



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).

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Updated 12 January 2024

What has been updated:

- Updated information about formulations no longer available in Australia. Reference to these vaccines has been removed from recommendations, but safety information has been retained.
- Rates in Table 1 that presents the range of reported rates of myocarditis per million doses for each dose of COVID-19 mRNA original formulation vaccines in high-risk age groups has been updated to reflect current evidence.
- Links have been added to 'Reporting Adverse Events' section regarding the COVID-19 vaccine claims scheme



Table of Contents

Guidance on Myocarditis and Pericarditis after COVID-19 vaccines	1
Table of Contents	2
Recommendations	3
Summary	3
Background	4
What is myocarditis and pericarditis?	4
What is the risk of myocarditis and pericarditis after COVID-19?	4
Myocarditis and pericarditis after COVID-19 vaccination	4
What is the risk of myocarditis after COVID-19 vaccination, and who is at greatest risk?	4
Is Was the risk of myocarditis higher with Moderna original formulation compared to Pfizer original formulation?	5
Does a longer interval between COVID-19 vaccine doses reduce the risk of myocarditis?	6
What is the risk of pericarditis after mRNA original formulation vaccines?	6
Can AstraZeneca cause myocarditis or pericarditis?	Error! Bookmark not defined.
Can Novavax cause myocarditis or pericarditis?	6
Did AstraZeneca cause myocarditis or pericarditis?	7
What is the risk of myocarditis and pericarditis in children aged 11 years or younger?	7
What is the risk of myocarditis and pericarditis following a bivalent mRNA vaccine?	7
Advice for people with a history of cardiac conditions	7
Advice for vaccine recipients regarding clinical features of myocarditis or pericarditis following COVID-19 vaccination	8
Assessment of possible myocarditis or pericarditis following vaccination	8
Referral & Management	9
Some people should consult a specialist before considering further doses	9
Future dose considerations following suspected vaccine-related myocarditis/pericarditis	9
Severity, outcomes, and long-term prognosis	10
Recommended long-term follow up	10
Reporting adverse events	10
More information	11
References	11

Recommendations

- For current ATAGI recommendations see the [Australian Immunisation Handbook](#). For people recommended COVID-19 vaccination, the benefit of protection against severe disease greatly outweighs the 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 of all COVID-19 vaccines. This may reduce the risk of myocarditis and/or pericarditis following vaccination. A shorter interval of three or four weeks between the first and second doses of the vaccines 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.

Summary

mRNA vaccines

- A small increased risk of myocarditis and/or pericarditis has been observed in people following vaccination with an mRNA vaccine compared with unvaccinated people.
- The risk was higher with Moderna original than with Pfizer original. There is no suggestion that rates are higher following the latest vaccine formulations compared with the original vaccines.
- 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.
- 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

- Myocarditis and/or pericarditis can occur after Novavax at a similar rate to the mRNA vaccine, according to global reports. Myocarditis has been reported in approximately 4 in every 100,000 doses in Australia. Pericarditis has been reported in 13 in every 100,000 doses but is more common in men aged 18-49 years with a rate of 270 per million doses.¹
- AstraZeneca was associated with a small increased risk of myocarditis and pericarditis, though this risk appeared lower than with Moderna or Pfizer.

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 prior to vaccination:
 - 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/.
- Although most myocarditis cases linked to COVID-19 vaccination have a relatively mild 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.^{2,3}

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

COVID-19 is estimated to cause myocarditis at a rate of approximately 30-32 excess cases per million.^{4,5} The risk of myocarditis following SARS-CoV-2 infection appears higher in those aged over 40.^{6,7} In males aged 16-40 years, it is uncertain whether the risk following COVID-19 remains higher than the risk following vaccination.^{5,8} Post COVID-19 condition ("long COVID") is also associated with several cardiovascular complications.⁹

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.¹⁰⁻¹² Myo/pericarditis was more common after the second dose of Moderna original formulation compared with second doses of Pfizer original formulation (see section below on *Was the risk higher for Moderna original formulation compared to Pfizer original formulation?*).

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 original formulation vaccines in high-risk age groups.

Vaccine Brand	Dose 1	Dose 2	Dose 3
Males aged 12 to 17 years			
Pfizer ^{4,5,13-20}	6 to 56	12 to 390	9 to 188
Moderna ^{4,5,15,17,18}	3 to 14	15 to 236	0 to 20
Females aged 12 to 17 years			
Pfizer ^{4,5,13-20}	0-2	3 to 50	0 to 36
Moderna ^{4,5,15,17,18}	1	1.3 to 50	0
Males aged 18 to 29 years			
Pfizer ^{1,10,13,17,18,22-25}	2 to 26	13 to 149	8 to 64
Moderna ^{13,17,18,20,23,24,26}	5 to 40	21 to 230	4 to 64
Females aged 18 to 29 years			
Pfizer ^{1,10,13,17,18,22-25}	0 to 8	2 to 35	0 to 11
Moderna ^{13,17,18,20,23,24,26}	0 to 1	0 to 47	0 to 6

NB: Data presented in this table is not intended to be comparable. Data from various countries and studies are not homologous in terms of follow up time and intervals. Most studies report rates that occurred between 7 to 28 days post vaccination.

Cases following additional doses, including with bivalent mRNA vaccines can occur²⁷⁻³⁰, however rates have not been fully characterised. There is no suggestion that rates are higher following the latest vaccine formulations compared to original mRNA vaccines.

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

Was the risk of myocarditis higher with Moderna original formulation compared to Pfizer original formulation?

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

Table 2. The range of excess cases of myocarditis reported per million doses following Moderna original formulation vaccine compared with Pfizer original formulation vaccine. There were 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 ³¹	Not Available	101	Not Available
Males aged 18 to 24 years ^{*#13,24,31-39}	3 to 33	4 to 241	4.6 to 6

^{*}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.³³

[#]Some studies included male adults aged 18 to 29 years.^{10,13,18} 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.²⁰

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 original formulation 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 original formulation were observed compared with Pfizer original formulation (aRR 1.61 95% CI: 1.02-2.54 p = 0.041).³⁹ A Canadian study also found a higher risk associated with Moderna original formulation compared with Pfizer original formulation. 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 original formulation compared with Pfizer original formulation.³⁵ 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 original formulation compared with Pfizer original formulation (300 vs 59 per million respectively).²⁴

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

Moderna original formulation was a safe vaccine and was more immunogenic than other COVID-19 vaccines. 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.⁴⁰⁻⁴²

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.^{24,43,44}

A study from Canada found that for both Pfizer original formulation and Moderna original formulation, 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 at 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 original formulation followed by Moderna original formulation at a ≤30 day interval.²⁴

What is the risk of pericarditis after mRNA original formulation 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 20 April 2023, the TGA has observed rates of pericarditis following the Pfizer original formulation vaccine at 44 per million for those aged 18-29 years and 45 per million for those aged 30-39 years. For the Moderna original formulation vaccine the observed rates for those aged 18-29 years were 53 per million and 50 per million for those aged 30-39 years.¹

Refer to the [TGA Safety report](#) for current rates, and rates for other age groups.

The risk of pericarditis following a dose of the latest vaccine formulations are likely similar.

Can Novavax cause myocarditis or pericarditis?

Myocarditis and/or pericarditis can occur after Novavax at a similar rate to the mRNA vaccines. Cases of myocarditis and pericarditis following Novavax have been reported in Australia and globally.^{1,45-47} Up to 20 April 2023 more than 250,000 doses of Novavax have been administered in Australia. It is estimated myocarditis occurs at a rate of 40 cases per million doses in Australia. Pericarditis has been reported to occur at a rate of 130 per million doses but is more common in men aged 18-29 years with a rate of 270 per million doses.^{1,31} 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 above *Does a longer interval between COVID-19 vaccine doses reduce the risk of myocarditis?*).

Did AstraZeneca cause myocarditis or pericarditis?

There was a small risk of myocarditis and/or pericarditis following AstraZeneca. This risk was 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)).⁴⁸ There were no confirmed cases in Australia.

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.^{31,49} At present there is no clear attributable risk of myocarditis and/or pericarditis from the COVID-19 vaccines in this age group.⁵⁰ ATAGI will continue to review the risk of myocarditis and pericarditis in children. Refer to the [TGA Safety report](#) for current Australian rates.

What is the risk of myocarditis and pericarditis following newer COVID-19 vaccines?

Rates of myocarditis and pericarditis following vaccination have remained very stable since the introduction of newer vaccines, such as the bivalent and XBB.1.5-containing vaccines.¹ In Australia, as of November 2024, myocarditis was reported in around 10-20 people per 1 million doses of Pfizer vaccines, around 20 people per 1 million doses of Moderna,¹ and around 40 people per 1 million doses of Novavax.

There are no additional concerns on a theoretical basis that rates would differ between newer COVID-19 vaccines and the ancestral (original strain) 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 dose considerations*)
- 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).¹² 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 Fever 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 (such as acute coronary syndrome) as indicated. Although more common in men following dose 2, myocarditis following vaccination does also occur in females and 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.

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 of someone presenting with ongoing non-specific symptoms within the first 1-2 weeks following a COVID-19 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.⁵¹ 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 are unavailable (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 who experienced chest pain following an earlier dose of COVID-19 vaccine can consider revaccination with an mRNA vaccine if:
 - investigations were performed and were normal (i.e. ECG, troponin, echocardiogram, or chest x-ray).
 - they are 40 years of age or older and investigations were not performed or available.
 - These individuals do not always require referral to a cardiologist or specialist immunisation service prior to revaccination.
- Myocarditis and/or pericarditis occurs after Novavax at a similar rate to the mRNA vaccines.¹
- The rates of myocarditis and/or pericarditis following Novavax in individuals who have had myocarditis/pericarditis following an mRNA vaccine, and visa versa, are unknown.

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.^{10,33,52} 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.⁵³⁻⁵⁸

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](#). Myocarditis and pericarditis are claimable clinical conditions under the COVID-19 vaccine claims scheme. More information on the scheme is [available here](#) and information on how to make a claim is [available here](#).

More information

- CSANZ: www.csanz.edu.au/
- PREDICT: <https://www.predict.org.au/chest-pain-guideline/>
- Australian Product Information on Pfizer, Moderna, Novavax COVID-19 vaccines, available on the TGA website: www.tga.gov.au/products/australian-register-therapeutic-goods-artg/product-information .
- Department of Health: 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>

References

1. Therapeutic Goods Administration (TGA). COVID-19 vaccine safety report - 20-04-23. Department of Health - Therapeutic Goods Administration 2023. Available from: <https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-20-04-23#myocarditis-and-pericarditis-after-covid19-vaccination> (Accessed 26 April 2023).
2. Marshall M, Ferguson ID, Lewis P, et al. Symptomatic Acute Myocarditis in 7 Adolescents After Pfizer-BioNTech COVID-19 Vaccination. *Pediatrics* 2021;148. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34088762>.
3. Snapiri O, Rosenberg Danziger C, Shirman N, et al. Transient Cardiac Injury in Adolescents Receiving the BNT162b2 mRNA COVID-19 Vaccine. *Pediatr Infect Dis J* 2021;40:e360-e3. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34077949>.
4. Patone M, Mei XW, Handunnetthi L, et al. Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex. *Circulation* 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35993236>.
5. Karlstad O, Hovi P, Husby A, et al. SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents. *JAMA Cardiol* 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35442390>.
6. Zuin M, Rigatelli G, Bilato C, et al. One-Year Risk of Myocarditis After COVID-19 Infection: A Systematic Review and Meta-analysis. *Canadian Journal of Cardiology* 2022. Available from: <https://www.sciencedirect.com/science/article/pii/S0828282X22010923>.
7. Haussner W, DeRosa AP, Haussner D, et al. COVID-19 associated myocarditis: A systematic review. *The American Journal of Emergency Medicine* 2022;51:150-5. Available from: <https://www.sciencedirect.com/science/article/pii/S0735675721008354>.
8. Rezler ZV, Ko E, Jin E, et al. The Impact of COVID-19 on the Cardiovascular Health of Emerging Adults Aged 18-25: Findings From a Scoping Review. *CJC Pediatric and Congenital Heart Disease* 2022. Available from: <https://www.sciencedirect.com/science/article/pii/S277281292200118X>.
9. Xie Y, Xu E, Bowe B, Al-Aly Z. Long-term cardiovascular outcomes of COVID-19. *Nat Med* 2022;28:583-90. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35132265>.
10. Mevorach D, Anis E, Cedar N, et al. Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel. *N Engl J Med* 2021;385:2140-9. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34614328>.
11. Witberg G, Barda N, Hoss S, et al. Myocarditis after Covid-19 Vaccination in a Large Health Care Organization. *N Engl J Med* 2021;385:2132-9. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34614329>.
12. Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on

Immunization Practices - United States, June 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:977-82. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34237049>.

13. Oster ME, Shay DK, Su JR, et al. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021. *JAMA* 2022;327:331-40. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35076665>.

14. Krug A, Stevenson J, Høeg TB. BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis. *Eur J Clin Invest* 2022;52:e13759. Available from:

15. Massari M, Spila Alegiani S, Morciano C, et al. Postmarketing active surveillance of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines in persons aged 12 to 39 years in Italy: A multi-database, self-controlled case series study. *PLoS Med* 2022;19:e1004056. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35900992>.

16. Le Vu S, Bertrand M, Jabagi MJ, et al. Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines. *Nat Commun* 2022;13:3633. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35752614>.

17. Hviid A, Nieminen TA, Pihlström N, et al. Booster Vaccination with SARS-CoV-2 mRNA Vaccines and Myocarditis Risk in Adolescents and Young Adults: A Nordic Cohort Study of 8.9 Million Residents. *medRxiv* 2022:2022.12.16.22283603. Available from: <http://medrxiv.org/content/early/2022/12/18/2022.12.16.22283603.abstract>.

18. Hartling L, Pillay J, Gaudet L, et al. Incidence, Natural History, Specific Populations and Hypothesized Mechanisms of Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination: Living Evidence Synthesis (Update #3).2022. Available from: https://sporevidencealliance.ca/wp-content/uploads/2022/10/COVID-END_SPOREA_Myo-and-Pericarditis-after-COVID-vaccination_UPDATE3-2022.09.26.pdf.

19. Mevorach D, Anis E, Cedar N, et al. Myocarditis after BNT162b2 Vaccination in Israeli Adolescents. *N Engl J Med* 2022;386:998-9. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35081295>.

20. Goddard K, Hanson KE, Lewis N, et al. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States. *Ann Intern Med* 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/36191323>.

21. Yamaguchi T, Iwagami M, Ishiguro C, et al. Updated report of COVID-19 vaccine safety monitoring in Japan: Booster shots and paediatric vaccinations. *The Lancet Regional Health - Western Pacific* 2022;27:100600. Available from: <https://www.sciencedirect.com/science/article/pii/S2666606522002152>.

22. Goddard K, Lewis N, Fireman B, et al. Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination. *Vaccine* 2022;40:5153-9. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35902278>.

23. Naveed Z, Li J, Wilton J, et al. Comparative Risk of Myocarditis/Pericarditis Following Second Doses of BNT162b2 and mRNA-1273 Coronavirus Vaccines. *Journal of the American College of Cardiology* 2022;80:1900-8. Available from: <https://doi.org/10.1016/j.jacc.2022.08.799> (Accessed 2022/11/13).

24. Buchan SA, Seo CY, Johnson C, et al. Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada. *JAMA Netw Open* 2022;5:e2218505. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35749115>.

25. Wong HL, Hu M, Zhou CK, et al. Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases. *Lancet* 2022;399:2191-9. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35691322>.

26. Wong H-L, Hu M, Zhou CK, et al. Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases. *The Lancet* 2022;399:2191-9. Available from.
27. Hause AM, Marquez P, Zhang B, et al. Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5-11 Years - United States, October 12-January 1, 2023. *MMWR Morb Mortal Wkly Rep* 2023;72:39-43. Available from.
28. Hause AM. Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Persons Aged ≥ 12 Years—United States, August 31–October 23, 2022. *MMWR Morbidity and Mortality Weekly Report* 2022;71. Available from.
29. Niklas Worm A, Emilia Myrup T, Jørgen Vinsløv H, Anders H. Safety of bivalent omicron-containing mRNA-booster vaccines: a nationwide cohort study. *medRxiv* 2023:2023.01.21.23284855. Available from: <http://medrxiv.org/content/early/2023/01/22/2023.01.21.23284855.abstract>.
30. Paul-Ehrlich-Institute. Suspected cases of side effects or vaccination complications after vaccination with the Omikron-adapted bivalent COVID-19 vaccines Comirnaty Original/Omicron BA.1, Comirnaty Original/Omicron BA.4-5, Spikevax bivalent/ Omicron BA.1 (until 31.10. reported in Germany in 2022. <https://www.pei.de/EN/newsroom/dossier/coronavirus/medicine-safety.html>: Paul-Ehrlich-Institute,; 2022. Available from: https://www.pei.de/SharedDocs/Downloads/EN/newsroom-en/dossiers/safety-reports/safety-report-27-december-2020-31-october-2022-from-bulletin-drug-safety-issue-4-2022-p-29-34.pdf?__blob=publicationFile&v=2 (Accessed 26 April 2023).
31. Therapeutic Goods Administration (TGA). COVID-19 vaccine weekly safety report - 08-09-2022. Department of Health - Therapeutic Goods Administration 2022. Available from: <https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-08-09-2022#myocarditis-and-pericarditis-with-mrna-vaccines> (Accessed 20 September 2022).
32. Shimabukuro T. COVID-19 vaccine safety update: Primary series in young children and booster doses in older children and adults. In: Practices ACol, editor.: CDC; 2022.
33. Medicine & Healthcare products Regulatory Agency (MHRA). Research and Analysis: Coronavirus vaccine - summary of Yellow Card reporting. UK Government; 2023. Available from: <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting> (Accessed 15 February 2023).
34. Hause AM, Baggs J, Marquez P, et al. Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults - United States, September 22, 2021-February 6, 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:249-54. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35176008>.
35. Abraham N, Spruin S, Rossi T, et al. Myocarditis and/or pericarditis risk after mRNA COVID-19 vaccination: a Canadian head to head comparison of BNT162b2 and mRNA-1273 vaccines. *Vaccine* 2022. Available from: <https://www.sciencedirect.com/science/article/pii/S0264410X22006673>.
36. Husby A, Hansen JV, Fosbol E, et al. SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study. *BMJ* 2021;375:e068665. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34916207>.
37. Centre Regional de Pharmacovigilance (CRPV). Enquête de pharmacovigilance du vaccin Pfizer – BioNTech Comirnaty. L'Agence nationale de sécurité du médicament et des produits de santé (ANSM); 2021.
38. Robert Koch Institut (RKI). Epidemiological Bulletin 46/2021. RKI; 2021.
39. Klein NP. VSD Head-to-Head comparison of Pfizer and Moderna (Data up to 10 Sept)

2021. Available from: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/08-COVID-Klein-508.pdf>.

40. Oliver S. Summary and Work Group Interpretation: Extended intervals for mRNA COVID-19 vaccines. CDC; 2022.
41. Tunis M, Warshawsky B, Ogunnaike-Cooke S. Canadian experience and evidence with COVID-19 vaccine primary series extended intervals. Public Health Agency of Canada; 2022.
42. WHO Team: Agenda PS, Immunization, Vaccines and Biologicals, Strategic Advisory Group of Experts on Immunization,. Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing. 2022. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1 (Accessed February 10 2022).
43. Skowronski DM, Setayeshgar S, Febriani Y, et al. Two-dose SARS-CoV-2 vaccine effectiveness with mixed schedules and extended dosing intervals: test-negative design studies from British Columbia and Quebec, Canada. *medRxiv* 2021:2021.10.26.21265397. Available from: <http://medrxiv.org/content/early/2021/10/26/2021.10.26.21265397.abstract>.
44. Amirthalingam G, Bernal JL, Andrews NJ, et al. Serological responses and vaccine effectiveness for extended COVID-19 vaccine schedules in England. *Nat Commun* 2021;12:7217. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34893611>.
45. European Medicines Agency (EMA). COVID-19 vaccines safety update. EMA; 2022.
46. U.S. Food and Drug Administration (FDA). FDA Briefing Document Novavax COVID-19 Vaccine. FDA: FDA Vaccines and Related Biological Products Advisory Committee Meeting; 2022.
47. Paul-Ehrlich-Institute. SAFETY REPORT. <https://www.pei.de/EN/newsroom/dossier/coronavirus/medicine-safety.html>; Paul-Ehrlich-Institute,; 2022. Available from: [https://www.pei.de/SharedDocs/Downloads/EN/newsroom-en/dossiers/safety-reports/safety-report-27-december-2020-30-june-2022.pdf?__blob=publicationFile&v=8](https://www.pei.de/SharedDocs/Downloads/EN/newsroom/en/dossiers/safety-reports/safety-report-27-december-2020-30-june-2022.pdf?__blob=publicationFile&v=8) (Accessed 14 Feb 2023).
48. !!! INVALID CITATION !!! 3. Available from.
49. Su J. COVID-19 vaccine safety updates: Primary series in children and adolescents ages 5–11 and 12–15 years, and booster doses in adolescents ages 16–24 years. In: (ACIP) ACoIP, editor.: CDC; 2022.
50. Piechotta V, Siemens W, Thielemann I, et al. Safety and effectiveness of vaccines against COVID-19 in children aged 5-11 years: a systematic review and meta-analysis. LID - S2352-4642(23)00078-0 [pii] LID - 10.1016/S2352-4642(23)00078-0 [doi]. 2023. Available from: <https://pubmed.ncbi.nlm.nih.gov/37084750/>.
51. Tschope C, Ammirati E, Bozkurt B, et al. Myocarditis and inflammatory cardiomyopathy: current evidence and future directions. *Nat Rev Cardiol* 2021;18:169-93. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/33046850>.
52. Montgomery J, Ryan M, Engler R, et al. Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military. *JAMA Cardiol* 2021;6:1202-6. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34185045>.
53. Samimisedeh P, Jafari Afshar E, Shafiabadi Hassani N, Rastad H. Cardiac MRI Findings in COVID-19 Vaccine-Related Myocarditis: A Pooled Analysis of 468 Patients. *J Magn Reson Imaging* 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35612967>.
54. Shiyovich A, Witberg G, Aviv Y, et al. Myocarditis following COVID-19 vaccination: magnetic resonance imaging study. *Eur Heart J Cardiovasc Imaging* 2021. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34739045>.

55. Hadley SM, Prakash A, Baker AL, et al. Follow-up cardiac magnetic resonance in children with vaccine-associated myocarditis. *Eur J Pediatr* 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35482094>.
56. Truong DT, Dionne A, Muniz JC, et al. Clinically Suspected Myocarditis Temporally Related to COVID-19 Vaccination in Adolescents and Young Adults: Suspected Myocarditis After COVID-19 Vaccination. *Circulation* 2022;145:345-56. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34865500>.
57. Kracalik I. Myocarditis Outcomes Following mRNA COVID-19 Vaccination Preliminary Data: data are subject to change. In: Vaccine Safety Team CDC COVID-19 Vaccine Task Force, editor.: CDC; 2022.
58. Amir G, Rotstein A, Razon Y, et al. CMR Imaging 6 Months After Myocarditis Associated with the BNT162b2 mRNA COVID-19 Vaccine. *Pediatr Cardiol* 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35320390>.