

# Myocarditis and the mRNA COVID-19 vaccine in New Zealand - information for health professionals

An increased risk of heart inflammation (myocarditis, pericarditis, or both) has been observed in people who have received mRNA COVID-19 vaccines in overseas studies, particularly in males under 30 years of age after the second vaccine dose.

This factsheet gives further details about the risk factors and diagnosis of myocarditis following immunisation with Comirnaty (Pfizer/BioNTech mRNA COVID-19 vaccine).

## Key questions about myocarditis for vaccinators and other health professionals

### *What is myocarditis and can it occur after Pfizer (Comirnaty) vaccination?*

Heart inflammation can affect the heart muscle (myocarditis), the lining around the heart (pericarditis) or both. An increased risk of myocarditis and pericarditis been observed in people who have received mRNA COVID-19 vaccines in overseas studies, particularly in males under 30 years of age after the second vaccine dose.

For 1-3 days after vaccination, some people can feel unwell with headaches, tiredness muscles aches, chills or a mild fever, this a normal response, and is more common after the second dose and in younger people. If unwell, you are advised to **rest, drink plenty of fluids and to avoid vigorous exercise**, until you are feeling better. If symptoms persist or worsen, to seek medical advice.

### *How do you recognise myocarditis?*

**Myocarditis symptoms include** chest pain, feelings of having a fast-beating, fluttering or pounding heart and shortness of breath.

One or more of these symptoms can occur shortly after vaccination due to stress or anxiety. However, if anyone experiences these symptoms after receiving Comirnaty (Pfizer mRNA vaccine) from more than 6 hours to 7 days (typically around 1 to 5 days), they should seek immediate medical attention.

### *How much higher is the risk of myocarditis due to COVID-19 than from Comirnaty?*

**The benefits of vaccination in protecting against COVID-19** greatly outweigh the risks of adverse events including myocarditis.

- The risk of myocarditis from COVID-19 infection is almost **four times higher** than from vaccination
- Confirmed cases of myocarditis or pericarditis are rare.
- Cases are more common following the second dose and in males 12 to 30 years. Even in this group, risk is less than 1 in 25,000 vaccine recipients.

### *How severe is myocarditis?*

Most reported cases of myocarditis and pericarditis, linked to mRNA vaccination, have required hospital care for assessment and monitoring, because sudden death is a rare complication of myocarditis.

**More than 8 out of 10 of the reported cases have recovered quickly with rest and commonly used oral anti-inflammatory medications such as ibuprofen.**

Longer-term follow-up of these cases is ongoing.

## Advice about being vaccinated

Comirnaty (Pfizer mRNA vaccine) **continues to be recommended** for all people from 12 years of age. The only contraindication to the vaccine is anaphylaxis to a vaccine component which is very rare and requires specialist review.

If feeling unwell after vaccination, it is advised to rest, drink plenty of fluids and avoid vigorous activities, such as going to the gym. Seek medical advice if symptoms worsen, or persist.

All episodes of myocarditis and pericarditis following Comirnaty should be reported to CARM.

For further advice and for plans for the patient's next vaccination, please call **0800 IMMUNE (0800 466 863)** or email **0800immune@auckland.ac.nz**

## In-depth information for health practitioners

### Potential risk

A risk of myocarditis and pericarditis has been observed in people who have received mRNA COVID-19 vaccines overseas, particularly in males under 30 years of age after the second vaccine dose.

IMAC emphasises that the overwhelming benefits of vaccination in protecting against COVID-19 greatly outweigh the rare risk of these conditions, and Comirnaty (Pfizer mRNA vaccine) continues to be recommended for all people  $\geq 12$  years of age who do not have any contraindications to the vaccine. Recent data from Israel showed three excess cases of myocarditis per 100,000 doses following Comirnaty vaccination versus 11 excess per 100,000 cases with COVID-19 infection.

### Outcomes

Most myocarditis and pericarditis cases linked to mRNA vaccination receive hospital care for assessment and monitoring. Most reported cases have been mild and patients have recovered quickly with standard treatment. Longer-term follow-up of these cases is ongoing. However, sudden death may be a rare complication of myocarditis so careful assessment and management of suspected cases is important.

### Diagnosis

Symptoms usually appear from 1 to 5 (median 2) days of vaccination and include acute chest pain or pressure, pain with breathing, palpitations, increased sweating, fainting or shortness of breath with exercise, at rest or when lying down. People who experience any of these symptoms after having Comirnaty should seek prompt medical attention.

Symptoms such as palpitations, chest pain or feeling short of breath can occur in the first hours after vaccination in some people – symptoms appearing in this time frame are consistent with an immunisation stress reaction. This is too soon after vaccine receipt for heart inflammation due to vaccination to appear.

Initial investigations for people presenting with symptoms or signs which may be consistent with myocarditis or pericarditis should include ECG, troponin, +/- CRP, chest X-ray, and investigations for other differential diagnoses as clinically indicated.

### References

- 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(27):977-82. doi: 10.15585/mmwr.mm7027e2
- COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS): updated guidance regarding myocarditis and pericarditis reported with COVID-19 mRNA vaccines. Retrieved 12 July 2021, from <https://www.who.int/news/item/09-07-2021-gacvs-guidance-myocarditis-pericarditis-covid-19-mrna-vaccines>
- Barda N, Dagan N, Ben-Shlomo Y et al (2021) Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting DOI: 10.1056/NEJMoa2110475
- Medsafe. Myocarditis and pericarditis – rare adverse reactions to Comirnaty (Pfizer COVID-19 vaccine). Alert Communication 21 July 2021. Retrieved 15 September 2021 from <https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-alert.ht>

- Findings consistent with myocarditis include elevated troponin and ECG changes including paroxysmal or sustained atrial or ventricular arrhythmias, AV node conduction delays, intraventricular conduction defects or frequent atrial or ventricular ectopy.
- Those suggestive of pericarditis include a pericardial rub, and with a large pericardial effusion pulsus paradoxus and distant heart sounds may be evident on clinical examination.
- ECG changes can include widespread ST segment elevation or PR depression.

If initial screening investigations are abnormal, **patients should urgently be referred to hospital** for further investigations and cardiac monitoring. Patients with more severe clinical presentations may require referral prior to full investigations.

If clinical suspicion of myocarditis or pericarditis is high, further advice should be sought, even if screening investigations are thought to be normal.

More information to assist in the diagnosis is available from <https://brightoncollaboration.us/myocarditis-case-definition-update/> including helpful pictorial algorithms.

### Precautions to vaccination with cardiac conditions

Most pre-existing cardiac conditions are not regarded as contraindications to Comirnaty vaccine. However, young people who have active or clinically unstable heart disease, should be advised to seek medical care promptly if they develop new or worsening pre-existing symptoms. A precautionary review in the days after their vaccination may also be advised. Those with a history of pericarditis or myocarditis, unrelated to Comirnaty, may have the vaccination if the condition is completely resolved, (i.e. no symptoms and no evidence of ongoing heart inflammation).

### Future vaccination

People who develop myocarditis or pericarditis attributed to their first dose of Comirnaty are advised to defer further doses. They should be referred to IMAC for clinical advice about alternate vaccine options. Vaccination is not advised for anyone with current active cardiac inflammation. High intensity exercise should be avoided until complete resolution of inflammation and normalisation of cardiac function.

All episodes of myocarditis and pericarditis following Comirnaty should be notified to CARM.

**CALL 0800 IMMUNE (466 863) FOR CLINICAL ADVICE, 8AM - 8PM, 7 DAYS PER WEEK**