22,031	3,613,053
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered

15,273	6652	198
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

Reporting rates per 1000 doses by jurisdiction

Australian Capital Territory	5.2	New South Wales	4.2
Northern Territory	6.2	Queensland	5.5
South Australia	5.2	Tasmania	7.9
Victoria	9.4	Western Australia	4.2

Most commonly reported COVID-19 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 17-23 May 2021 were headache, muscle pain, fever, chills and fatigue.

The most common reactions reported for the Comirnaty (Pfizer) COVID-19 vaccine in the week of 17-23 May 2021 were headache, muscle pain, lethargy, fever and injection site reactions.

Public access to vaccine adverse event reports

The first adverse event reports for the Comirnaty vaccine are now available in the TGA's public Database of Adverse Event Notifications (//www.tga.gov.au/database-adverse-event-notifications-daen) (DAEN). As part of our commitment to transparency, the TGA publishes adverse event reports for all medicines and vaccines in the DAEN 90 days after they are received.

Adverse event reports come from various sources including members of the public, doctors, nurses, state and territory health departments, pharmacists and pharmaceutical companies. During the 90 days between receiving and publishing adverse event reports, the TGA reviews and checks reports and analyses the data to look for safety issues relating to medicines and vaccines.

Reports for the AstraZeneca vaccine will become available in the DAEN from mid-June, as the first doses of it were administered in Australia a couple of weeks after the start of the rollout.

For privacy reasons, people who experience an adverse event cannot be identified in the DAEN. Information in the database also cannot be used to determine whether a medicine or vaccine is safe or not. If a medicine or vaccine is approved for use by the TGA, it means that the benefits are considered to outweigh its risks, if used as authorised.

Reports of death following vaccination, particularly in the elderly

The TGA uses its adverse event reporting system to closely monitor reports of death following COVID-19 vaccination. During the early stages of the vaccine rollout in Australia and many other countries, deaths were reported following vaccination in older people living in aged care as this is where the vaccine rollout started. Many of these deaths were in frail elderly people and were coincidental with vaccination. This was confirmed following review by the TGA and medicine regulators in the UK, Europe and the US which found no specific safety concerns from use of the vaccines in older people (//www.tga.gov.au/alert/covid-19-vaccines-safety-and-effectiveness-older-adults).

However, it is possible in frail older people that even relatively mild and expected adverse reactions following the vaccination may contribute to deterioration of an underlying illness. For this reason, the Product Information documents for both the Pfizer (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=comirnaty) and the AstraZeneca (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=COVID-19%20Vaccine%20AstraZeneca&r=/) vaccines provide advice about vaccinating frail elderly people (over 85 years old) and warn that the potential benefits of vaccination must be weighed against the potential risks for each individual person.

To 23 May 2021, 3.6 million doses of COVID-19 vaccines have been given in Australia. In this period, the TGA has received 210 reports of deaths following immunisation – 109 have been reported for the Pfizer vaccine, 94 for the AstraZeneca vaccine and seven where the vaccine was not specified. Most of these reports (93%) were for people 65 years of age and over, and over three quarters were 75 years of age and over. Many of the deaths relate to elderly aged-care residents.

The TGA reviews all deaths reported after vaccination and monitors for safety signals. Part of our analysis includes comparing expected natural death rates to observed death rates following immunisation. To date, the observed number of deaths reported after vaccination is actually less than the expected number of deaths.

Each year in Australia, there are about 160,000 deaths, equating to 13,300 a month or 3050 each week. In the most recent reporting year (2018) (https://www.aihw.gov.au/reports/life-expectancy-death/deaths-in-australia/contents/age-at-death) two-thirds of these deaths were in people aged 75 years and over.

Additionally, deaths from COVID-19 disease overwhelmingly occur in the elderly. While the 20-29 age group has had the highest number of cases of COVID-19 in Australia (followed by the 30-39 age group), 94 % (852 of 910) of COVID-19 deaths in Australia (https://www.health.gov.au/resources/covid-19-cases-by-age-group-and-sex) have been in those aged 70 or over.

Apart from the single Australian case in which death was linked to TTS, COVID-19 vaccines have not been found to cause death. Given the benefits of vaccination with regard to preventing severe disease, hospitalisation and death from COVID-19, particularly in older age groups, immunisation is strongly encouraged as we head into the winter months.

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.

Thrombosis with thrombocytopenia syndrome

Thrombosis with thrombocytopenia syndrome (TTS) 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. The TGA and other medicines regulators around the world continue to monitor and investigate this issue.

Earlier this week, the Australian Technical Advisory Group on Immunisation (ATAGI) released a joint statement with the Thrombosis and Haemostasis Society of Australia and New Zealand (https://www.health.gov.au/news/joint-statement-from-atagi-and-thanz-on-thrombosis-with-thrombocytopenia-syndrome-tts-and-the-use-of-covid-19-vaccine-astrazeneca) (THANZ). This update notes that the risk of developing TTS after receiving the AstraZeneca vaccine does not appear to be higher in people who have previously had a clot such as deep vein thrombosis or pulmonary embolism. The update also states that there appears to be no increased risk in those with a history of coronary heart disease, stroke or thrombocytopenia or those receiving anticoagulation therapy. ATAGI recommends that these people can receive the AstraZeneca vaccine.

However, ATAGI recommends that the Comirnaty (Pfizer) vaccine be used in people with:

- a history of cerebral venous sinus thrombosis (CVST) or idiopathic splanchnic (mesenteric, portal and splenic) venous thrombosis
- a history of heparin-induced thrombocytopenia (HIT)
- anti-phospholipid syndrome with thrombosis

- a serious reaction to a previous dose of the AstraZeneca vaccine such as anaphylaxis or TTS.

TTS cases in Australia

Medical officers at the TGA continue to investigate suspected cases of TTS and share information with other medicines regulators. As previously reported (//www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-20-05-2021), 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 six reports of blood clots and low blood platelets have been assessed as confirmed TTS likely to be linked to the AstraZeneca vaccine. These cases were in two women from NSW (a 60-year-old and an 82-year-old), a 72-year-old male from WA, a 51-year-old woman from WA, a 73-year-old woman from Victoria and a 63-year-old man from Queensland.

In addition, there were three cases classified as probable this week. These cases were in an 85-year-old woman from NSW, a 62-year-old man from Victoria and a 76-year-old woman from Victoria.

This takes the total Australian reports of cases assessed as TTS following the AstraZeneca vaccine to 27 confirmed cases and six probable cases.

We have information about all but two cases at this stage:

- 17 have been discharged from hospital and are recovering
- four have left hospital but require outpatient medical care
- nine patients remain in hospital.

As previously reported, one case in a 48-year-old woman from NSW was unfortunately fatal.

Updated reporting rates of TTS in Australia have been published in the latest statement from ATAGI (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-26-may-2021). These reporting rates remain consistent with what is being seen internationally, including in Europe, the UK, the Middle East and Canada. It is important to highlight that due to better awareness, early diagnosis and appropriate treatment, the outcome and prognosis of the majority of those who have experienced this syndrome is good.

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.

Myocarditis and pericarditis

The TGA continues to investigate a small number of Australian cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) following vaccination with Comirnaty. There is no indication at the moment that these cases are due to the vaccine but the TGA is collaborating with international medicine regulators on this issue.

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

The latest from ATAGI – published 27 May 2021 (https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-26-may-2021)

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

Top 3 questions about COVID-19 vaccines this week – stopping transmission, virus mutation and people who want to wait for vaccination (https://www.health.gov.au/news/top-3-covid-19-vaccine-questions-vaccines-and-stopping-transmission-virus-mutation-and-people-who-want-to-wait-for-vaccination-0)

The Australian Academy of Science – The AstraZeneca vaccine and TTS (https://www.science.org.au/curious/people-medicine/what-we-know-about-astrazeneca-vaccine-and-blood-clots)

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

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

URL: https://www.tga.gov.au/node/937546 (https://www.tga.gov.au/node/937546)