



Australian Government



# Guidance on Myocarditis and Pericarditis after COVID-19 vaccines

The following guidance is endorsed by the Australian Technical Advisory Group on Immunisation (ATAGI) and the Cardiac Society of Australia and New Zealand (CSANZ).

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*What has been updated:*

- *Updated rates of myocarditis and pericarditis following COVID-19 vaccination by age, gender, and dose*
- *Updated evidence on the long-term outcomes of people with myocarditis or pericarditis following vaccination*
- *Updated recommendations for revaccination in people with a history of myocarditis or pericarditis following vaccination*
- *Guidance name changed to include all COVID19 vaccine(s), not just mRNA*



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## Recommendations

- The overwhelming benefits of vaccination in protecting against COVID-19 greatly outweigh the rare risk of myocarditis and/or pericarditis.
- Providers should consider the potential risk of myocarditis and pericarditis when selecting a COVID-19 vaccine brand and dose interval, considering the individual's age, gender, preferences, and any precautions to specific vaccine brands.
- ATAGI recommends an 8-week interval between dose one and dose two for the Pfizer, Moderna and Novavax vaccines, particularly for males aged 12 to 39 years. This may reduce the risk of myocarditis and/or pericarditis following vaccination. ATAGI recommends a 12-week interval between dose one and dose two for the AstraZeneca vaccine. A shorter interval (down to three weeks for Pfizer and Novavax; four weeks for Moderna and AstraZeneca) between the first and second doses is acceptable for people who are moderately to severely immunocompromised [see Box on Immunocompromising Conditions], those at risk of severe disease [see Medical Conditions Table], and adults aged 65 years and older.

### mRNA vaccines

- A small increased risk of myocarditis and/or pericarditis has been observed in people following vaccination with an mRNA vaccine (i.e. Pfizer or Moderna) compared with unvaccinated people.
- The risk is higher with Moderna than with Pfizer
- Pericarditis and myocarditis after COVID-19 vaccines have been mostly reported in males under 40 years of age, and mostly after the second dose. However, these conditions do occur in both females and males, at any age, and after any dose, including a third or fourth dose.
- The recommended interval of 8 weeks between dose one and dose two of an mRNA vaccine may reduce the risk of these conditions, compared with a shorter interval.

### Non mRNA vaccines

- AstraZeneca is associated with a small increased risk of myocarditis and pericarditis, though this risk appears lower than with Moderna or Pfizer.
- Myocarditis and/or pericarditis can occur after Novavax. A small number of cases have been reported in the clinical trial and in Australia. The TGA assessed these Australian cases as likely vaccine-related. The recommended interval of 8 weeks between dose one and dose two of the Novavax vaccine may reduce the risk of these conditions.

### Precautions

- People with a history of any of the following conditions can receive a COVID-19 vaccine but should consult a GP, immunisation specialist service or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:
  - Recent (i.e., within the last 3 months) myocarditis or pericarditis
  - Acute rheumatic fever or acute rheumatic heart disease (i.e., with evidence of active inflammation)
  - Acute decompensated heart failure

### Investigation and management

- Adults who present with chest pain following a COVID-19 vaccine should be investigated for other causes of chest pain (such as acute coronary syndrome), in addition to myocarditis and pericarditis.
- Guidance on the assessment of children or adolescents presenting with chest pain following an COVID-19 vaccine is available at [www.predict.org.au/mrna-chest-pain-guideline/](http://www.predict.org.au/mrna-chest-pain-guideline/).
- Although most myocarditis cases linked to COVID-19 vaccination have a relatively mild and self-limiting course, fatal cases have been reported, including in females.
- Follow up studies show that most cases of myocarditis following vaccination have persistent changes on cardiac MRI. The clinical significance of these changes, and the long-term

outcomes of myocarditis and/or pericarditis following vaccination generally, are under active investigation.

#### **Future vaccine dose recommendations:**

- For people who have had confirmed myocarditis and/or pericarditis attributed to a COVID-19 vaccine, further doses should be considered on a case-by-case basis with a cardiologist or specialist immunisation service, and usually deferred until recovery from symptoms.

## **Background**

### **What is myocarditis and pericarditis?**

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 pericarditis are seen in the general population from a variety of causes, and not all cases that occur after vaccination are necessarily caused by the vaccine.

Myocarditis and/or pericarditis have been reported as rare side effects after COVID-19 vaccines particularly in young males aged 16-40 years. Cases have also been reported in females and rarely in children.<sup>1,2</sup>

### **What is the risk of myocarditis and pericarditis after COVID-19?**

COVID-19 is estimated to cause myocarditis at a rate of approximately 30-32 excess cases per million.<sup>3,4</sup> In males aged 16-40 years, it is uncertain whether the risk following COVID-19 remains higher than the risk following vaccination.<sup>4</sup> Post COVID-19 condition ("long COVID") is also associated with several cardiovascular complications.<sup>5</sup>

## **Myocarditis and pericarditis after COVID-19 vaccination**

### **What is the risk of myocarditis after COVID-19 vaccination, and who is at greatest risk?**

Reported rates of myocarditis after COVID-19 vaccination vary by country, vaccine type, age, gender, and interval between vaccine doses. The majority of cases of myocarditis reported after COVID-19 vaccines have occurred in males under 40, and the majority have occurred within 1-5 days (median 2 days) following the second dose of an mRNA vaccine.<sup>6-8</sup> Myo/pericarditis is more common after the second dose of Moderna compared with second doses of Pfizer and AstraZeneca (see section below on *Is the risk higher for Moderna compared to Pfizer?*).

Table 1 summarises the range of reported rates of **myocarditis** following vaccination in higher-risk age groups from several studies and international surveillance systems. Study methodology and populations differ amongst data sources and direct comparisons should be made with caution. Please note, these values represent the range of myocarditis rates reported by various sources and are not confidence intervals.

**Table 1:** The range of reported rates of **myocarditis** per million doses for each dose of COVID-19 vaccines in high-risk age groups.

Vaccine Brand	Dose 1	Dose 2	Dose 3
<i>Males aged 12 to 17 years</i>			
Pfizer <sup>9-12</sup>	7	71* to 136	11-61
Moderna <sup>11</sup>	Not Available	237	Not Available
<i>Females aged 12 to 17 years</i>			
Pfizer <sup>9,11-14</sup>	1	2-28	0-0.7
Moderna <sup>9,12,13,15</sup>	0	0 to 28*	Not Available
<i>Males aged 18 to 29 years #</i>			
Pfizer <sup>9,11,13,14,16-19</sup>	1 to 26	25 to 94	4.1 to 30
Moderna <sup>9,11,13,15-19</sup>	10 to 57	56 to 300	8.7 to 21
<i>Females aged 18 to 29 years #</i>			
Pfizer <sup>9,12-14</sup>	0-8	4-27	0.6-2.2
Moderna <sup>9,12,13,15</sup>	0-1	7-69	0.6-2.2
<i>Females and males aged 18 to 29 years</i>			
Pfizer <sup>20</sup>	23	29	17
Moderna <sup>20</sup>	60	68	23
AstraZeneca <sup>20</sup>	10	16	Not available

\* Some studies report separate rates for adolescents age 12-15 and 16-17 years.<sup>10,12</sup>

# Some studies included male adults aged 18 to 24 years only.<sup>9,12-15,17</sup> and some studies were combined for Pfizer and Moderna<sup>12</sup>

Data from Israel's active surveillance system has reported the risk for all adults aged 30 years and older following dose 4 of Pfizer vaccine as approximately 3 cases per million doses.<sup>21</sup> Early data from the USA reports that rates following dose 4 in those aged over 50 are not above background rates.<sup>12</sup> It is important to consider that individuals who experience myocarditis or pericarditis following dose 1 or dose 2 are not likely to have received a third or fourth dose, so comparison of rates and determining the risk of recurrence is challenging.

The risk following a fourth dose in a heterologous vaccine schedule is not yet known.

See the sections below for details on the non-mRNA vaccines.

### Is the risk of myocarditis higher with Moderna compared to Pfizer?

Data from multiple studies and countries' surveillance systems have demonstrated a higher risk of myocarditis after Moderna compared with Pfizer, summarised in Table 2.

**Table 2.** The range of excess cases of myocarditis reported per million doses following Moderna vaccine compared with Pfizer vaccine. There are many factors that influence these rates such as case definitions and if the data is from an active or passive surveillance system.

Age and Gender Cohort	Dose 1	Dose 2	Dose 3
Males aged 12 to 17 years <sup>11</sup>	Not Available	101	Not Available
Males aged 18 to 24 years <sup>*#9,11-14,17-20,22,23</sup>	3 to 33	4 to 241	4.6 to 6

<sup>\*</sup>A UK study included females and males in their assessment. In adult females and males aged 18 to 29 years, the study reported excess rates of 33 cases per million doses after dose 1, 43 cases per million doses after dose 2, and 6 cases per million doses after dose 3 of Moderna compared to Pfizer.<sup>20</sup>

<sup>#</sup>Some studies included male adults aged 18 to 29 years.<sup>10,13,18</sup> A Danish study included adolescent and adult males aged 12 to 39 years and reported an excess of 76 cases per million doses after dose 2 of Moderna compared to Pfizer.<sup>20</sup>

In a head-to-head analysis of Vaccine Safety Datalink data from the USA, the rate differential was only statistically significant when observed for either dose for all ages and sex, noting that Moderna was only recently registered in the US for children and adolescents under 18 years of age. For people aged 18-39 years, in the 0-7 days following vaccination an estimated eight excess cases per million doses of Moderna were observed compared with Pfizer (aRR 1.61 95% CI: 1.02-2.54 p = 0.041).<sup>23</sup> A Canadian study also found a higher risk associated with Moderna compared with Pfizer. They found that the vaccine attributable risk (the risk when background cases are removed) in males aged 18-28 years was 3.06 (95% CI: 1.4-6.69, p = 0.007) times higher for Moderna compared with Pfizer.<sup>18</sup> Another Canadian study also found the rate of myocarditis in males aged 18-24 to be 5.1 (95% CI: 1.9-15.5) times higher for Moderna compared with Pfizer (300 vs 59 per million respectively).<sup>13</sup>

There is no evidence that the severity of the myocarditis and pericarditis cases differs when comparing Moderna and Pfizer.

Moderna remains a safe vaccine and is more immunogenic than other COVID-19 vaccines, therefore ATAGI supports individual and provider risk-benefit decisions around vaccine brand preference.

### Does a longer interval between COVID-19 vaccine doses reduce the risk of myocarditis?

The USA, Canada and WHO have a preferential recommendation for an 8-week interval between doses in a 2-dose primary series for all COVID-19 mRNA vaccinations for all ages.<sup>24-26</sup>

These recommendations are based on an observed higher vaccine effectiveness and the potential for reduced risk of myocarditis and/or pericarditis with a longer inter-dose interval.<sup>13,27,28</sup>

A preprint study from Canada found that for both Pfizer and Moderna, a higher rate of myocarditis and/or pericarditis was observed in people aged 12 years and older when the interval between dose one and dose two was 30 days or less. When compared with an interval of 56 or more days, those who received dose two 30 or less days after dose one were ~3 times more likely to develop myocarditis and/or pericarditis (353 vs 103.2 per million). The risk was greatest when receiving Pfizer followed by Moderna at a ≤30 day interval.<sup>13</sup>

### What is the risk of pericarditis after mRNA vaccines?

The highest risk of **pericarditis** is in people aged 18-39 years for any dose of an mRNA vaccine. The risk is similar in males and females. As of 08 September 2022, the TGA has observed rates of pericarditis following the Pfizer vaccine at 37 per million for those aged 18-29 years and 40 per million for those aged 30-39 years. For Moderna vaccines the observed rates for those aged 18-29 years were 44 per million and 43 per million for those aged 30-39 years.<sup>11</sup> Refer to the [weekly TGA Safety report](#) for up-to-date rates, and rates for other age groups.

## Can AstraZeneca cause myocarditis or pericarditis?

There is a small risk of myocarditis and/or pericarditis following AstraZeneca. This risk is lower than following an mRNA vaccine.

A UK study in December 2021 found the risk was highest in men under 40 years of age at 8-14 days after dose 2 (estimated excess of 14 cases per million doses (95% CI 8-17)).<sup>3</sup> UK Yellow Card reports also indicate a risk in young adults (18-29 years) as 10 per million doses after dose one and 16 per million after dose two.<sup>20</sup>

## Can Novavax cause myocarditis or pericarditis?

Myocarditis and/or pericarditis can occur after Novavax. Cases of myocarditis and pericarditis following Novavax have been reported in clinical trials and in Australia.<sup>29,30</sup> Up to 4 September 2022, 8 cases of myocarditis and 27 cases of pericarditis from 213,900 doses administered in Australia had been reported to the TGA and were assessed as being likely to be vaccine-related.<sup>11</sup> The small number of total doses given globally prevents the calculation of a precise risk at this time. ATAGI will continue to monitor data as it emerges and update advice accordingly.

**Providers are recommended to extend the interval for the primary schedule to 8 weeks between dose one and two for Novavax**, particularly for males aged 12-39, given the potential to reduce the risk of myocarditis and pericarditis, as observed with mRNA vaccines (see section below; Does a longer interval between COVID-19 vaccine doses reduce the risk of myocarditis?).

## What is the risk of myocarditis and pericarditis in children aged 11 years or younger?

Very few cases of myocarditis and/or pericarditis have been reported in children aged 11 years or younger.<sup>11,31</sup> At present there is no clear attributable risk of myocarditis and/or pericarditis from the COVID-19 vaccines in this age group. ATAGI will continue to review the risk of myocarditis and pericarditis in children. Refer to the weekly TGA Safety report for up-to-date Australian rates.

## What is the risk of myocarditis and pericarditis following a bivalent mRNA vaccine?

There are currently no published studies on the rates of myocarditis and/or pericarditis following bivalent mRNA vaccines. The clinical trials of the bivalent vaccine did not observe any cases of myocarditis or pericarditis<sup>32,33</sup>, but were not powered to detect rare events. There are no additional concerns on a theoretical basis that the rates would be different to the rates observed for the ancestral (original strain) mRNA vaccines.

## Advice for people with a history of cardiac conditions

COVID-19 vaccines are recommended with no specific precautions for people with a history of chronic cardiovascular conditions, including coronary artery disease, myocardial infarction, stable heart failure, arrhythmias, rheumatic heart disease (RHD), Kawasaki Disease, congenital heart disease, cardiomyopathy, or cardiac transplant, and in people with implantable cardiac devices. There are no current data suggesting that the risk of developing myocarditis or pericarditis after vaccination is any higher in these groups than in the general population.

People with a history of any of the following conditions **can receive** COVID-19 vaccines, but should consult a GP, immunisation specialist service or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Current or recent (i.e., within past 3 months) myocarditis or pericarditis due to causes other than vaccination (for vaccine-related myo/pericarditis, refer to Future Does Recommendations)
- Acute rheumatic fever or acute rheumatic heart disease (i.e., with evidence of active inflammation)
- Acute decompensated heart failure

These individuals should be counselled to monitor for potential symptoms of myocarditis and pericarditis after vaccination. 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.

## Advice for vaccine recipients regarding clinical features of myocarditis or pericarditis following COVID-19 vaccination

During the consent process, all people who receive a COVID-19 vaccine should be advised of the very rare risk of myocarditis and/or pericarditis after vaccination, the possible symptoms (presented in **Table 3**), and what to do if symptoms develop.

Symptoms typically start within a few days after vaccination (median 2 days).<sup>8</sup> People who experience any of these symptoms after receiving a COVID-19 vaccine 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 have underlying heart dysfunction should seek medical attention for new onset or worsening of pre-existing symptoms following vaccination.

**Table 3:** Symptoms and signs of myocarditis or pericarditis

	Myocarditis	Pericarditis
Symptoms	Chest pain, pressure or discomfort Palpitations Shortness of breath Non-specific symptoms e.g. fatigue	Chest pain which may be sharp, worse when lying down, and alleviated when sitting up and leaning forward Pain on deep inspiration
Signs	May have normal examination Tachycardia Severe myocarditis: signs of cardiac dysfunction e.g. third heart sound, oedema	Pericardial rub on auscultation

## Assessment of possible myocarditis or pericarditis following vaccination

Initial investigations can be performed in the primary care setting, based on clinical judgement, if:

- the patient is not acutely unwell, and has mild symptoms
- the referring practice can **obtain and review all the results** of initial investigations within **12 hours**. If required, contact your local pathology service to ensure this before sending the patient for blood tests.

Patients with significant clinical suspicion of myocarditis and/or pericarditis should immediately be referred to ED.

Chest pain is a common presentation in adults and has a broad differential. Adults who present with chest pain following a COVID-19 vaccine should be investigated for other causes of chest pain (such as acute coronary syndrome) as indicated, based on their history and examination findings. Although more common in men following dose 2, myocarditis following vaccination does also occur in females and has been described after any dose. Chest pain is less common in children and adolescents.



The Paediatric Research in Emergency Departments International Collaborative, ACEM, ATAGI, New Zealand Immunisation Advisory Centre, and CSANZ have developed an algorithm for the assessment of children and adolescents with possible vaccine-induced myocarditis/pericarditis, available at: [www.predict.org.au/mrna-chest-pain-guideline](http://www.predict.org.au/mrna-chest-pain-guideline).

Myocarditis and pericarditis following vaccination can present with atypical features, such as the absence of chest pain, or the presence of abdominal pain or other non-specific symptoms. It is important to consider myocarditis in the differential diagnosis if someone presents with ongoing non-specific symptoms in the 1-2 weeks following a COVID19 vaccine. If unsure, practitioners should consult their local cardiology service for advice.

## Referral & Management

Patients with confirmed 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 of myocarditis and pericarditis is determined on a case-by-case basis and often supportive treatment is all that is required.<sup>34</sup> Patients may require referral to a cardiologist in the acute setting for advice regarding management (depending on the patient's location a telehealth consult may be appropriate with a cardiologist and/or medical retrieval team). All children and adolescents with a confirmed diagnosis should be referred to a cardiologist in the acute setting.

After a diagnosis of myocarditis and/or pericarditis, cardiology follow-up will be required for at least 12 months. People for whom management in the community is advised should be reviewed by their general practitioner every 1-2 days. Advise patients to avoid high-intensity exercise or competitive sports until resolution of symptoms and ECG changes, and normalisation of cardiac function.

## Some people should consult a specialist before considering further doses

The following people should **not** proceed with further doses until they have discussed the risks and benefits with a cardiologist or specialist immunisation service:

- Individuals with suspected **myocarditis** following vaccination and no clear alternative diagnosis
- Individuals with suspected **pericarditis** following vaccination with abnormal investigations (i.e. ECG, troponin, echocardiogram, or chest x-ray) and no clear alternative diagnosis
- Individuals aged 39 years or younger with suspected **pericarditis** where investigations were not performed or available (i.e. ECG, echocardiogram, or chest x-ray). A normal troponin may have been performed.

## Future dose considerations following suspected vaccine-related myocarditis/pericarditis

The decision to have future doses of COVID-19 vaccine following suspected vaccine-related myocarditis/pericarditis is made on a case-by-case basis. Individuals should defer revaccination until they have been **symptom-free for at least 6 weeks**.

The following list of considerations may aid in the decision-making process:

- Those at risk of severe illness will benefit most from receiving all recommended doses of COVID-19 vaccine. These include:
  - People aged 65 years and older
  - People who are [severely immunocompromised](#)
  - People with a disability or complex medical conditions
  - Those with [medical conditions](#) at high risk of severe disease

- Each additional dose of vaccine provides a smaller increment of protection against severe disease. E.g. receiving dose 3 of a COVID-19 vaccine is likely to provide greater incremental benefit than receiving dose 4.
- People aged 40 or older who experienced chest pain following an earlier dose of COVID-19 vaccine can consider revaccination with mRNA vaccine if:
  - investigations were performed and were normal (i.e. ECG, troponin, echocardiogram, or chest x-ray), for any age, or
  - investigations were not performed or available
  - These individuals do not always require referral to a cardiologist or specialist immunisation service prior to revaccination.
- The risk of myocarditis and pericarditis following AstraZeneca is lower than with the mRNA vaccines, though cases do rarely occur. The highest risk is in males aged 40 years and younger.
- Myocarditis and/or pericarditis can occur after Novavax. The small number of doses given globally prevents the calculation of a precise risk. Some cases of myocarditis and pericarditis have been reported in the clinical trial and the Australian surveillance system and have been assessed as likely vaccine-related.
- The rates of myocarditis and/or pericarditis following the non-mRNA vaccines in individuals who have had myocarditis/pericarditis following an mRNA vaccine are unknown.
- Individuals considering AstraZeneca or Novavax should consult the [AstraZeneca vaccine information](#) or [Novavax vaccine information](#) page to consider other risks and benefits of these vaccines.

## Severity, outcomes, and long-term prognosis

It is important to consider pericarditis and myocarditis separately when reviewing clinical outcomes. Most myocarditis cases linked to COVID-19 vaccination have required hospitalisation, with the majority of cases having a relatively mild and self-limiting course.<sup>6,20,35</sup> Fatal cases have been reported, including in females.

Preliminary long-term follow up studies on myocarditis in adolescents and young adults indicate that most patients recover quickly from symptoms and they are mostly mild. Follow-up cardiac MRI studies of patients who had experienced myocarditis following mRNA COVID-19 vaccination frequently demonstrated late gadolinium enhancement (LGE) in areas of their myocardium. Some studies have shown improved but persistent LGE a few months after onset of myocarditis. In other contexts, these changes have represented myocardial scarring. The clinical significance of these findings following myocarditis after COVID-19 vaccination is currently unknown, with longer term follow-up studies still in progress.<sup>36-41</sup>

There are yet to be studies on severity and outcomes of cases of myocarditis after other COVID-19 vaccines.

Pericarditis cases are often managed in primary and/or ambulatory care and also have a short, self-limiting course. There are yet to be studies on long term outcomes following pericarditis after any COVID-19 vaccines.

ATAGI will continue to monitor long term follow up studies for myocarditis and pericarditis after COVID-19 vaccines.

## Recommended long-term follow up

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 for at least 12 months. There will usually be some restriction of exercise (particularly strenuous exercise or competitive sport) if they have confirmed myocarditis.

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 (where applicable), 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/](http://www.csanz.edu.au/)
- PREDICT: <https://www.predict.org.au/chest-pain-guideline/>
- Australian Product Information on [Pfizer](#) and [Moderna](#) COVID-19 vaccines, available on the TGA website.
- Department of Health: [www.health.gov.au/covid19-vaccines](http://www.health.gov.au/covid19-vaccines)
- Brighton Collaboration case definitions of myocarditis and pericarditis are available at <https://brightoncollaboration.us/myocarditis-case-definition-update/>.
- CDC case definitions: <https://www.fda.gov/media/150054/download>

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