



Australian Government



Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines

The following guidance has been developed jointly by the Australian Technical Advisory Group on Immunisation (ATAGI) and the Cardiac Society of Australia and New Zealand (CSANZ).

Version 1.1 – 6 August 2021

What has been updated:

- *People with a history of myocarditis or pericarditis > 6 months ago can be vaccinated without any additional precautions*
- *People who have precautions to vaccination can consult a GP, immunisation specialist or cardiologist before vaccination*



Key Points

- A risk of myocarditis and pericarditis has been observed in people who have received mRNA COVID-19 vaccines in overseas studies, particularly in males under 30 years of age after the second vaccine dose.
- This association is based on data from the USA and Europe, where these mRNA vaccines have been extensively used.
- ATAGI and CSANZ emphasise that the overwhelming benefits of vaccination in protecting against COVID-19 greatly outweigh the rare risk of these conditions, and Comirnaty (Pfizer mRNA vaccine) continues to be recommended for all people ≥ 16 years of age who do not have any contraindications to the vaccine, in those aged 12-15 with specific medical conditions that increase their risk of severe illness from COVID-19, and in Aboriginal and Torres Strait Islanders aged 12-15.
- COVID-19 Vaccine AstraZeneca is not associated with an increased risk of myocarditis/pericarditis. Cases have been reported after this vaccine, however have not been reported more frequently than what is expected in the absence of vaccination (the 'background rate').
- Most myocarditis and pericarditis cases linked to mRNA vaccination have been mild and patients have recovered quickly. Longer-term follow-up of these cases is ongoing.
- Symptoms typically appear within 1-5 days of vaccination and include chest pain, palpitations (irregular heartbeat), syncope (fainting) or shortness of breath. People who experience any of these symptoms after having an mRNA COVID-19 vaccine should seek prompt medical attention. Initial investigations for people presenting with symptoms or signs of myocarditis or pericarditis should include ECG, troponin, chest X-ray, and other investigations for other differential diagnoses as clinically indicated.
- Most pre-existing cardiac conditions are **not** regarded as contraindications to vaccination. Comirnaty is a recommended vaccine for people with a history of heart conditions: this includes myocarditis, pericarditis or endocarditis > 6 months prior to vaccination, coronary artery disease, myocardial infarction, stable heart failure, arrhythmias, rheumatic fever, prior history of rheumatic heart disease (RHD), Kawasaki Disease, most congenital heart disease and people with implantable cardiac devices
- People with a history of any of the following conditions can receive an mRNA vaccine (e.g. Comirnaty) but should consult a GP or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:
 - Recent (i.e. within the past 6 months) or current inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis
 - Acute rheumatic fever or acute rheumatic heart disease
 - People aged 12-29 years with dilated cardiomyopathy
 - Complex or severe congenital heart disease including single ventricle (Fontan) circulation
 - Acute decompensated heart failure
 - Cardiac transplant recipients.
- People who develop myocarditis or pericarditis attributed to their first dose of Comirnaty are advised to defer further doses of an mRNA COVID-19 vaccine and to discuss this with their treating doctor.

Background

Myocarditis refers to inflammation of the heart muscle, and pericarditis refers to inflammation of the thin sac that surrounds the heart. These conditions can occur separately or together (myopericarditis). Myocarditis and/or pericarditis have been reported as rare side effects after mRNA COVID-19 vaccines (including Comirnaty (Pfizer) and Spikevax (Moderna)) in adults, particularly young adults, in several countries including the USA, Israel, UK and Italy.¹⁻⁶ Cases have also been reported in adolescents.^{7,8} As of 25 July 2021, 84 cases of myocarditis and/or pericarditis have been reported in Australia to the Therapeutic Goods Administration following Comirnaty (Pfizer) vaccine.⁹ It is important to note these are not all necessarily caused by the vaccine as myocarditis and pericarditis occur in the absence of vaccination, e.g. for people aged 18-34 years the estimated incidence in females is 16 per million (95% prediction interval 8-32), and for males is 37 (16 – 88).¹⁰

COVID-19 Vaccine AstraZeneca has not been associated with an increased risk of myocarditis/pericarditis. Cases have been reported after the COVID-19 Vaccine AstraZeneca, however, cases have not been reported more frequently than what is expected in the absence of vaccination (the 'background rate')

Most myocarditis and pericarditis cases linked to mRNA vaccination have required hospitalisation, however most have responded well to standard treatment with a mild and self-limiting course.^{1,6} Symptoms typically appear within 1- 5 days (median 2 days) after vaccination.¹¹ In an analysis of myocarditis cases reported after mRNA vaccines in the US Vaccine Adverse Events Reporting System (VAERS), 76% of cases were in males, and the median age of the 323 reported cases meeting US CDC's case definition was 19 years (range = 12-29 years).¹⁰

The risk of myocarditis or pericarditis appears to be higher following the second dose of an mRNA COVID-19 vaccine, but cases have also been reported after the first dose. 76% of cases reported to the US VAERS occurred after a second dose.¹¹ The crude reporting rate in males aged 12-29 years was 40.6 cases per million second doses of an mRNA COVID-19 vaccine, and in females aged 12-29 years was 4.2 cases per million. The rate in males aged 30 years or older was 2.4 cases per million second doses, and in females of the same age was 1.0 case per million second doses. Further analysis of rates and risks after vaccination is ongoing.

Myocarditis and pericarditis, due to a variety of causes, are also commonly seen in the general population. Importantly, myocarditis is also a possible complication of COVID-19.¹²

Recommendations

ATAGI and CSANZ emphasise that the overwhelming benefits of vaccination using an mRNA vaccine in protecting individuals against COVID-19 and its serious outcomes such as hospitalisation and death as well as the wider benefits of reducing spread of the disease in the community, greatly outweigh the rare risk of myocarditis or pericarditis after vaccination.

Comirnaty continues to be recommended for all people ≥ 16 years of age who do not have any contraindications to the vaccine, for those aged 12-15 with specific medical conditions that increase their risk of severe illness from COVID-19 and for all Aboriginal and Torres Strait Islanders aged 12-15. For further information refer to the [Clinical guidance on use of COVID-19 vaccine in Australia in 2021](#).

Advice for people with a history of cardiac conditions

Comirnaty continues to be one of the recommended vaccines to prevent COVID-19 in people with a history of most chronic cardiovascular conditions, including prior myocarditis, pericarditis or endocarditis > 6 months ago, coronary artery disease, myocardial infarction, stable heart failure, arrhythmias, prior history of rheumatic heart disease (RHD), Kawasaki Disease, most congenital heart disease and people with implantable cardiac devices. No specific precautions are recommended for people in these groups. There is no current data suggesting that their risk of developing myocarditis or pericarditis after vaccination is any higher than for the general population.

People with a history of any of the following conditions **can receive** an mRNA vaccine (e.g. Comirnaty) but should consult a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Recent (i.e. within the past 6 months) or current inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis
- Acute rheumatic fever or acute rheumatic heart disease
- People aged 12-29 years with dilated cardiomyopathy
- Complex or severe congenital heart disease including single ventricle (Fontan) circulation
- Acute decompensated heart failure
- Cardiac transplant recipients

There is a theoretical concern that patients with these conditions may be at increased risk of developing myocarditis and/or pericarditis after a dose of an mRNA COVID-19 vaccine, although there is no evidence to confirm this at present. Pericarditis is more frequently recurrent than myocarditis. These patients should be counselled about the symptoms to look out for after vaccination, and some may be advised by their cardiologist to schedule a routine visit with their general practitioner a few days after vaccination to screen for any concerning symptoms or signs. **Vaccination should be deferred in people with ongoing cardiac inflammation**, or an alternative vaccine (e.g. COVID-19 Vaccine AstraZeneca) considered in people aged ≥ 60 years.

Advice for people who experience myocarditis/pericarditis attributed to an mRNA COVID-19 vaccine

People who experience myocarditis and/or pericarditis after an mRNA COVID-19 vaccine should be referred to a cardiologist for further assessment and management, to investigate for possible causes other than vaccination, and for follow-up.

Currently, ATAGI advises people who have had myocarditis or pericarditis attributed to an mRNA COVID-19 vaccine where other causes have been excluded, to defer future doses of mRNA COVID-19 vaccine, and to discuss this with their treating doctor. It should be noted that Spikevax (Moderna) is also an mRNA vaccine and therefore not recommended for people who have experienced myocarditis and/or pericarditis after Comirnaty.

Additional advice on second dose vaccination in this context will be provided in the near future.

For further advice on mixed schedules, refer to [ATAGI clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances](#).

What to look out for after vaccination

During the consent process, all people who receive Comirnaty should be advised of the very rare risk of myocarditis and/or pericarditis after vaccination, and should be advised of possible symptoms, which include:

- chest pain, pressure or discomfort
- palpitations (irregular heartbeat, skipped beats or 'fluttering').
- syncope (fainting)
- shortness of breath
- pain with breathing.

Symptoms typically start within a few days after vaccination (median 2 days).¹¹ People who experience any of these symptoms after receiving Comirnaty should seek prompt medical attention. People who feel well and do not have any of these symptoms after vaccination can continue with their usual physical activity and do not routinely need to avoid physical exertion.

People who already have underlying heart dysfunction should seek medical attention for new onset or worsening of pre-existing symptoms following vaccination.

Assessment of suspected myocarditis or pericarditis

People presenting with any of the above symptoms within the first 2 weeks of receiving Comirnaty should be assessed by a healthcare professional, and those who appear unwell should be referred immediately to an emergency department. Initial investigations should include:

- a 12-lead ECG
- troponin
- chest X-ray
- other tests for other differential diagnoses as clinically indicated.

Findings consistent with pericarditis include a pericardial rub on auscultation, widespread ST-elevation or PR depression on ECG, and pericardial effusion on imaging.

Findings consistent with myocarditis are varied and may include:

- elevated troponin
- ECG showing ST or T-wave abnormalities, premature atrial or ventricular complexes
- abnormal echocardiogram or cardiac MRI.

Brighton Collaboration case definitions of myocarditis and pericarditis are available at <https://brightoncollaboration.us/myocarditis-case-definition-update/>.

If the ECG and/or troponin are abnormal, patients will require further assessment, including an echocardiogram and other investigations or imaging as deemed necessary by their treating physician. It is important to assess for the presence of other causes of myocarditis/pericarditis, and for other more common causes of the patient's symptoms, including acute coronary syndrome.

If patients who are investigated for myocarditis and/or pericarditis after Comirnaty have a normal ECG and troponin, they should be advised to avoid high-intensity exercise or competitive sports until symptoms have subsided, and to return for assessment in 1-2 days if symptoms are ongoing. If clinical suspicion of myocarditis or pericarditis is high, a cardiologist should be consulted even if investigation results are normal.

Management

Patients with established myocarditis should be admitted to hospital for cardiac monitoring (ideally continuous ECG monitoring), until the cardiac biomarker levels have peaked and symptoms have resolved. Treatment is determined on a case-by-case basis and often supportive treatment is all that is required.¹³

People who have had confirmed myocarditis attributed to Comirnaty should be followed up by a cardiologist. A repeat echocardiogram and ECG are likely to be required.

People who have had confirmed myocarditis or pericarditis should be advised to avoid high intensity exercise or competitive sports until resolution of symptoms and ECG changes, and normalisation of cardiac function.

Prognosis and long term follow up

There are currently no available data on the long-term outcomes of people who have had myocarditis and/or pericarditis after an mRNA COVID-19 vaccine. A number of large studies monitoring outcomes are currently being undertaken in the United States and Canada. Importantly, most people who have had myocarditis and/or pericarditis due to other causes recover completely and have no ongoing impairment of cardiac function, and early data suggest this is likely for those after Comirnaty.

Patients with myocarditis and/or pericarditis after an mRNA COVID-19 vaccine whose symptoms resolve quickly, who do not have any arrhythmia associated with the acute myocarditis, and who have not had prolonged impairment of ventricular systolic function, should be followed up by a specialist for at least 12 months.

For any patient who is found to have a persisting abnormality, e.g. heart block or ventricular tachycardia, persisting ventricular dysfunction, or persisting abnormalities on a cardiac MRI, follow-up should be extended in consultation with their treating specialist.

Reporting adverse events

Suspected cases of myocarditis or pericarditis following a COVID-19 vaccine should be reported to your jurisdiction vaccine safety service, with details available at the [Therapeutic Goods Administration](#) website.

More information

- CSANZ: www.csanz.edu.au/
- [Australian Product Information on Comirnaty COVID-19 Vaccine](#), available on the TGA website.
- Department of Health: www.health.gov.au/covid19-vaccines

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