

Long-term outcomes of myocarditis and pericarditis following vaccination with Comirnaty (Pfizer/BioNTech COVID-19 vaccine)

A survey of adolescents, adults, and their healthcare professionals in Aotearoa New Zealand

September 2024

About the study

Why was this study done?

Myocarditis and pericarditis were found to be rare reactions to the Comirnaty (Pfizer/BioNTech COVID-19) vaccine. This study was done to help us understand the social, physical, and mental health outcomes for those who had myocarditis or pericarditis following Comirnaty vaccination.

What are myocarditis and pericarditis?

Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the membrane (or sac) covering the heart. When both the heart muscle and the membrane covering the heart get inflamed at the same time it is called myopericarditis. In this report, both myocarditis and myopericarditis are referred to as myocarditis.

Myocarditis and pericarditis are often caused by infections or autoimmune diseases. The virus that causes COVID-19 (SARS-CoV-2) can also cause myocarditis and pericarditis.

Who could participate in the study?

People aged 12 years and over with a report submitted to the Centre for Adverse Reactions Monitoring (CARM) who had myocarditis or pericarditis diagnosed after vaccination with Comirnaty. At least 90 days had to have passed since the myocarditis or pericarditis was diagnosed before someone could participate.

What did the study involve?

The study involved surveying people who had myocarditis or pericarditis after vaccination (participant survey). People were asked about their recovery, including their physical and mental health, and the impact of myocarditis or pericarditis on their daily lives. For people under 16 years of age, a parent or guardian could do the survey on their behalf. The surveys were completed on the telephone with trained nurse interviewers.

Participants could nominate their healthcare providers to be surveyed as well (healthcare provider survey). Healthcare providers were asked about the participants' diagnosis, recovery, cardiac (heart) tests that were done, and prescribed medicines. The healthcare provider surveys were completed online or on a paper form.

When was this study done?

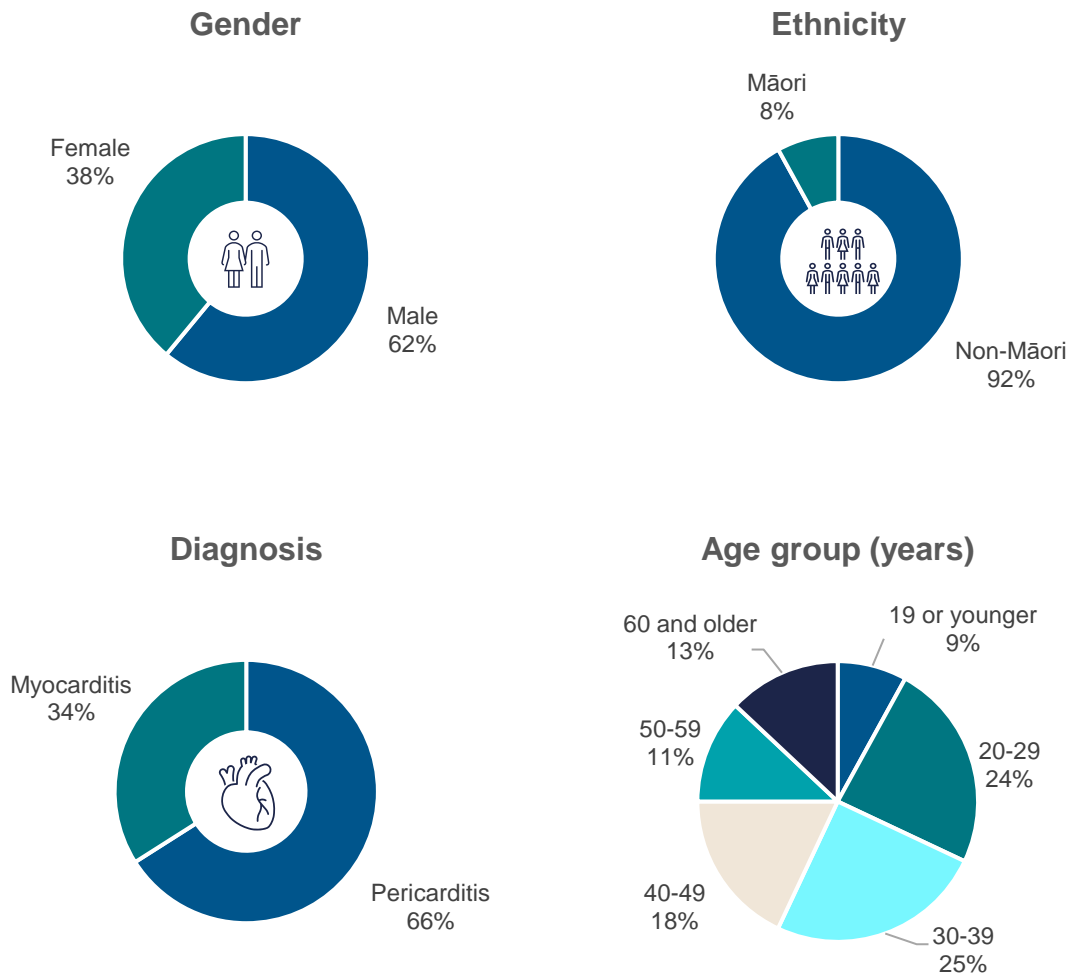
The study was conducted from March through October 2022. Analysis was carried out through 2023 and completed in 2024.

Results

Information about the participants

We analysed responses from 298 consumer surveys and 161 healthcare provider surveys. Gender, ethnicity, diagnosis, and age group information is shown in [Figure 1](#).

Figure 1: Gender, ethnicity, diagnosis, and age group information about the 298 study participants

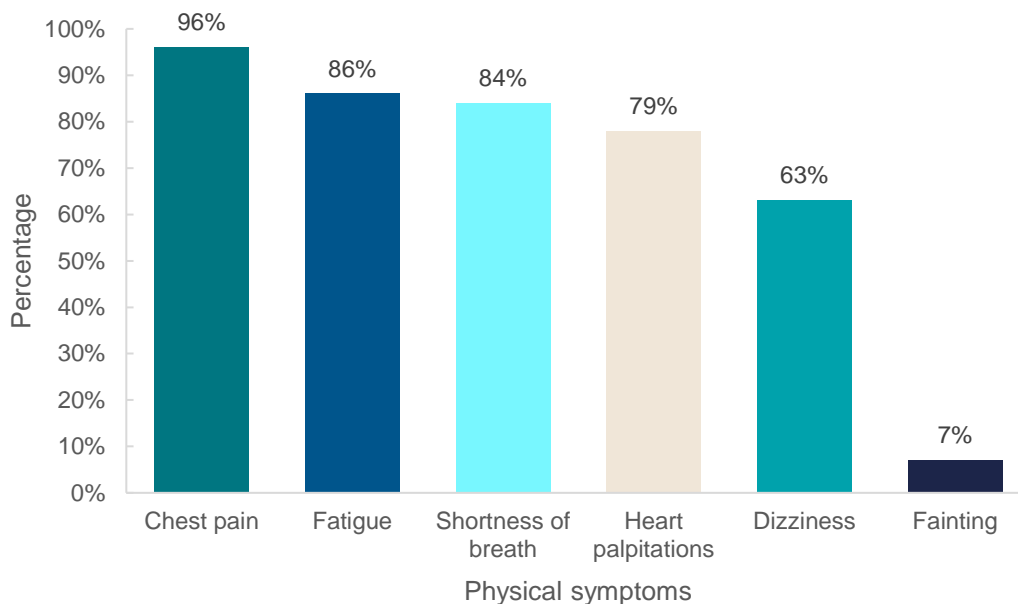


What physical symptoms did people have?

We asked which of the typical symptoms of myocarditis and pericarditis participants had experienced – chest pain, fatigue, shortness of breath, heart palpitations, dizziness, and fainting.

[Figure 2](#) shows the percentage of participants who had experienced a given symptom at any time since they had myocarditis or pericarditis. Chest pain was experienced by 96% of participants and was the most common symptom reported.

Figure 2: Percentage of participants who had experienced a physical symptom at any time



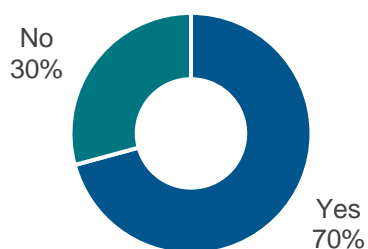
What psychological symptoms did people have?

In addition to physical symptoms, participants were asked to report if they experienced any psychological symptoms such as feeling nervous, feeling worried, having little interest in things, and feeling down.

Feeling nervous, anxious or on edge was the most common symptom, experienced by about 70% of those that responded. Other psychological symptoms are shown in [Figure 3](#).

Figure 3: Symptoms related to mental health experienced by participants

Feeling nervous, anxious or on edge



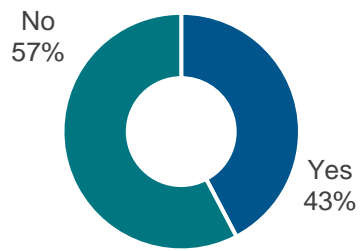
Feeling down, depressed, or hopeless



Having little interest or pleasure in doing things



Not being able to stop or control worrying



Yes, means the symptom was experienced and no means the symptom was not experienced.

What were the results of the heart tests?

The healthcare provider (HCP) survey provided the types of heart tests that were ordered to diagnose patients. Common heart tests that are done in people with myocarditis or pericarditis include a blood test to measure a heart enzyme (called troponin) and a heart tracing (called an electrocardiogram or ECG). Sometimes a more detailed picture of the heart is needed. This could be a heart ultrasound scan (called an echocardiogram or ECHO) or a magnetic resonance imaging scan of the heart (called a cardiac MRI). The exact tests that are done will depend on each individual situation and the doctor's assessment. [Figure 4](#) shows tests ordered by healthcare providers. Not all healthcare providers had tests results available at the time of the survey. The results of available tests are summarised in [Figure 5](#).

Figure 4: Types of heart tests participants had at the time of diagnosis

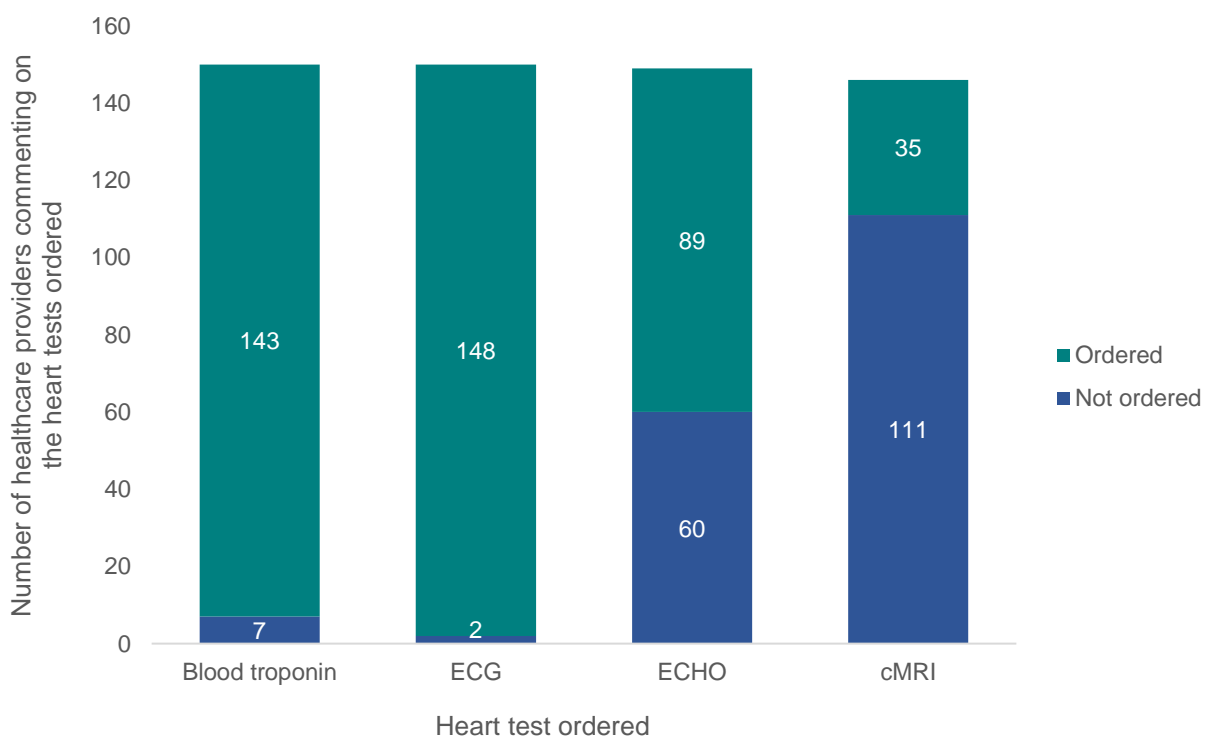
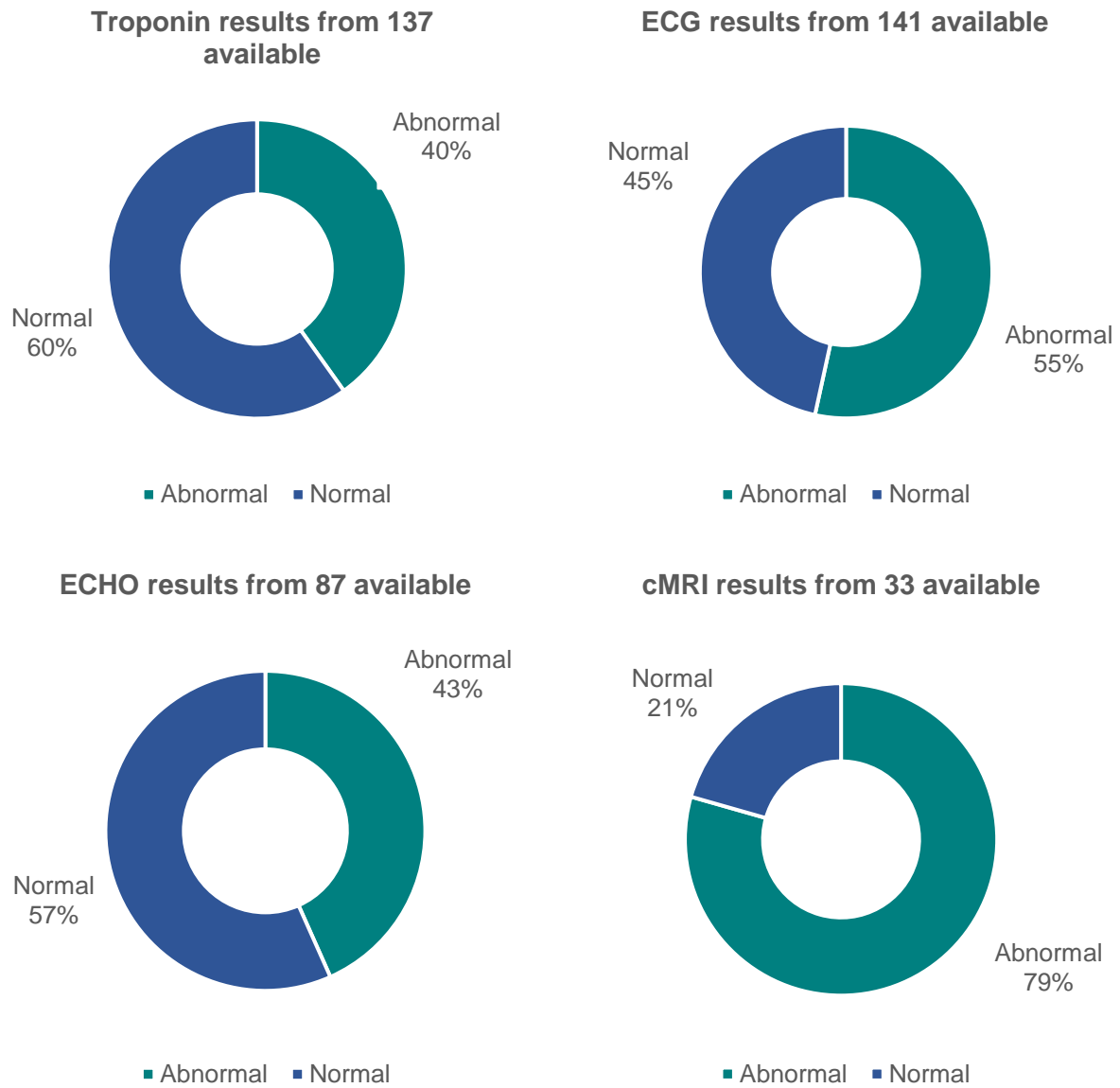


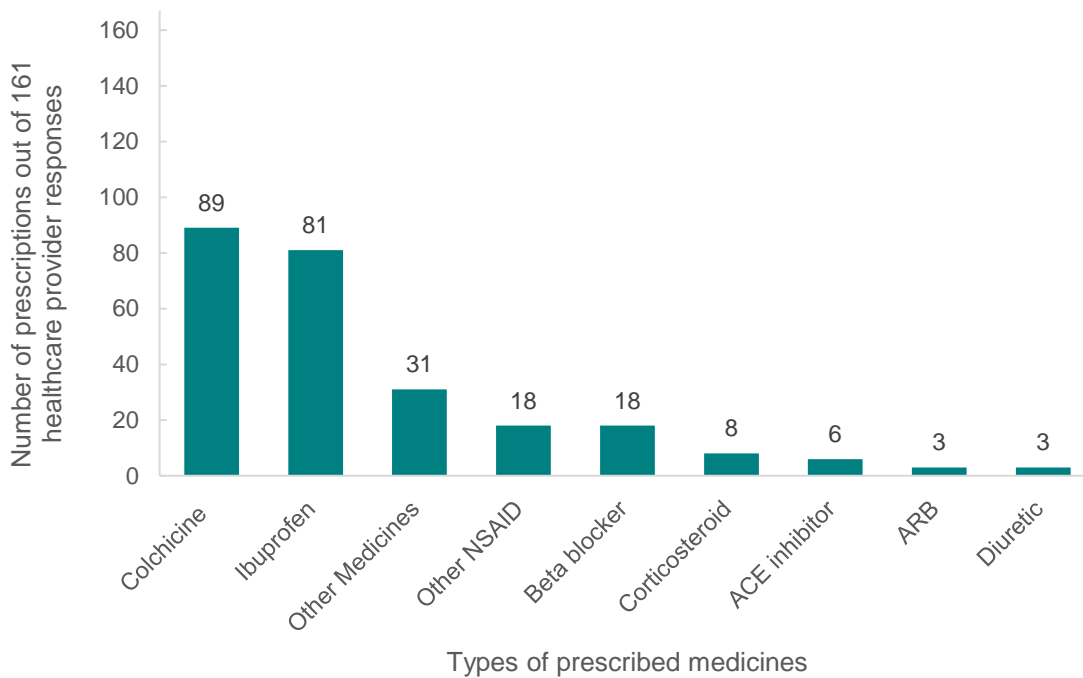
Figure 5: Results of the heart tests participants had at the time of diagnosis



What were the most common medicines prescribed?

We asked healthcare providers to comment on the prescribed medicines that were given to participants with myocarditis and pericarditis. The term NSAID stands for non-steroidal anti-inflammatory drug and examples are aspirin and ibuprofen. The most prescribed medicines were colchicine and ibuprofen. The frequency of medicines prescribed by healthcare providers is shown in [Figure 6](#).

Figure 6: Frequency of medicines prescribed by healthcare providers

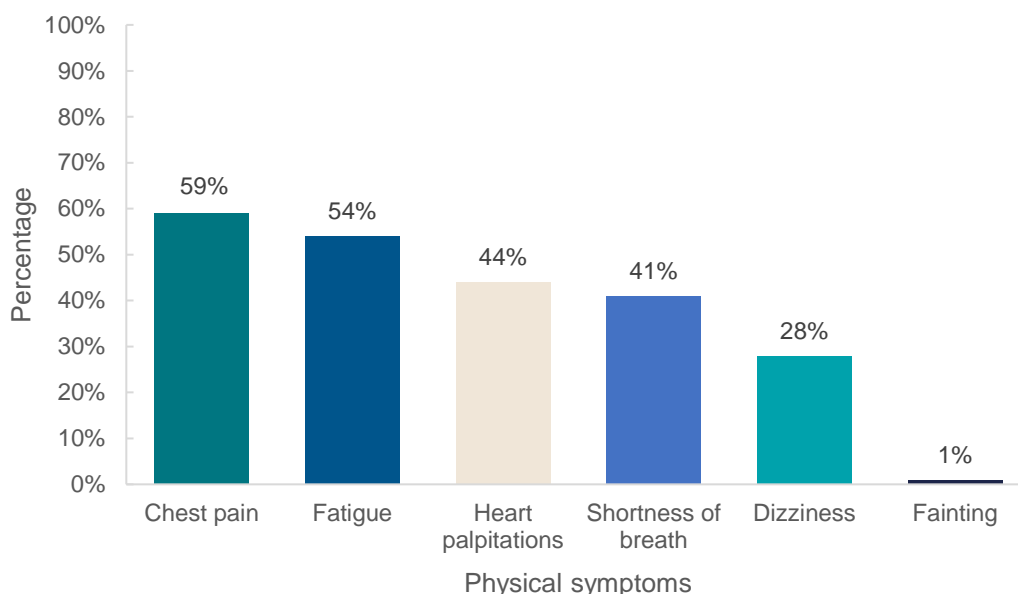


*NSAID= non-steroidal anti-inflammatory drug; ACE= angiotensin-converting enzyme; ARB = Angiotensin receptor blockers

How many people were considered to have recovered from myocarditis or pericarditis by their healthcare provider?

Out of the 150 healthcare provider surveys with a known recovery status, 84 (56%) reported that they considered their patient recovered and 66 (44%) unrecovered. From the consumer survey, 59% of participants stated they were still experiencing chest pain at the time of the survey. The percentage of ongoing symptoms at the time of the consumer survey are shown in [Figure 7](#).

Figure 7: Percentage of participants who were still experiencing a symptom at the time of the survey



What was the impact on people's daily lives?

Participants shared additional information with the interviewer about their experience following their diagnosis via an open-ended question at the end of the consumer survey. There were 7 common themes that emerged which are shown in [Figure 8](#). The most common theme was the impact of myocarditis and pericarditis on general wellbeing. Participants commented on changes to their physical ability, mental wellbeing, and impacts on family life, work, and lifestyle.

Figure 8: Common themes that emerged from thematic analysis of the consumer open-ended question.



Where can you go for more information?

For information on this study

Visit the Health New Zealand website: <https://www.tewhatauora.govt.nz/for-the-health-sector/vaccine-information/vaccine-service-delivery/covid-19-vaccine-delivery/covid-19-vaccine-myocarditis-and-pericarditis-study>

For information about COVID-19 vaccines

Visit the Health New Zealand website: <https://info.health.nz/covid-19-vaccines>

For information about COVID-19

Visit the Health New Zealand website: <https://info.health.nz/conditions-treatments/infectious-diseases/covid-19/>

For information about similar studies on long-term outcomes of myocarditis or pericarditis following COVID-19 vaccination

- [https://doi.org/10.1016/S2352-4642\(22\)00244-9](https://doi.org/10.1016/S2352-4642(22)00244-9) (United States)
- <https://doi.org/10.1016/j.vaccine.2023.12.070> (Australia)
- <https://doi.org/10.1016/j.ahj.2023.11.006> (Germany)

For any questions you have about your own health

If you need health advice, please contact your usual healthcare provider. You can also call Healthline for advice for free, 24 hours a day, 7 days a week on 0800 611 116, or visit their website: www.healthline.govt.nz.

Technical information about the study	
Sponsor:	Medsafe (New Zealand Medicines and Medical Devices Safety Authority)
Other agencies involved in the study:	Health New Zealand Te Whatu Ora National Public Health Service and Centre for Adverse Reactions Monitoring (CARM)
Ethics approval:	This study received full ethics approval from the Health and Disability Ethics Committee (HDEC)
Registration:	The study was prospectively registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12622000506796)