Australian Government

COVID-19 VACCINATION

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), the Cardiac Society of Australia and New Zealand (CSANZ), the Royal Australian College of General Practitioners (RACGP), the Australian College of Remote and Rural Medicine (ACRRM), and the Australasian College of Emergency (ACEM)

Updated 8 November 2021

What has been updated:

- Minor changes to **Figure 2:** Approach to revaccination in people with pericarditis attributed to an mRNA COVID-19 vaccine

Key Points

- A small increased risk of pericarditis and/or myocarditis has been observed in people who have received an mRNA COVID-19 vaccine (including Comirnaty (Pfizer) and Spikevax (Moderna), compared to unvaccinated people.
- COVID-19 itself is associated with a substantially higher risk of myocarditis and other cardiac complications compared to vaccination.
- ATAGI, CSANZ, RACGP, ACCRM and ACEM therefore emphasise that the overwhelming benefits of vaccination in protecting against COVID-19 greatly outweigh the rare risk of myocarditis and/or pericarditis. Comirnaty and Spikevax continue to be recommended for all people aged 12 years and above.
- Pericarditis and myocarditis after mRNA COVID-19 vaccines have been reported most commonly in males under 30 years of age, and most commonly after the second vaccine dose. Most myocarditis and pericarditis linked to mRNA vaccination has been mild and patients have recovered quickly. Longer-term follow-up is ongoing.
- Vaxzevria (AstraZeneca) is not associated with an increased risk of myocarditis and/or pericarditis. While cases have been reported after this vaccine, they have not been reported more frequently than what is expected in the absence of vaccination (the 'background rate').
- Pre-existing cardiac conditions are **not** regarded as a contraindication to vaccination.
- People with a history of any of the following conditions can receive an mRNA vaccine (e.g. Comirnaty or Spikevax) 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
- Symptoms of myocarditis or pericarditis typically appear within 1-5 days of an mRNA vaccine dose and may 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 assessment and investigation can be done in a general practice or an ambulatory outpatient cardiology setting for patients who are not acutely unwell and when initial investigation results can be obtained and reviewed within 12 hours. Based on a clinical severity and risk assessment, some patients may require review in an emergency department.
- Initial investigations should include ECG and blood troponin levels. A chest X-ray, and other investigations for other differential diagnoses should be undertaken as clinically indicated.
- Emergency department guidance on the assessment of children or adolescents presenting with chest pain following an mRNA COVID-19 vaccine is available at https://www.predict.org.au/mrna-chest-pain-guideline/.
- Future vaccine dose recommendations vary depending on investigation results.
- Further doses of an mRNA COVID-9 vaccine **can** be given to people who have been investigated for **pericarditis** but who had normal ECG, troponin and inflammatory markers, and who have been symptom-free for at least 6 weeks. This includes people with a clinical diagnosis of pericarditis despite normal investigations.

- For people with suspected or proven pericarditis and abnormal investigation results, the need and choice of further doses is informed by age and sex (refer to Figure 2 for future dose recommendations).
- People who have had confirmed **myocarditis** attributed to a dose of Comirnaty or Spikevax should defer further doses of an mRNA COVID-19 vaccine and if they are ≥ 18 years can consider Vaxzevria on a case-by-case basis, after they have recovered from their symptoms.

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). Pericarditis can be seen recurrently, while this is less frequently described with myocarditis. Myocarditis and pericarditis are also commonly seen in the general population from a variety of causes, and not all cases that occur after vaccination are necessarily caused by the vaccine. Overall, myocarditis occurs more commonly in males than in females.[1] The estimated 'background rate' of myocarditis or pericarditis for females aged 18-34 years is 16 per 100,000 person years (95% prediction interval 8-32), and for males aged 18-34 years is 37 per 100,000 person years (16 – 88).[2]

Myocarditis and/or pericarditis have been reported as rare side effects after mRNA COVID-19 vaccines (Comirnaty and Spikevax), particularly in young adults, in several countries including the USA, Israel, UK, Canada and Italy.[3–9] Cases have also been reported in adolescents.[10,11] Vaxzevria has not been associated with an increased risk of myocarditis/pericarditis. Cases have been reported after Vaxzevria, however, cases have not been reported more frequently than the background rate.

COVID-19 itself is associated with a substantially higher risk of myocarditis and other cardiac complications compared with vaccination. COVID-19 is estimated to cause myocarditis at a rate of 11.0 events per 100,000 persons (risk ratio 18.28; 95% CI, 3.95 - 25.12), whilst Comirnaty (Pfizer) vaccine has been estimated to cause myocarditis at an overall rate of 2.7 events per 100,000 persons (risk ratio 3.24; 95% CI 1.55 to 12.44).[12]

The majority of cases of myocarditis/pericarditis reported after mRNA COVID-19 vaccines have occurred in males, and the majority have occurred within 1- 5 days (median 2 days) following the second dose.[13–15] One study in Israel showed the overall risk difference for myocarditis following the second compared with first doses was 1.76 per 100,000 persons (95% CI 1.33 – 2.19).[13] The incidence ratio of myocarditis following the second dose and compared to the prepandemic rate was 5.34 (95% CI 4.48 to 6.40), and was highest for males aged 16 to 19 years at 13.6 (95% CI 9.3 – 19.2). The main risk window was the first week after the second dose.

Similar findings were reported in an analysis of 2459 cases of myopericarditis and 877 reports of pericarditis in the US Vaccine Adverse Events Reporting System (VAERS) to October 6 2021 (Table 1).[16] 67% of cases after the first dose and 81% of cases after the second dose occurred in males. The highest crude reporting rate was in males aged 16-17 years within 7 days after the second dose of Comirnaty (69.1 cases per million doses). Reporting rates were similar in males aged 18-24 following the second dose of Comirnaty (36.8 per million) compared with Spikevax (38.5 per million). Rates were much lower in females of the same age (<10 per million). Of 877 patients who met the CDC case definition of myocarditis or myopericarditis, about 95% had required hospitalisation. Of these 95% had been discharged and 77% confirmed to have recovered from symptoms at time of report.

Table 1: Reporting rates of myocarditis (per 1 million doses administered) to the United States VAERS after mRNA COVID-19 vaccines, 7-day risk period (N = 935).[16]

	Pfizer		Moderna	
	(All)		(All)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	**2.3**	**21.5**	0.0	not calculated
16-17	**2.8**	**37.4**	0.0	not calculated
18-24	1.2	**18.1**	**3.1**	**20.7**
25-29	0.7	**5.7**	1.8	**11.2**
30-39	0.6	**2.8**	1.4	**3.6**
40-49	0.2	1.5	0.2	**2.1**
50-64	0.3	0.4	0.5	0.5
65+	0.1	0.2	0.0	0.3

A US Vaccine Safety Datalink (VSD) analysis also examined outcomes in the 1-21 day risk interval after COVID-19 vaccination and compared rates with vaccinees using a 22-42 day non-risk interval.[17] The adjusted rate ratio (aRR) of myocarditis/pericarditis after Comirnaty or Spikevax was 1.72 for the 1-21 day interval group ($p < 0.001$). In a subgroup analysis the aRR was 12.61 (95% CI 5.27 – 34.47, $p < 0.001$) for 18-39 year olds, equivalent to an excess of 8.4 cases of myocarditis/pericarditis per million doses. For 12-17 year olds (who had only received Comirnaty), the estimated excess cases in the 0-7 day risk interval was 25.9 per million for both doses, and 54.0 per million after dose 2.

This early evidence from the VSD analysis suggests that the risk of myocarditis may be higher, albeit still rare, following Spikevax compared with Comirnaty. In 18-39 year olds, an overall adjusted rate ratio of 2.72 (95% CI 1.25 – 6.05, $p = 0.012$) in the 7 days following vaccination, equivalent to 13.3 excess cases of myocarditis/pericarditis per million doses caused by Spikevax as compared to Comirnaty was seen.[17] When pericarditis was excluded, the aRR was 2.28 (95% CI 1.00 – 5.22, $p = 0.049$), equivalent to 9.7 excess cases of myocarditis per million Moderna doses. Conversely, data from the United States FDA Biologics Effectiveness and Safety (BEST) System did not identify a difference in the incidence rate ratio between Comirnaty and Spikevax.[18]

In Canada, the reporting rates in one province (Ontario) for myocarditis/pericarditis were also higher following Spikevax (6.6 per million following dose 1; 28.2 per million following dose 2) compared with Comirnaty (6.4 per million following dose 1; 8.7 per million following dose 2).[9] There is no evidence that severity in the myocarditis and pericarditis cases differs when comparing the Spikevax and Comirnaty associated cases in any of these vaccine safety systems.

In the UK, the overall reporting rate (including non-vaccine attributable causes) for myocarditis after both first and second dose as at 29 September 2021 is 7.6 reports per million doses of Comirnaty, and 29.8 per million doses of Spikevax.[19] For pericarditis the overall reporting rate is 5.9 reports per million doses of Comirnaty and 17.7 per million doses of Spikevax. Updated data from the MHRA is available at https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting.

Up-to-date data on cases and rates of myocarditis and pericarditis reported to the Australian Therapeutic Goods Administration is available at https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

Most myocarditis cases linked to mRNA vaccination have required hospitalisation, with the majority responding well to standard treatment and having a mild and self- limiting course.[3,8,13] In a case series of 25 children aged 12-18 with probable myopericarditis after mRNA COVID-19 vaccination, 92% had normal cardiac function on echocardiogram.[21] Pericarditis cases are often managed in primary and/or ambulatory care and also have a short, self-limiting course

Recommendations

ATAGI, CSANZ, RACGP, ACRRM and ACEM emphasise that the overwhelming benefits of vaccination using an mRNA vaccine to protect individuals from 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 and Spikevax continue to be recommended for all people aged ≥ 12 years.

Advice for people with a history of cardiac conditions

Comirnaty and Spikevax continue to be recommended to prevent COVID-19 in 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. 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** Comirnaty or Spikevax 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 (see Future Does Recommendations)
- Acute rheumatic fever or acute rheumatic heart disease (i.e., with evidence of active inflammation)
- Acute decompensated heart failure

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.

Vaxzevria (AstraZeneca) can be considered as an alternative vaccine in individuals ≥ 18 years, particularly in people aged ≥ 60 years.

What to look out for after vaccination

During the consent process, all people who receive Comirnaty or Spikevax should be advised of the very rare risk of myocarditis and/or pericarditis after vaccination and be advised of the symptoms in **Table 2**, and what to do if they develop.

Symptoms typically start within a few days after vaccination (median 2 days).[15] People who experience any of these symptoms after receiving Comirnaty or Spikevax 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 2: 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 in a primary care setting

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 before sending the patient for blood tests to ensure this.

Patients with possible myocarditis and/or pericarditis should immediately be referred to ED if any of the following apply:

- they are acutely unwell as assessed by the clinician (any age)
- they have any chest pain and are aged ≥ 30 years
- they have abnormal ECG findings (refer to Table 2 below)
- initial investigations cannot be performed and reviewed within **12 hours**

Refer to **Table 3** below for the initial investigations recommended for the evaluation of myocarditis or pericarditis.

Table 3: Initial diagnostic evaluation of myocarditis and pericarditis

Investigation	**Findings**	
	Myocarditis	Pericarditis
12- lead ECG	• ST or T-wave abnormalities#, Q waves • Premature atrial complexes • Premature ventricular complexes • Can be normal	• Widespread ST elevation (typically concave up) • PR depression • Small QRS (reflecting pericardial effusion) • Can be normal or atypical
Troponin	• Commonly raised, however absence of elevation* does not exclude myocarditis	• May be increased (suggestive of myopericarditis)
Inflammatory markers: CRP, ESR	• Commonly raised (although nonspecific)	• Commonly raised (although nonspecific)

Investigation	Findings	
Chest X-ray (PA)	• Heart size can be normal or enlarged (in children this is defined as cardiothoracic ratio >0.5)	• Typically normal • Rarely, large pericardial effusion can lead to cardiomegaly

#N.B. T wave inversion in anterior leads can be normal in people aged ≤ 16 years

* If ongoing clinical concern, could consider repeating troponin in 12 hours

Referral & Management

Patients with confirmed myocarditis or pericarditis may require referral to a cardiologist for advice regarding management (depending on the patient's location a telehealth consult may be appropriate with a cardiologist and/or medical retrieval team).

Further investigations may be required, including:

- Investigations to exclude other causes e.g., viral illness
- Echocardiogram
- Coronary angiography or CT coronary angiogram for selected patients who may present with features indistinguishable from acute coronary syndrome
- Cardiac MRI
- Endomyocardial biopsy is rarely indicated (as determined by cardiologist)

Treatment of myocarditis and pericarditis is determined on a case-by-case basis and often supportive treatment is all that is required.[22]

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.

Follow up in the community

- 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.
- After a diagnosis of myocarditis and/or pericarditis, cardiology follow-up will be required for at least 12 months. A repeat ECG and echocardiogram are likely to be required.

Follow up of patients with normal investigations

- Patients with minor symptoms, normal ECG, and no elevation in troponin and/or inflammatory markers can be monitored in the community with GP review every 1-2 days.
- Investigations should be repeated if symptoms are persistent.
- Advise patients to avoid high-intensity exercise or competitive sports until symptoms have resolved.
- Clinical judgement should be used as to the need for specialist consultation. Refer to ED or discuss with a cardiologist if there are any abnormalities on repeat investigations, or if any concerning symptoms (even if investigations are normal).

Assessment of possible myocarditis or pericarditis in an emergency department setting

Chest pain is a common emergency department presentation in adults and has a broad differential. Adults who present with chest pain following mRNA 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.

Chest pain is less common in children and adolescents. **Figure 1** outlines the recommended investigations in children and adolescents with possible vaccine-induced myocarditis/pericarditis, developed by the Paediatric Research in Emergency Departments International Collaborative, ACEM, ATAGI, New Zealand Immunisation Advisory Centre and Cardiac Society of Australia and New Zealand and is available at: https://www.predict.org.au/mrna-chest-pain-guideline

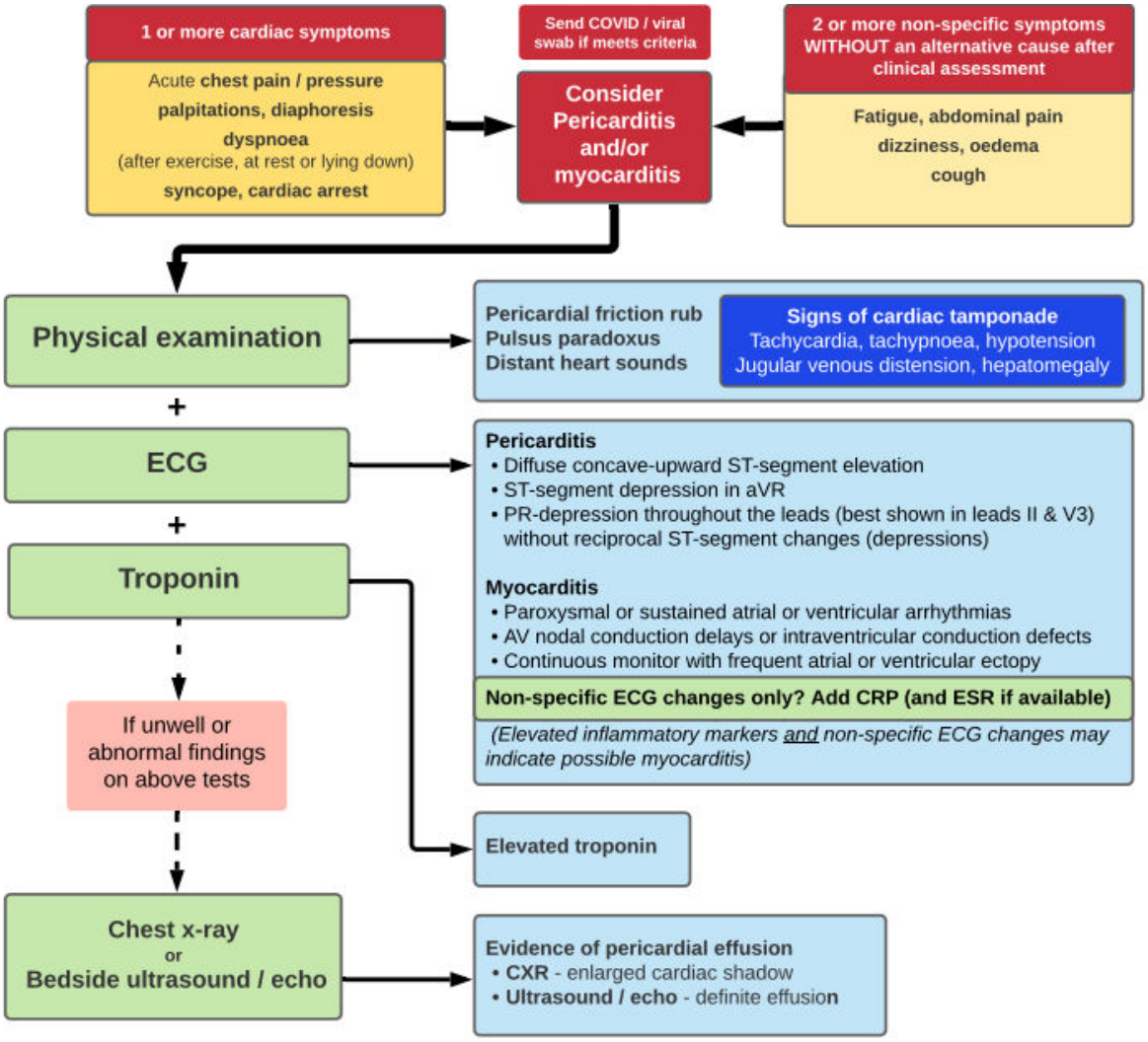

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Figure 1: Australian and New Zealand guideline for assessment of possible vaccine-induced pericarditis/myocarditis in children and adolescents presenting to the ED[23]

Future dose recommendations

Recommendations regarding future COVID-19 vaccine doses will depend on the specific diagnosis (i.e., myocarditis or pericarditis), level of certainty of the diagnosis, and the patient's age. Options include deferring any further COVID-19 vaccine until further information is available, choosing an alternate vaccine formulation, or proceeding with further mRNA COVID-19 vaccine doses.

Myocarditis

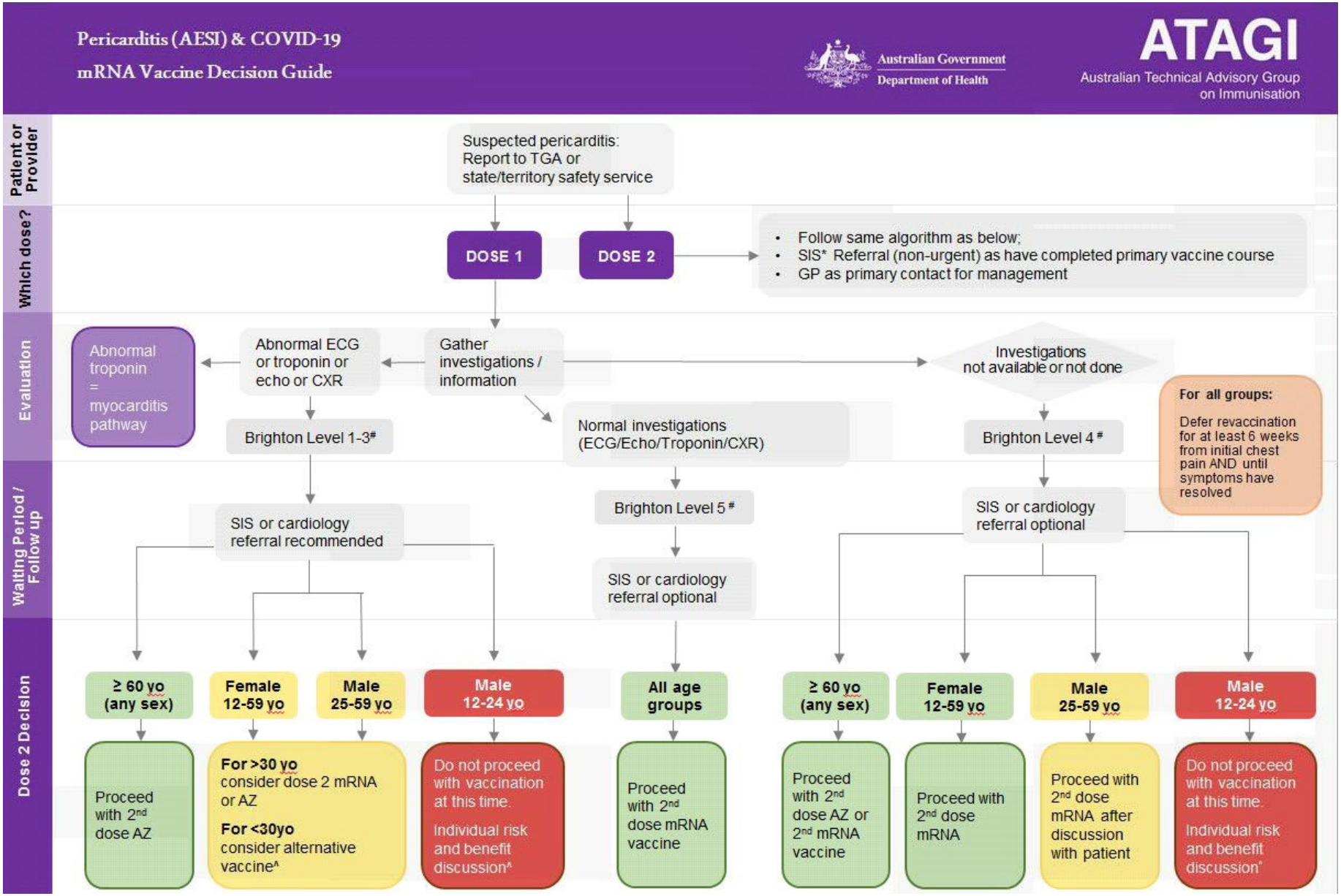
As the more serious adverse event following immunisation (AEFI), myocarditis should be discussed with a specialist immunisation service (SIS) and/or cardiologist prior to administering a subsequent COVID-19 vaccine dose.

Pericarditis

Figure 2 outlines the approach to revaccination in people with pericarditis attributed to an mRNA COVID-19 vaccine. Referral to a specialist immunisation service (SIS) or cardiologist is not always required.

People who have had a clinical diagnosis of pericarditis following an mRNA vaccine but who have normal investigations (i.e., ECG, echocardiogram, troponin and chest X-ray) can receive further doses after full recovery. Patients should be symptom free for at least 6 weeks. The need and choice of further doses is informed by investigation findings, age and sex.

Figure 2: Approach to revaccination in people with pericarditis attributed to an mRNA COVID-19 vaccine



* SIS = specialist immunisation service; # Brighton case definitions available at https://brightoncollaboration.us/myocarditis-case-definition-update/
^AZ not licensed for <18yo; Source: Adapted from Pericarditis (AESI) & COVID-19 mRNA Vaccine Decision Guide (SAEFVIC)[24]

Prognosis and long term follow up

There are currently limited available data on the long-term outcomes of people who have had myocarditis and/or pericarditis after an mRNA COVID-19 vaccine. Studies monitoring outcomes are ongoing in the United States and Canada. Short to medium term follow-up data is reassuring. Importantly, most people who have had myocarditis and/or pericarditis due to other causes recover completely and have no ongoing impairment of cardiac function.[25] Early data suggest this is likely for cases associated with mRNA COVID-19 vaccination.

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. 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/
- https://www.predict.org.au/chest-pain-guideline/
- Australian Product Information on Comirnaty and Spikevax COVID-19 vaccines, available on the TGA website.
- 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/.

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