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

Health New Zealand
Te Whatu Ora

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Acknowledgements

The study team would like to express our gratitude to the participants of this study who have shared their experiences of myocarditis and/or pericarditis and their journeys. We would also like to acknowledge and thank the healthcare professionals for their participation in the survey.

The study team extends our deepest sympathies to the family, whānau, and friends of the individuals in Aotearoa New Zealand who were seriously impacted by myocarditis following administration of the Pfizer/BioNTech (Comirnaty) vaccine.

The study team would also like to recognise the members of the Research Oversight Committee, as well as staff at the Centre for Adverse Reactions Monitoring (CARM), Reach Aotearoa, the Ministry of Health | Manatū Hauora, and Health New Zealand | Te Whatu Ora for their contributions to this study.

This work was sponsored and funded by Medsafe, the New Zealand Medicines, and Medical Devices Safety Authority in Aotearoa New Zealand. There are no conflicts of interest to disclose.

Executive summary

As a response to the COVID-19 pandemic that began in 2020, the Aotearoa New Zealand government conducted the country's largest ever mass vaccination campaign with the Pfizer/BioNTech COVID-19 mRNA vaccine (Comirnaty). Through spontaneous reporting in Aotearoa New Zealand and internationally, myocarditis and pericarditis were found to be rare adverse events of COVID-19 vaccines. Health New Zealand | Te Whatu Ora was commissioned by Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) to undertake a research study into the long-term outcomes of individuals diagnosed with myocarditis and/or pericarditis following vaccination with Comirnaty. International literature suggested that myocarditis diagnosed after vaccination was generally milder than myocarditis induced by viral infection, however little was known about the long-term outcomes for affected individuals.

The purpose of this study was to explore individuals' experiences by surveying people diagnosed with myocarditis and/or pericarditis following vaccination with Comirnaty, and their healthcare providers, at least 90 days after diagnosis. The main outcomes examined were current health, mental health, physical functioning, and daily activities. The study was not designed to confirm whether the cases of myocarditis or pericarditis were related to or caused by the vaccination event. It's important to note that myocarditis and/or pericarditis can also be caused by COVID-19 infection and other viral infections.

Data collection for this study occurred between 30 March 2022 and 1 October 2022. Participants were primarily surveyed via telephone by experienced nurse interviewers from a partner health research company, Reach Aotearoa, formerly known as CBG Health Research. For participants who consented and nominated a healthcare provider, an online and paper survey were sent to the nominated provider.

The study enrolled people that were at least 12 years old, who had received at least one dose of the Comirnaty vaccine and had been diagnosed with myocarditis or pericarditis following vaccination. Recruitment was limited to those with a clinical diagnosis that was reported to the Centre for Adverse Reactions Monitoring (CARM).

A total of 298 participants were included in the analysis with a median age of 36.5 years. There were 100 participants with myocarditis and 198 participants with pericarditis. A total of 161 healthcare provider surveys were included.

Qualitative analysis of open-ended free responses from participants found common themes relating to physical ability, mental wellbeing, and impacts on family life, work, and lifestyle. Themes also emerged relating to accessing follow up care and advice, vaccine mandates, interactions with government agencies, and information provided prior to vaccination. The key finding was that many participants felt unsupported and felt that a lack of clear pathways within government agencies led to unnecessary frustration and difficulty receiving support such as ACC payments and vaccine mandate exemptions. Myocarditis and pericarditis had a significant impact on the lives of participants.

As a result of the findings of this study, it is suggested the pathways related to supporting those with potential vaccination adverse reactions could be improved. This includes improving co-operation between government agencies that are involved in healthcare, such as Health New Zealand, ACC, and the Ministry of Health to provide better co-ordinated care for people affected by vaccine adverse events.

There is an opportunity to improve the level of information which Health New Zealand | Te Whatu Ora provides professionals and the public about the potential risks and benefits of vaccination, and

about the support available for individuals who experience significant adverse events. Active monitoring feeds into evidence-based decision making and provision of information to consumers and healthcare professionals. Continuing to strengthen active safety monitoring will aid in the early detection of vaccine adverse reactions and assist with communicating to the public. Consumer safety is a key priority in any Aotearoa New Zealand vaccination campaign. The National Immunisation Technical Advisory Group that was established in 2024 will aid in providing evidence-based advice and recommendations for future vaccination campaigns.

1 Introduction

COVID-19 is a disease caused by SARS-CoV-2, a coronavirus that emerged in 2019. COVID-19 was first recognised by the World Health Organisation as a public health emergency of international concern on 30 January 2020. In 2020, the global reported case fatality rate for COVID-19 was 2.2% [1]. In the early weeks of the pandemic, some countries experienced widespread illness amongst their populations with a higher case fatality rate. In Italy, the first instance of community transmission was detected on 20 February 2020. By March 2020 there were more than 100,000 cases and 12,000 deaths, leading to a case fatality ratio of 11.8% [2]. Due to the unfolding events internationally, and the lack of treatment options for the disease at the time, Aotearoa New Zealand responded to the pandemic with measures including border closures, managed isolation, and quarantine (MIQ), and periods of wide-ranging restrictions for the public, known as lockdowns.

In 2020, the government of Aotearoa New Zealand negotiated advanced purchase agreements for four COVID-19 vaccines (from the manufacturers: Pfizer/BioNTech, AstraZeneca, Janssen (Johnson & Johnson) and Novavax) [3]. Following approval to market by Medsafe and after consideration of the available vaccine options, the government decided to predominantly use the Pfizer/BioNTech COVID-19 vaccine in Aotearoa New Zealand. The Pfizer/BioNTech COVID-19 vaccine is an mRNA (messenger ribonucleic acid) vaccine, with the brand name Comirnaty. Vaccination of the then eligible population commenced in February 2021.

The COVID-19 Vaccine and Immunisation programme (CVIP) was established to deliver Aotearoa New Zealand's largest ever vaccination programme, with the goal of vaccinating as many of the eligible population as possible throughout 2021. In 2022 and 2023, CVIP was integrated into the National Immunisation Programme (NIP) as the Prevention Directorate, which is now part of the National Public Health Service in Health New Zealand. Both CVIP and the NIP are referred to throughout this report.

The safety and efficacy of Comirnaty was reported in clinical trials [4]. However, as with all clinical trials for new medicines (including vaccines), post-marketing surveillance is required to fully characterise the safety profile and monitor for very rare reactions. Medsafe, the Vaccine Safety team in Prevention, and the Centre for Adverse Reactions Monitoring (CARM) have worked collaboratively to monitor the safety of COVID-19 vaccines used in Aotearoa New Zealand.

Myocarditis and pericarditis have been recognised by Medsafe and other international regulators as very rare adverse reactions following vaccination with COVID-19 vaccines, including Comirnaty [5, 6]. Of note, myocarditis and pericarditis have also been documented to occur after SARS-CoV-2 infection [7-10]. There are other well-known causes of myocarditis and pericarditis such as other infections and autoimmune diseases [8-11]. Myocarditis, in general and after vaccination, is more common in males than females, and in younger people [12].

International data suggests that most people presenting with myocarditis and/or pericarditis after vaccination with a COVID-19 vaccine have a mild form of myocarditis, with quick resolution of symptoms compared to other causes of myocarditis [13-17]. However, there is limited information on the long-term outcomes for people who experience myocarditis or pericarditis following vaccination with Comirnaty.

To gain further insight into these long-term outcomes, Medsafe commissioned a study to survey consumers that were clinically diagnosed with myocarditis and/or pericarditis following Comirnaty vaccination, and their healthcare providers. The aim of the study was to understand the long-term health, psychosocial, and physical outcomes of affected people.

1.1 Myocarditis and pericarditis

Myocarditis and pericarditis are inflammatory conditions that affect the heart. Myocarditis is an inflammation of the myocardium (heart muscle) while pericarditis is an inflammation of the pericardium (a sac-like membrane around the heart). Myocarditis and pericarditis can occur at the same time, which is referred to as myopericarditis. A high-level overview of the clinical picture of myocarditis and pericarditis is provided in Table 1. This includes common causes and symptom presentations, the potential diagnostic work-up and clinical findings, management, and prognosis of each condition. This information is not intended to be exhaustive or to guide clinical practice. Not all individuals will experience the same symptoms or severity of illness, and different treatments are appropriate for different people.

Table 1: Myocarditis and pericarditis clinical picture [18-23]

	Myocarditis	Pericarditis
Causes	Infectious (viral and bacterial), medicines, toxins, autoimmune diseases, idiopathic or unknown cause.	Infectious (viral and bacterial), neoplastic, systemic inflammatory diseases, post cardiac injury syndromes, idiopathic or unknown cause.
Symptoms	Chest pain, fatigue, fever, palpitations, exercise intolerance, shortness of breath, feeling faint. Symptoms can be non-specific.	Chest pain (often worse on lying down or deep breathing), fatigue, fever, exercise intolerance, shortness of breath.
Diagnostic work-up	Clinical history, physical examination, blood test for cardiac and inflammatory biomarkers, electrocardiogram (ECG), chest X-ray, echocardiogram (ECHO), cardiac MRI (cMRI), endomyocardial biopsy (rarely performed).	Clinical history, physical examination, blood test for cardiac and inflammatory biomarkers, electrocardiogram (ECG), chest X-ray, echocardiogram (ECHO), cardiac MRI (cMRI).
Clinical findings	Elevated troponin, ECG changes, abnormal cardiac function, or signs of myocardial inflammation on cardiac imaging.	Pericardial friction rub, characteristic changes on ECG, new or worsening pericardial effusion, or signs of pericardial inflammation on cardiac imaging.
Management	Supportive: rest and avoidance of aerobic exercise. If presenting with heart failure: standard heart failure treatments, e.g., ACE inhibitors, beta-blockers, diuretics. Corticosteroids sometimes used. Additional complications may require further treatment.	Supportive: rest. Medicines such as NSAIDs, colchicine, and corticosteroids (not first line) sometimes used. Complications may require further treatment.
Prognosis	Most commonly full recovery. In rare cases, myocarditis can lead to arrythmias, heart failure, or sudden unexpected death.	Most commonly full recovery. Rarely can be complicated by arrythmias, constrictive pericarditis, pericardial effusion, cardiac tamponade, or death.

1.2 International evidence on long-term outcomes

There are some published studies and case reports, as well as studies currently in progress, on the medium to long-term outcomes for people who develop myocarditis and/or pericarditis following COVID-19 vaccination.

The Centres for Disease Control and Prevention (CDC) in the United States (US) commenced a follow-up study of consumers aged 12-29 years who developed myocarditis after mRNA COVID-19 vaccination (Comirnaty and Spikevax) in August 2021 [24]. Surveys were conducted with the consumer (or parent/guardian) and healthcare providers involved in the consumer's care to assess clinical outcomes and quality of life at least 90 days since the symptom onset of myocarditis. The study collected data for 519 of 836 (62.1%) eligible consumers and found that most of the participants (81.4%) were considered recovered by their healthcare provider and quality of life measures were reported to be similar to pre-pandemic levels among people of similar ages in the US. However, there was a difference in symptom resolution as reported by healthcare providers and their patients. Healthcare providers reported that out of 393 patients, 62 (15.8%) had at least one symptom at the time of their last encounter. Comparatively, out of 357 patients surveyed, 178 (49.9%) reported experiencing at least one symptom in the two weeks prior to the survey.

One retrospective cohort study from a global federated health research network examining vaccine associated pericarditis found that patients with COVID-19 infection-related pericarditis were more likely to be diagnosed with cardiovascular sequalae than COVID-19 infected patients with myocarditis [25]. This study also reported that patients diagnosed with new-onset pericarditis from COVID-19 infection had a six-month all-cause mortality odds ratio of 2.55 compared to matched controls. In contrast, myocarditis developed after COVID-19 infection had a six-month all-cause mortality odds ratio of 1.36.

The Paul-Ehrlich-Institute (PEI), the Federal Institute for Vaccines and Biomedicines, and the MYKKE Registry (including the Paediatric Heart Association) in Germany performed a prospective study to follow up children and adolescents who presented with myocarditis in temporal association with COVID-19 vaccination [26]. Among 56 participants who were followed for at least 12 months, a clinical course of vaccine-associated myocarditis was generally mild and different to non–vaccine-associated myocarditis.

Australia's AusVaxSafety published a long-term follow up study of people who have experienced myocarditis after COVID-19 vaccination. Approximately 55% of survey reports at 6 months, reported ongoing symptoms [27].

2 Study methodology

2.1 Equity consultation

Equity specialists from Ministry of Health | Manatū Hauora were consulted to ensure that principles of Te Tiriti o Waitangi were embedded in the study. Expertise was drawn from the Ministry of Health Māori Health directorate and Health Surveys teams, the disability sector, and the Pacific health sector so that the specific needs of and implications for Māori, Pacific, and disabled people were considered for the study design, analysis, and data management plans.

2.2 Research Oversight Committee (ROC)

Before the study commenced, a Research Oversight Committee (ROC) was established to provide oversight of the study, to ensure that equity remained a key focus, and that the objectives of the study were met. As Medsafe is the study sponsor, the Group Manager Medsafe was appointed as Chair of the ROC, with other members including the Group Manager Vaccine Safety (as principal investigator), a representative from CARM, a biostatistician, a cardiologist, a member from Māori Health Insights team in the Ministry of Health, and a lay member to represent the interests of the public.

The ROC held their initial meeting in December 2021 after appointing a chair and selecting members. The ROC met a total of four times. The list of members, summary of meetings, and meeting agendas of the ROC can be found in Appendix 1.

2.3 Ethics approval

Ethics approval for the study, then provisionally titled '*Long-term outcomes of myocarditis and pericarditis after Pfizer-BioNTech (Comirnaty) COVID-19 vaccination in children and adults'* was provided by the COVID-19 Emergency Standard Operating Procedure (ESOP) pathway on 18 February 2022. The study has been conducted in full conformance with principles of the Declaration of Helsinki, Good Clinical Practice (GCP) [28], and within the laws and regulations governing research in Aotearoa New Zealand. The study was prospectively registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12622000506796) [29].

2.4 Study design

This was a cross-sectional study conducted from 30 March 2022 through 1 October 2022, which surveyed consumers who experienced clinically diagnosed myocarditis and/or pericarditis following vaccination with Comirnaty.

The primary outcome of the study was to understand the impact of myocarditis and pericarditis on people's health, physical functioning, mental health, and daily activities (e.g., school, university, or work attendance) at least 90 days after their diagnosis. The study was not designed to confirm whether the cases of myocarditis or pericarditis were related to or caused by the vaccination event.

Data were collected using two surveys:

- **consumer survey** – the vaccine recipient (or parent/guardian) were asked about health, psychological and physical outcomes, daily activities, medicines, and relevant medical history.
- **healthcare provider survey** – consumer nominated healthcare providers were asked about the vaccine recipients' clinical diagnosis, recovery, test results, medicines, and relevant medical history.

A concentrated effort was made to ensure consumers and healthcare providers invited to participate were given sufficient opportunity to participate. Reach Aotearoa attempted to contact consumers by

telephone up to 10 times to schedule a time for the survey to be completed. Healthcare provider surveys were initially delivered online only, but a paper-based postal survey was later offered after a low initial response rate of 32% from the first 150 invited healthcare professionals.

Potential participants were identified from a review of AEFI reports for myocarditis and/or pericarditis submitted to CARM. People who met the eligibility criteria (*2.5 Population selection*) were sent information about the study by post, prior to being contacted by phone by a study nurse. People could opt out of the study or request more information about the study at any time by contacting the study team using the contact details provided, or at the time of being contacted by phone by the study nurse.

To increase transparency and awareness of the study, information about the study was published on the Ministry of Health website before recruitment began, which has since been relocated to a Health New Zealand page: COVID-19 vaccine: myocarditis and pericarditis study [30]. Consumers and healthcare professionals were encouraged to report suspected cases of myocarditis and/or pericarditis if they had not already been reported to CARM.

Consumer surveys

Consumer surveys were delivered primarily through telephone interviews conducted by experienced nurse interviewers from Reach Aotearoa (previously known as CBG Health Research). Face to face and virtual (online) interviews were also available on a case-by-case basis. Translators were available on request.

Participants were surveyed on psychological symptoms and physical symptoms. Psychological symptoms were proxies of anxiety or depression: feeling down, depressed, or hopeless; little interest or pleasure in doing things; feeling nervous, anxious, or on edge; and not being able to stop or control worrying. For physical symptoms, participants responded whether they had experienced any of six physical symptoms since their diagnosis (chest pain, shortness of breath, palpitations, fatigue, dizziness, fainting) and whether they had experienced the symptom(s) in the two weeks prior to the survey.

At the end of the survey, all participants were given the opportunity to answer the question: *"Is there anything else that you would like to share about your (or your child's) experience of myocarditis/pericarditis?"* For most responses, these were recorded as stated by consumers. However, in some cases they were paraphrased by the interviewer. These free text responses were categorised using thematic analysis. Quotations representative of the wider sentiments of each theme were compiled. Identifying details were redacted for privacy reasons.

If a consumer consented for their nominated healthcare provider (i.e., general practice doctor or specialist) to be contacted, the provider was sent an online survey link via email.

Healthcare provider surveys

Healthcare providers were surveyed on diagnostic tests performed, the consumer's medical history, and treatment. For each diagnostic test, blood troponin, ECG, ECHO and cMRI, healthcare providers were asked if the test was performed and if so, whether the results came back abnormal. In addition, healthcare providers were asked if the consumer was prescribed Colchicine, Ibuprofen, other nonsteroidal anti-inflammatory drugs, corticosteroid, beta-blocker, ACE inhibitor, angiotensin receptor blocker, diuretic, or other medicines.

2.5 Population selection

The eligible population included adults and children ≥12 years of age with a clinical diagnosis of myocarditis and/or pericarditis after Comirnaty vaccination reported to CARM. For the purposes of this study, a clinical diagnosis meant that a diagnosis was received from a healthcare provider. The following criteria were used at the point of recruitment to determine eligibility:

Inclusion criteria

- Adults and children ≥12 years of age with a clinical diagnosis of myocarditis and/or pericarditis (includes myopericarditis), after any dose of Comirnaty (primary course or booster course), and their healthcare providers.
- A report of myocarditis and/or pericarditis submitted to CARM by the person themselves, or by someone on their behalf (such as a healthcare professional or family member). Note that in cases where the report submitted to CARM was unclear, information was requested by medical assessors at CARM to verify the case.
- Participants were not required to meet specific diagnostic criteria, such as the CDC criteria, to be eligible.
- Myocarditis and/or pericarditis diagnosed up to and including 28 February 2022, and at least 3 months prior to the survey (minimum of 3 months post-diagnosis).

Exclusion criteria

- Children <12 years of age.
- People who did not receive a clinical diagnosis of myocarditis and/or pericarditis. This included self-diagnosis, or where a diagnosis of myocarditis or pericarditis was considered as part of the differential diagnosis but was not given as a final diagnosis.
- Myocarditis and/or pericarditis diagnosed after 28 February 2022, and/or less than 3 months by the end of the specified recruitment period.
- People who did not receive a dose of Comirnaty prior to being diagnosed with myocarditis or pericarditis.
- People who experienced myocarditis and/or pericarditis after vaccination with another COVID-19 vaccine (for example, the AstraZeneca Vaxzevria vaccine).
- People who did not provided sufficient contact information in the CARM report to be able to make initial contact.
- Circumstances that interfered with the participant's ability to give informed consent (including a diminished understanding or comprehension of English and an interpreter was unavailable).

2.6 Analysis

Participant demographic characteristics collected were summarised to provide an overview of the surveyed population. For each diagnosis category, myocarditis, pericarditis, and total, the counts and percentages of consumers belonging to each are stratified by Brighton level criteria, age group, gender, and ethnicity.

For analysis, participants diagnosed with myopericarditis were combined with those with myocarditis, resulting in two categories of diagnosis: myocarditis and pericarditis. It was considered that myocardial involvement clinically justified grouping a myopericarditis diagnosis into myocarditis and there is precedent for all three conditions (myocarditis, pericarditis, and myopericarditis) to be classified as only myocarditis [12]. Additionally, neither the ICD-10 diagnostic classification system nor the Brighton classification system includes a distinct code for myopericarditis.

All cases of clinically diagnosed myocarditis and/or pericarditis reported to CARM were categorised according to the Brighton Collaboration case definition [31]. This was based on information available

in the CARM report. The Brighton classification provides a level of certainty around the diagnosis and has five levels:

- Level 1: Definitive case
- Level 2: Probable case
- Level 3: Possible case
- Level 4: Reported myocarditis or pericarditis with insufficient evidence to meet the case definition
- Level 5: Not a case of myocarditis or pericarditis

The assigned Brighton classification was used to conduct subgroup analysis in the study. No people meeting the Level 5 classification (not a case) were included in the study. Chi-square tests were carried out to test if associations exist between demographic characteristics and whether someone was a participant or non-participant. In addition, pertinent information obtained in the surveys that impacted the existing Brighton classification for an individual (e.g., cardiac MRI results) was incorporated prior to analysis. Flowcharts used to guide assessments are included in Appendix 2.

The consumer survey categorised ethnicity into four categories: New Zealand European and Other, Māori, Pacific, and Asian. 'Other' refers to any response that was not Māori, Pacific, Asian, or New Zealand European. Participants who reported more than one ethnicity were categorised to only one group, using the priority order of Māori, Pacific, Asian, New Zealand European and Other. For analysis, due to sparse numbers of participants in some ethnic groups, the four categories were further simplified to compare Māori and non-Māori. The non-Māori group included the New Zealand European and Other, Pacific, and Asian categories. Age was categorised into 10-year age groups.

Counts and percentages were stratified by clinical characteristics collected including vaccine dose after which the diagnosis was made, if a subsequent COVID-19 vaccine was received after diagnosis, whether the participant was admitted to the hospital or ICU/HDU, time between receiving vaccine and the diagnosis, and time between diagnosis and completing the survey. Admission was defined as spending one or more nights in hospital.

A participant was categorised as having had follow-up care if the participant had attended an appointment with a general practitioner (GP), Māori health provider, or specialist after the initial diagnosis but prior to the survey. If the participant did not attend the appointment, had it scheduled for a future date after the survey, or had not seen any medical professionals after their diagnosis, they were considered as having had no follow-up.

The count and percentage of consumers that experienced psychological (feeling down, depressed, or hopeless; little interest or pleasure in doing things; feeling nervous, anxious, or on edge; and not being able to stop or control worrying) and physical symptoms (chest pain, shortness of breath, palpitations, fatigue, dizziness, fainting) were stratified by diagnosis, gender, ethnicity, and age group.

Free text responses to the question: *"Is there anything else that you would like to share about your (or your child's) experience of myocarditis/pericarditis?"* were manually reviewed and categorised into seven themes: impact of diagnosis on wellbeing, experience with the healthcare system, follow up care and support, vaccine mandates and exemptions, follow up advice and communications, Accident Compensation Corporation (ACC), and information prior to vaccination.

Using results from the healthcare provider survey, for each diagnostic test, the count and percentage of consumers that received the test and returned abnormal results were presented, stratified by diagnosis. The same was done for medicines prescribed.

Lastly, six measures of recovery as self-reported by the participant were examined: presence of ongoing symptoms, current health, school/university attendance, paid work, unpaid work, and physical activity. Responses were only included in the questions applicable to the analysis (e.g., adults who did not usually attend school or university were excluded from the school/university analysis). Healthcare providers were asked to describe the patient's recovery as of last follow-up visit. The options were: fully recovered, most likely recovered but awaiting additional information, improved but not fully recovered, no change, and worsened. These were grouped into two categories, recovered (fully or most likely) and unrecovered (all other responses).

3 Results

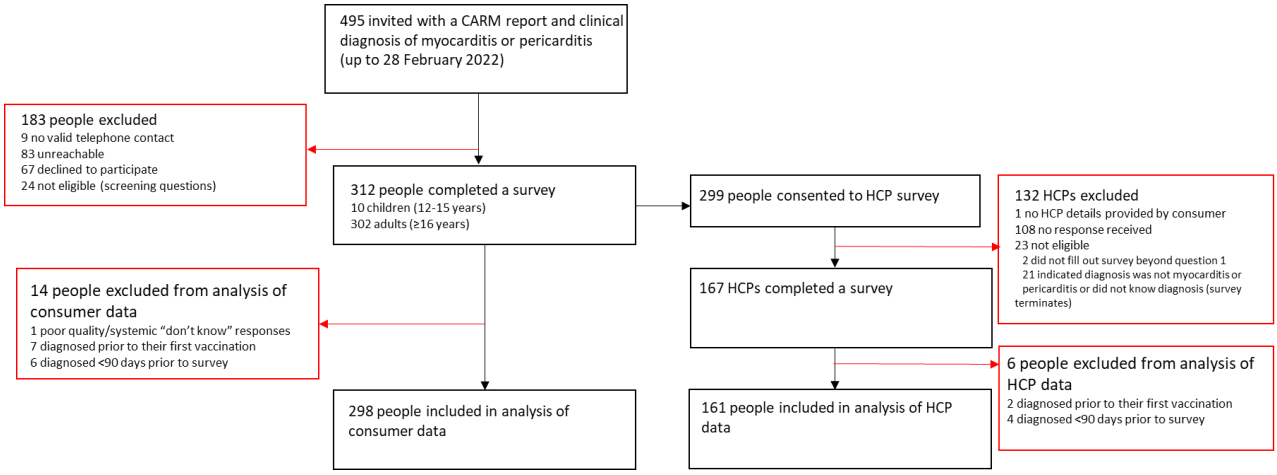
3.1 Survey population

From February 2021 through February 2022, more than 10 million doses of Comirnaty were administered throughout Aotearoa New Zealand. After screening CARM reports for eligibility against the inclusion criteria, 495 consumers were invited to participate (Figure 1). Of the 495 consumers invited, 312 (63.0%) completed the survey including 302 adults and 10 children (12-15 years). Participation in the study was found to be significantly associated with age and ethnicity (Appendix 3, Table A3.1).

Out of the 312 completed surveys, one survey was excluded from the consumer data analysis because of systematic "don't know" responses. During analysis, it was determined that 13 participants were surveyed even though their diagnosis was made less than 90 days prior to being enrolled and/or they were diagnosed prior to their first vaccination with Comirnaty. These 13 participants were excluded as they did not meet the original eligibility criteria, resulting in 298 consumer surveys to analyse. Of the 298 consumer surveys included in the analysis, 110 (36.9%) were Brighton Criteria level 4, a reported myocarditis or pericarditis with insufficient evidence to meet the case definition.

Of the 312 participants who completed the survey, 299 (95.8%) consented to their healthcare provider being contacted. There were 161 (53.8%) healthcare provider surveys completed and included for analysis. Survey questions and redacted deidentified data (responses to multiple choice, non-open-ended questions) can be found on the COVID-19 vaccine: myocarditis and pericarditis study page on the Health New Zealand website (see Appendix 4 for more information).

Figure 1: Selection process for the survey of consumers diagnosed with myocarditis and pericarditis and their healthcare providers (HCPs) in Aotearoa New Zealand, 30 March 2022 through 1 October 2022



3.2 Participant demographics

Among 298 consumer survey participants, 100 (33.6%) had a diagnosis of myocarditis and 198 (66.4%) had a diagnosis of pericarditis (Table 2). The median age of all participants was 36.5 years (range 12-83). The median age was 37.9 years (range 12-82) for participants with myocarditis and 36.0 years (range 12-83) for participants with pericarditis. Of 298 participants, 113 (37.9%) were female, 185 (62.1%) were male, 247 (82.9%) reported their ethnicity as New Zealand European or

other ethnicity, 23 (7.7%) as Māori, 21 (7.0%) as Asian, six (2.0%) as Pacific peoples, and one (0.3%) did not specify. The demographic makeup was similar across diagnosis. Stratification of diagnosis, gender, and ethnicity by age is provided in Appendix 5, Table A5.1 and other clinical history is available in Appendix 6, Table A6.1.

After being diagnosed with myocarditis and/or pericarditis, 214 (71.8%) of the 298 participants had not received another COVID-19 vaccine at the time of survey and 84 (28.2%) participants had received at least one subsequent COVID-19 vaccine. Of those that received at least one subsequent COVID-19 vaccine, 46 (15.4%) received a further dose of Comirnaty, and 41 (13.8%) received a non-mRNA vaccine following their diagnosis.

There were 145 (48.7%) participants who stated they were admitted to a hospital at the time of initial diagnosis. Of the 145 admitted, 84 (57.9%) were diagnosed with myocarditis and 61 (42.1%) with pericarditis. Furthermore, 24 (16.6%) of the 145 participants admitted to hospital reported being admitted to an Intensive Care Unit (ICU) or High Dependency Unit (HDU). Among the 24 admitted to ICU/HDU, 14 (58.3%) had myocarditis and 10 (41.7%) had pericarditis.

Of all 298 participants, 247 (82.9%) had follow-up care with any health service after their diagnosis. Of which, 83 (33.6%) and 164 (66.4%) of participants had myocarditis and pericarditis, respectively.

Table 2: Demographic characteristics, further vaccination after diagnosis, and hospitalisation among survey participants diagnosed with myocarditis and pericarditis following Comirnaty vaccination, Aotearoa New Zealand, 2022

	Myocarditis n=100 (%)	Pericarditis n=198 (%)	Total n=298 (%)
Brighton Criteria Level			
1	33 (33.0)	1 (0.5)	34 (11.4)
2	56 (56.0)	69 (34.8)	125 (41.9)
3	1 (1.0)	28 (14.1)	29 (9.7)
4	10 (10.0)	100 (50.5)	110 (36.9)
Age group			
12-19	12 (12.0)	14 (7.1)	26 (8.7)
20-29	25 (25.0)	46 (23.2)	71 (23.8)
30-39	15 (15.0)	59 (29.8)	74 (24.8)
40-49	20 (20.0)	34 (17.2)	54 (18.1)
50-59	13 (13.0)	21 (10.6)	34 (11.4)
60-69	7 (7.0)	12 (6.1)	19 (6.4)
70-79	5 (5.0)	11 (5.6)	16 (5.4)
≥80	3 (3.0)	1 (0.5)	4 (1.3)
Median age			
Years (range)	37.9 (12-82)	36.0 (12-83)	36.5 (12-83)
Gender			
Female	37 (37.0)	76 (38.4)	113 (37.9)
Male	63 (63.0)	122 (61.6)	185 (62.1)

Ethnicity			
Māori	8 (8.0)	15 (7.6)	23 (7.7)
Pacific	4 (4.0)	2 (1.0)	6 (2.0)
Asian	5 (5.0)	16 (8.1)	21 (7.0)
New Zealand European/Other	83 (83.0)	164 (82.8)	247 (82.9)
Unspecified	-	1 (0.5)	1 (0.3)
Comirnaty dose diagnosis reported after			
First	27 (27.0)	68 (34.3)	95 (31.9)
Second	55 (55.0)	85 (42.9)	140 (47.0)
Third or subsequent	18 (18.0)	45 (22.7)	63 (21.1)
Subsequent COVID-19 vaccine after diagnosis (any)			
Yes	32 (32.0)	52 (26.3)	84 (28.2)
No	68 (68.0)	146 (73.7)	214 (71.8)
Subsequent COVID-19 vaccine after diagnosis (mRNA)			
Yes	14 (14.0)	32 (16.2)	46 (15.4)
No	86 (86.0)	166 (83.8)	252 (84.6)
Subsequent COVID-19 vaccine after diagnosis (non-mRNA) [a]			
Yes	20 (20.0)	21 (10.6)	41 (13.8)
No	80 (80.0)	177 (89.4)	257 (86.2)
Admitted to hospital			
Yes	84 (84.0)	61 (30.8)	145 (48.7)
No	15 (15.0)	137 (69.2)	152 (51.0)
Unknown	1 (1.0)	-	1 (0.3)
Admitted to ICU / HDU			
Yes	14 (14.0)	10 (5.1)	24 (8.1)
No	15 (15.0)	137 (69.2)	152 (51.0)
Unknown	71 (71.0)	51 (25.8)	122 (40.9)
Follow-up care with any health services			
Yes	83 (83.0)	164 (82.8)	247 (82.9)
No	17 (17.0)	34 (17.2)	51 (17.1)

a: Three participants went on to receive both a further dose of Comirnaty and a non-mRNA vaccine.

3.3 Participant survey responses

3.3.1 Psychological symptoms

Not all participants responded to the questions about psychological symptoms. Among those that responded, 207 of 295 (70.2%) reported feeling nervous from their diagnosis (Table 3). This was followed by 164 of 295 (55.6%) feeling down, 143/291 (49.1%) having little interest, and 126 of 292 (43.2%) feeling worried.

Psychological symptoms were more frequently reported among participants diagnosed with pericarditis than myocarditis and among females compared to males. Furthermore, Māori participants reported feeling psychological symptoms more frequently than non-Māori. Lastly, 20–29-year-olds reported feeling nervous, worried, or down more frequently compared to other age groups.

3.3.2 Physical symptoms

Chest pain was the most frequently reported physical symptom, experienced by 287 (96.3%) participants, followed by fatigue (256; 85.9%), shortness of breath (251; 84.2%), palpitations (234; 78.5%), and dizziness (189; 63.4%) (Table 4). Twenty-two (7.4%) participants reported fainting.

Participants diagnosed with pericarditis reported experiencing chest pain, shortness of breath, palpitations, dizziness, and fainting more often than those diagnosed with myocarditis. However, participants diagnosed with myocarditis more frequently reported experiencing fatigue. Similarly, females reported experiencing physical symptoms more frequently than males and Māori participants reported shortness of breath, palpitations, dizziness, and fainting more often than non-Māori. Non-Māori reported experiencing fatigue and chest pain more frequently than Māori. Chest pain was most frequently reported by 12–49-year-olds and palpitations was most frequently reported by 20-29-year-olds.

Regarding physical symptom resolution, 59.1% of participants reported that their chest pain was unresolved at the time of survey. In addition, 54.4%, 43.6%, 41.3%, 27.9%, and 1.3% of participants reported unresolved symptoms of fatigue, palpitations, shortness of breath, dizziness, and fainting, respectively (Appendix 7, Table A7.1).

Other participant survey questions and redacted deidentified data (responses to multiple choice, non-open-ended questions) can be found on the COVID-19 vaccine: myocarditis and pericarditis study page on the Health New Zealand website (see Appendix 4 for more information).

Table 3: Self-reported psychological symptoms, by diagnosis, gender, ethnicity, and age

	n/N (%)[a]			
Category	Feeling nervous	Feeling worried	Little interest	Feeling down
Overall	207/295 (70.2)	126/292 (43.2)	143/291 (49.1)	164/295 (55.6)
Diagnosis				
Myocarditis	59/99 (59.6)	40/98 (40.8)	44/97 (45.4)	45/98 (45.9)
Pericarditis	148/196 (75.5)	86/194 (44.3)	99/194 (51.0)	119/197 (60.4)
Gender				
Female	88/112 (78.6)	55/111 (49.5)	57/107 (53.3)	67/111 (60.4)
Male	119/183 (65.0)	71/181 (39.2)	86/184 (46.7)	97/184 (52.7)
Ethnicity				
Māori	17/23 (73.9)	11/22 (50.0)	13/21 (61.9)	15/22 (68.2)
Non-Māori	190/272 (69.9)	115/270 (42.6)	130/270 (48.1)	149/273 (54.6)
Age				

	n/N (%)[a]			
Category	Feeling nervous	Feeling worried	Little interest	Feeling down
12-19	15/26 (57.7)	11/26 (42.3)	12/26 (46.2)	12/26 (46.2)
20-29	59/69 (85.5)	41/69 (59.4)	38/69 (55.1)	46/70 (65.7)
30-39	57/73 (78.1)	30/71 (42.3)	38/72 (52.8)	39/72 (54.2)
40-49	39/54 (72.2)	21/54 (38.9)	22/53 (41.5)	30/54 (55.6)
50-59	19/34 (55.9)	13/34 (38.2)	20/34 (58.8)	22/34 (64.7)
60-69	10/19 (52.6)	5/18 (27.8)	6/19 (31.6)	7/19 (36.8)
70-79	7/16 (43.8)	4/16 (25.0)	7/15 (46.7)	8/16 (50.0)
80+	1/4 (25.0)	1/4 (25.0)	0/3 (0.0)	0/4 (0.0)

a: 'Don't know' responses were excluded from this table.

Table 4: Self-reported physical symptoms, by diagnosis, gender, ethnicity, and age

	n/N (%)[a]					
Category	Chest pain	Shortness of breath	Palpitations	Fatigue	Dizziness	Fainting
Overall	287/298 (96.3)	251/298 (84.2)	234/298 (78.5)	256/298 (85.9)	189/298 (63.4)	22/298 (7.4)
Diagnosis						
Myocarditis	94/100 (94.0)	80/100 (80.0)	70/100 (70.0)	89/100 (89.0)	55/100 (55.0)	5/100 (5.0)
Pericarditis	193/198 (97.5)	171/198 (86.4)	164/198 (82.8)	167/198 (84.3)	134/198 (67.7)	17/198 (8.6)
Gender						
Female	109/113 (96.5)	99/113 (87.6)	96/113 (85.0)	107/113 (94.7)	78/113 (69.0)	11/113 (9.7)
Male	178/185 (96.2)	152/185 (82.2)	138/185 (74.6)	149/185 (80.5)	111/185 (60.0)	11/185 (5.9)
Ethnicity						
Māori	22/23 (95.7)	21/23 (91.3)	20/23 (87.0)	17/23 (73.9)	19/23 (82.6)	2/23 (8.7)
Non-Māori	265/275 (96.4)	230/275 (83.6)	214/275 (77.8)	239/275 (86.9)	170/275 (61.8)	20/275 (7.3)

	n/N (%)[a]					
Category	Chest pain	Shortness of breath	Palpitations	Fatigue	Dizziness	Fainting
Age						
12-19	26/26 (100.0)	21/26 (80.8)	15/26 (57.7)	20/26 (76.9)	15/26 (57.7)	0/26 (0.0)
20-29	71/71 (100.0)	63/71 (88.7)	67/71 (94.4)	59/71 (83.1)	51/71 (71.8)	6/71 (8.5)
30-39	74/74 (100.0)	59/74 (79.7)	61/74 (82.4)	64/74 (86.5)	49/74 (66.2)	6/74 (8.1)
40-49	53/54 (98.1)	48/54 (88.9)	46/54 (85.2)	50/54 (92.6)	28/54 (51.9)	4/54 (7.4)
50-59	30/34 (88.2)	28/34 (82.4)	25/34 (73.5)	30/34 (88.2)	22/34 (64.7)	3/34 (8.8)
60-69	18/19 (94.7)	16/19 (84.2)	11/19 (57.9)	15/19 (78.9)	14/19 (73.7)	0/19 (0.0)
70-79	12/16 (75.0)	13/16 (81.2)	9/16 (56.2)	16/16 (100.0)	8/16 (50.0)	3/16 (18.8)
80+	3/4 (75.0)	3/4 (75.0)	0/4 (0.0)	2/4 (50.0)	2/4 (50.0)	0/4 (0.0)

a: 'Don't know' responses were excluded from this table.

3.4 Participant comments

Participants shared additional information with the interviewer about their experience of myocarditis or pericarditis via the open-ended question at the end of the survey. These responses were categorised via thematic analysis (Figure 2).

Figure 2: Common themes that emerged from thematic analysis of the consumer open-ended question.

3.4.1 Theme: Impact of myocarditis / pericarditis on wellbeing

The most common theme was the impact of myocarditis and pericarditis on their general wellbeing. The main topics that surfaced in this theme related to participants' physical ability, mental wellbeing, and impacts on family life, work, and lifestyle. Representative quotations are shown below.

- Physical health
  - *"It sucks... was very active [doing sporting activity], working out five times a week, now cannot do these things."*
  - *"Lack of energy, affecting his daily activities."*
  - *"Tried to exercise again and pericarditis symptoms returned."*
  - *"Chest pain is extreme… not being able to walk without a cane."*
- Mental wellbeing
  - *"This experience has caused anxiety and depression."*
  - *"I still feel anxious about my heart. I never had a problem in the past."*
- Family life
  - *"Feels a bit useless. It has placed more pressure on her husband to help out around the house despite working full time himself."*
  - *"No longer able to do the usual things she would do with her grandchildren... Grateful to have a supportive family."*
  - *"I wonder when I will be able to go for a bike ride with my [child]. I wonder when I will be able to climb a hill briskly without thought again."*
  - *"I can't even mow my tiny piece of lawn or play with my child without having symptoms and having to stop."*
  - *"Not being able to take care of my [#] children is just awful. I can't even kick a ball with my sons anymore."*
- Work
  - *"Before I was diagnosed, I was a full-time worker and into [sporting activity], since I got it, I couldn't work at all or do any exercise."*
  - *"I still can't work. I can't even walk upstairs to get a cup of tea… I am 60% better and hope I can build up my physical health so I can return to work."*
  - *"I am no longer able to work. I have [#] small children."*
- Lifestyle
  - *"We have had to sell our beloved house… the personal loss is profound."*
  - *"Huge life change. It has impacted me. My family and friends have noticed. I used to be so active."*

3.4.2 Theme: Experience with the healthcare system

The second most common theme had to do with experience with the healthcare system. Most comments related to interactions with healthcare providers. Some participants reported difficulty getting a diagnosis, or feeling like their symptoms were dismissed, or that they were not believed by healthcare providers. In some cases, there was a perceived reluctance of healthcare providers to diagnose myocarditis/pericarditis or link their diagnosis or symptoms to Comirnaty. Some participants had mixed experiences with the healthcare system, finding some aspects of their care good and expressing frustrations with other parts.

- *"I was initially told a number of times in ED that I was having anxiety attacks. I felt like no one was listening to me which made it even harder."*

- *"I struggled without a diagnosis for some time. I felt super let down. It took 4+ months before I felt like someone was listening."*
- *"Was dismissed and no one wanted to help me… felt helpless."*
- *"ED were amazing and ambulance staff but not so much the doctors in hospital… thank goodness my GP pushed to have some follow up… had big discussion with my GP regarding further vaccines. She was terrific."*
- *"Reluctance from healthcare professionals to link his reaction to the vaccination."*
- *"Was anxious about having the booster and I was fobbed off. I am not an 'anti-vaxxer'. Doctors need to listen and be more empathetic."*
- *"Pro-vaccination but very confusing at the same time to be going through this experience. Socially I felt embarrassed to talk to my GP about it initially. Scared they would think I was anti-vax."*

3.4.3 Theme: Follow up care and support

Participants also made comments regarding their experience with follow up care and support after their diagnosis. Many reported difficulties seeing a specialist and having to use the private system to access cardiologist care. Participant concerns included lengthy waiting times, being discharged from hospital before they felt ready to go home, and a lack of follow-up care or support after their diagnosis.

- *"Disappointed with lack of after care. Absolutely no specialist follow-up. Very disappointing."*
- *"Time it took to get follow-up appointments with cardiologist were so long. Five months before I could see a doctor and still waiting for MRI results. Very frustrating."*
- *"We can't afford it, but it is getting to the point where I might have to go to a private cardiologist as I have heard nothing back since December and I still have all of the symptoms."*
- *"At every step of the way I didn't want to cause harm and cause unnecessary anxiety or vaccine hesitancy in others. I wanted others to face an easier journey than I had had, and for as much good to come of my event as possible. I was and remain concerned that the only supports for the vaccine injured was the anti-vaccination movement and dubious telegram groups."*
- *"Utter frustration that I had to go privately to get any help. Was told it would take one year to get any cardiac test. I would still be waiting for a diagnosis. I had to go privately."*
- *"People should be able to find a way to get help. ACC, GPs, they are busy, but we are struggling too. There will always be a small percentage of people who have side effects from vaccines. We are vaccinating a lot of people and so the people who have side effects need good help."*
- *"I felt completely unsupported. It was emotionally exhausting."*

3.4.4 Theme: Vaccine mandates and exemptions

Comments regarding experience with vaccine mandates and exemptions was another theme made by participants. This included having to be vaccinated due to their job requirements, a difficult exemption application process, and having exemption applications declined. Some participants stated they were concerned about mandates being bought back.

- *"I needed the vaccinations for my job. I was being told by the cardiologist that I should wait for my booster. Had the mandates not been lifted I wouldn't have been able to work. It was very upsetting being denied a temporary vaccine exemption… it feels wrong to go against the advice of your treating clinician, it undermines the relationship."*

- *"Very, very hard at the time when I couldn't get the exemption. I couldn't go anywhere. They could have approved an exemption for people like me. I still wore a mask everywhere. Very disappointing and sad. I am not anti-vax - I had the vaccine."*
- *"I still have symptoms, and I couldn't work due to the mandate rules. Initially I was declined an exemption and I had to fight for it. Eventually I got it."*

3.4.5 Theme: Follow up advice and communication

Another theme that emerged was a lack of clear medical advice and information for their diagnosis:

- *"Conflicting information from different clinicians (ED doctors, specialists, GP) about his diagnosis of pericarditis."*
- *"I was given conflicting advice by the specialists with regards boosters. It all felt political."*
- *"Lack of information. Means you turn to Google which is depressing reading, especially if you don't understand everything you read. The cardiac nurse from the hospital was amazing though."*
- *"No medical advice. No one there to tell me what to do and what not to do for my heart… I desperately wanted advice, and no one was there to give me advice to give me confidence. First few nights I was too scared to go to sleep. I was in bed for a month, and I felt completely alone."*

3.4.6 Theme: Accident Compensation Corporation (ACC)

Participants made comments about their experience dealing with ACC. This includes people who found the ACC process difficult and long. Some participants were not aware that they could apply for compensation.

- *"I had used up all of my sick leave. I wasn't aware you could apply for ACC. Should have been offered to us, I was left in the dark. They should have been clearer with me. I am still dealing with ACC. Only just in process of getting compensation now. Frustrating."*
- *"ACC – although accepting my vaccine injury treatment injury claim – decided seven days was sufficient time to recover… it took… nearly 8 months after the claim, for full cover to be approved."*
- *"ACC have been a nightmare. It has been a financial battle. I can no longer work. My questions have never properly been answered. I have a family and bills to pay. The government have not helped me at all… ACC has only just accepted my claim."*

3.4.7 Theme: Information prior to vaccination

Comments about the provision of information before vaccination and informed consent were also made. This includes participants who reported that they were not informed about the possible risk of myocarditis and/or pericarditis, or who felt that the information and advice given was inadequate or incorrect:

- *"When I had the first vaccine, I was given a brochure Re:side effects which I read from front to back. There was absolutely nothing on the brochure related to this. Even in fine print it should be mentioned that there is a rare possibility to have this heart problem. It would be most helpful."*
- *"To hear… myopericarditis repeatedly be reported as a mild consequence of vaccination was a huge insult and should immediately stop. This is not a mild sequela for many. This is a profound life changing and devastating event."*
- *"There was no info when I had the vaccine about seeking help if heart issues - not on pamphlets and not from doctors."*

3.5 Healthcare provider diagnostic testing

The diagnostic tests performed by healthcare providers at the time of the initial diagnosis for the participants in this study are provided in Table 5. Of the 161 healthcare providers surveyed, 143 (95.3%) reported that troponin was measured. Out of 137 available results, 55 (40.1%) reported an abnormal troponin result. The percentage of abnormal troponin results among those diagnosed with myocarditis (92.6%) was higher than those diagnosed with pericarditis (6.0%). More frequently prescribed medicines for pericarditis were colchicine and ibuprofen while beta-blockers and ACE inhibitors were more frequent for myocarditis.

Table 5: Diagnostic tests and prescribed medicines at initial diagnosis as reported by healthcare providers

Diagnostic tests and prescribed medicines	Myocarditis n/N (%)	Pericarditis n/N (%)	Total [a] n/N (%)
Blood troponin			
Measured	54/55 (98.2)	89/95 (93.7)	143/150 (95.3)
Abnormal	50/54 (92.6)	5/83 (6.0)	55/137 (40.1)
ECG at initial diagnosis			
Performed	54/54 (100.0)	94/96 (97.9)	148/150 (98.7)
Abnormal	31/51 (60.8)	46/90 (51.1)	77/141 (54.6)
ECHO at initial diagnosis			
Performed	51/57 (89.5)	38/92 (41.3)	89/149 (59.7)
Abnormal	26/51 (51.0)	11/36 (30.6)	37/87 (42.5)
cMRI at initial diagnosis			
Performed	28/53 (52.8)	7/93 (7.5)	35/146 (24.0)
Abnormal	22/27 (81.5)	4/6 (66.7)	26/33 (78.8)
Prescribed medicines at initial diagnosis			
Colchicine	24/60 (40.0)	65/101 (64.4)	89/161 (55.3)
Ibuprofen	19/60 (31.7)	62/101 (61.4)	81/161 (50.3)
Other NSAID [b]	3/60 (5.0)	15/101 (14.9)	18/161 (11.2)
Corticosteroid	2/60 (3.3)	6/101 (5.9)	8/161 (5.0)
Beta-blocker	12/60 (20.0)	6/101 (5.9)	18/161 (11.2)
ACE inhibitor	6/60 (10.0)	0/101 (0.0)	6/161 (3.7)
ARB [c]	2/60 (3.3)	1/101 (1.0)	3/161 (1.9)
Diuretic	3/60 (5.0)	0/101 (0.0)	3/161 (1.9)
Other Medicines	13/60 (21.7)	18/101 (17.8)	31/161 (19.3)

a: The number of healthcare providers surveys returned was 161; 60 surveys for participants with myocarditis and 101 for participants with pericarditis. Responses of "don't know" have been excluded; where the denominator is less than the values listed above, it is due to the exclusion of "don't know" responses.

b: Nonsteroidal Anti-Inflammatory Drugs

c: ARB- Angiotensin receptor blocker

3.6 Recovery in participant and healthcare provider surveys

From the healthcare provider survey, healthcare providers reported 84 (52.2%) of their patients as recovered, 66 (41.0%) unrecovered, and the remaining 11 (6.8%) had an unknown recovery status (Table 6). When stratified by diagnosis, myocarditis was the diagnosis for 44 (52.4%) of recovered and 14 (21.2%) of unrecovered, compared to 40 (47.6%) of recovered and 52 (78.8%) of unrecovered for pericarditis. Recovery status was similar for Māori and non-Māori.

Among the 66 participants considered unrecovered by their healthcare provider, 38 (57.6%) stated on the participant survey that they were not hospitalised for their diagnosis and 53 (80.3%) were still experiencing chest pain.

Among the 84 participants considered recovered by their healthcare provider, 3 (3.6%) stated on the participant survey that their current health as excellent, 29 (34.5%) as very good, 32 (38.1%) as good, 9 (10.7%) as fair, and 11 (13.1%) as poor. Additionally, 25 (29.8%) stated their ability to do paid work had changed.

Other healthcare provider survey questions and redacted deidentified data (responses to multiple choice, non-open-ended questions) can be found on the COVID-19 vaccine: myocarditis and pericarditis study page on the Health New Zealand website (see Appendix 4 for more information).

Table 6: Diagnosis, demographics, ongoing symptoms, and other measures by recovery status as determined by healthcare providers

	Recovered n=84 (%)	Unrecovered n=66 (%)
Diagnosis		
Myocarditis	44 (52.4)	14 (21.2)
Pericarditis	40 (47.6)	52 (78.8)
Gender		
Female	30 (35.7)	29 (43.9)
Male	54 (64.3)	37 (56.1)
Ethnicity		
Māori	6 (7.1)	6 (9.1)
Non-Māori	78 (92.9)	60 (90.9)
Age		
12-19	9 (10.7)	5 (7.6)
20-29	16 (19.0)	18 (27.3)
30-39	14 (16.7)	21 (31.8)
40-49	14 (16.7)	7 (10.6)
50-59	11 (13.1)	4 (6.1)
60-69	7 (8.3)	2 (3.0)
70-79	3 (3.6)	2 (3.0)
80+	2 (2.4)	1 (1.5)
Unknown	8 (9.5)	6 (9.1)
Healthcare provider responses		
Restrict physical activity		
No	11 (13.1)	13 (19.7)
Yes	38 (45.2)	44 (66.7)
Unknown	35 (41.7)	9 (13.6)
Previous medical conditions		
No	37 (44.0)	36 (54.5)
Yes	43 (51.2)	27 (40.9)
Unknown	4 (4.8)	3 (4.5)

Participant responses		
Hospitalisation at initial diagnosis		
Hospitalised (no ICU/HDU)	45 (53.6)	24 (36.4)
ICU/HDU	5 (6.0)	4 (6.1)
Not hospitalised	33 (39.3)	38 (57.6)
Unknown	1 (1.2)	0 (0.0)
After which dose was diagnosis made		
First	22 (26.2)	21 (31.8)
Second	46 (54.8)	28 (42.4)
Third or subsequent	15 (17.9)	17 (25.8)
Don't know/prefer not to say	1 (1.2)	0 (0.0)
Still experiencing symptoms at the time of the survey		
Chest pain		
No	33 (39.3)	13 (19.7)
Yes	45 (53.6)	53 (80.3)
Don't know/prefer not to say	6 (7.1)	0 (0.0)
Shortness of breath		
No	39 (46.4)	16 (24.2)
Yes	29 (34.5)	39 (59.1)
Don't know/prefer not to say	16 (19.0)	11 (16.7)
Palpitations		
No	31 (36.9)	21 (31.8)
Yes	25 (29.8)	39 (59.1)
Don't know/prefer not to say	28 (33.3)	6 (9.1)
Fatigue		
No	31 (36.9)	14 (21.2)
Yes	41 (48.8)	45 (68.2)
Don't know/prefer not to say	12 (14.3)	7 (10.6)
Dizziness		
No	31 (36.9)	22 (33.3)
Yes	17 (20.2)	28 (42.4)
Don't know/prefer not to say	36 (42.9)	16 (24.2)
Fainting		
No	2 (2.4)	5 (7.6)
Yes	3 (3.6)	0 (0.0)
Don't know/prefer not to say	79 (94.0)	61 (92.4)
Health now compared to before the diagnosis		
A lot better	0 (0.0)	1 (1.5)
A little better	6 (7.1)	0 (0.0)
The same	21 (25.0)	5 (7.6)
A little worse	39 (46.4)	24 (36.4)
A lot worse	17 (20.2)	35 (53.0)
Don't know/prefer not to say	1 (1.2)	1 (1.5)
Current health		
Excellent	3 (3.6)	2 (3.0)
Very good	29 (34.5)	13 (19.7)
Good	32 (38.1)	21 (31.8)
Fair	9 (10.7)	12 (18.2)

Poor	11 (13.1)	18 (27.3)
Psychological symptoms		
Little interest		
No	45 (53.6)	26 (39.4)
Yes	37 (44.0)	39 (59.1)
Don't know/prefer not to say	2 (2.4)	1 (1.5)
Feeling down		
No	48 (57.1)	14 (21.2)
Yes	35 (41.7)	50 (75.8)
Don't know/prefer not to say	1 (1.2)	2 (3.0)
Feeling nervous		
No	30 (35.7)	10 (15.2)
Yes	53 (63.1)	55 (83.3)
Don't know/prefer not to say	1 (1.2)	1 (1.5)
Not stop worrying		
No	51 (60.7)	35 (53.0)
Yes	33 (39.3)	28 (42.4)
Don't know/prefer not to say	0 (0.0)	3 (4.5)
Ability to go to school has changed		
No	9 (10.7)	5 (7.6)
Yes	3 (3.6)	3 (4.5)
Unknown/did not attend school	72 (85.7)	58 (87.9)
Ability to do paid work has changed		
No	40 (47.6)	16 (24.2)
Yes	25 (29.8)	36 (54.5)
Don't know/prefer not to say	19 (22.6)	14 (21.2)
Back to same level of physical activity		
No	50 (59.5)	57 (86.4)
Yes	33 (39.3)	8 (12.1)
Don't know/prefer not to say	1 (1.2)	1 (1.5)
Previous COVID-19 infection		
No	59 (70.2)	41 (62.1)
Yes	24 (28.6)	25 (37.9)
Don't know/prefer not to say	1 (1.2)	0 (0.0)

4 Discussion

Following the largest ever mass vaccination campaign in Aotearoa New Zealand history, this study surveyed participants on their recovery after a clinical diagnosis of myocarditis and/or pericarditis following administration of Comirnaty. Almost three out of five (60%) participants reported that their chest pain was unresolved at the time of survey and a little over half reported unresolved symptoms of fatigue. Additionally, almost three out of four (75%) participants reported feeling nervous and half were feeling down after their diagnosis.

The qualitative analysis of participant responses from the open-ended question found common themes relating to physical ability, mental wellbeing, and impacts on family life, work, and lifestyle that supported the main survey results. Themes also emerged surrounding follow-up care and advice, vaccine mandates, interactions with the healthcare system, and information provided prior to vaccination. Although there were some positive comments made towards specific healthcare providers and organisations, the general sentiment from participants was negative. Participants spoke to feeling inadequately warned about potential risks prior to vaccination, and of feeling unsupported during their diagnostic journey and recovery.

Internationally, there is limited evidence on the medium-to-long-term outcomes of myocarditis and/or pericarditis following COVID-19 vaccination. To the best of our knowledge, there have been three studies published [24, 26, 27] as of June 2024. Our study findings are broadly in line with the findings of these studies, in which over 50% of participants surveyed reported unresolved symptoms. It was noted by the CDC that a possible explanation for the persistence of symptoms such as chest pain and palpitations was depression or anxiety [24]. The prevalence of somatic symptoms in the Aotearoa New Zealand population is high; somatic symptoms are medically unexplained physical symptoms that have a psychological cause, such as anxiety leading to palpitations [32]. The New Zealand Health survey 2021/2022 found that 18% of adults had experienced moderate levels of psychological distress in the four weeks prior to survey, however one in nine adults (11.2%) experienced high or very high levels of distress. For young people aged 15-24 years, high or very high levels of psychological distress increased from 5.1% in 2011/2012 to 23.6% in 2021/2022 [33].

Pericarditis is generally considered a milder illness than myocarditis and is associated with fewer serious sequelae [31]. There is some indication that this is not the case for COVID-19 infection associated myocarditis and pericarditis. One retrospective cohort study from a global federated health research network found that COVID-19 patients with pericarditis were more likely to be diagnosed with cardiovascular sequalae than COVID-19 patients with myocarditis [25]. This study also reported that patients diagnosed with new-onset pericarditis from COVID-19 infection had a six-month all-cause mortality odds ratio of 2.55 compared to matched controls. In contrast, myocarditis developed after COVID-19 infection had a six-month all-cause mortality odds ratio of 1.36. There is a need for further research examining the differences in outcomes for myocarditis and pericarditis between COVID-19 infection, COVID-19 vaccination, and non-COVID-19 associated cases. Myocarditis and pericarditis are different conditions, and the level of care and testing required differs between patients. Pericarditis can be more challenging to diagnose than myocarditis.

4.1 Strengths

We included both participants diagnosed with myocarditis and pericarditis in the study. Myocarditis and pericarditis are similar, and sometimes co-occurring, conditions; our study which includes both adds to the international knowledge base. The existing literature is more focused on post vaccination myocarditis, such as the CDC study which only included individuals diagnosed with myocarditis [24].

Our study had a wide age range (12-83 years) and included both male and female participants. Although internationally, vaccine associated myocarditis and pericarditis were more frequently

diagnosed in young men, these conditions can occur in anyone [9]. Our broad study population increases the relevance of the study for people who do not fit the typical profile; 43% of our study participants were aged over 40 and 38% were female.

We had highly trained personnel for administering the survey questions. Surveyors were from nursing backgrounds, possessed well-developed public communication skills, and were trained to conduct this specific survey.

The use of CARM for recruitment presented both strengths and limitations (see below). The strength of using CARM was that it provided a centralised, easily accessible database, and less costly way for contacting potential participants. Recruitment began during the largest outbreak of COVID-19 in Aotearoa New Zealand when Omicron cases started to spread in early 2022. This would have made other recruitment methods less practical and costly. Additionally, because of the heightened public attention to COVID-19 vaccines, CARM experienced a large uptake in spontaneous reporting of adverse reactions. While not all cases of myocarditis and pericarditis following vaccination are submitted to CARM, it is believed CARM received a substantial proportion of those cases.

4.2 Limitations

This study is subject to several limitations. Firstly, we only contacted individuals who had a report made to CARM about their case. CARM runs a spontaneous reporting system, i.e., reporting is voluntary, and it is possible there are differences between the population experiencing adverse events following immunisation who are reported to CARM and those who are not. Recruitment was challenging from the start, where we found participation to be significantly associated with age and ethnicity (Appendix 3), Māori were less likely to participate. Engaging with Māori and Pacific Health would provide further insights into the impact of rare serious reactions among Māori and Pacific peoples.

Second, patients were surveyed at least 90 days after their diagnosis. This means they were asked to remember information e.g., the dose after which they were diagnosed, symptom resolution, etc. on things that happened more than 90 days prior to the survey. This could potentially affect the accuracy of some responses and introduce recall or self-reporting bias.

Third, healthcare providers were contacted after the patient survey was completed and after participants provided consent for their healthcare provider to be contacted. Therefore, there was a delay between participant survey completion and healthcare provider survey completion. On average, the delay was 53 days. It is possible that the participants' health may have changed during this interval, which makes it difficult to compare how participants view their recovery with how the healthcare provider described participants' recovery.

Fourth, data about clinical tests were taken from healthcare provider responses rather than from a clinical chart review. Therefore, we were limited to only the responses and interpretation of results from the healthcare provider, and we were unable to verify the clinical data provided. We requested that the healthcare provider consulted their patient's records when they completed the survey to minimise errors.

Finally, there was no control group, e.g., patients diagnosed with non-vaccine induced myocarditis or pericarditis. This means we could not investigate if there are any differences in the recovery times, clinical test results, or physical and psychological symptoms between vaccine and non-vaccine induced myocarditis or pericarditis. The New Zealand Health Survey 2021/2022 indicated that a high proportion of adults experienced psychological distress and potentially somatic symptoms during the COVID-19 pandemic [33]. During a period of significant change in Aotearoa New Zealand, a control group would have been a useful measure to contextualise ongoing symptoms and psychological well-being in our study population.

5 Key learnings and opportunities for future

In addition to providing important new information on outcomes in people diagnosed with myocarditis and pericarditis after Comirnaty vaccination, this study has highlighted several key learnings and opportunities for immunisation programmes in Aotearoa New Zealand. Although some areas where challenges have been identified were specific to earlier phases of the COVID-19 pandemic response, and specific policies such as vaccine mandates (which ended on 26 September 2022 [34]), these could provide learnings for future pandemics and vaccination campaigns.

1. **Develop consistent and improved cooperation between Māori Health, Pacific Health, disability services, Health New Zealand | Te Whatu Ora, the Ministry of Health | Manatū Hauora, and ACC.**

   Participants indicated a lack of awareness of the support services available to them and barriers to accessing care. There should be better communication, collaboration, and clearer pathways for support of individuals affected by serious adverse reactions following vaccinations, even though these are rare.

   Agencies, Iwi-Māori Partnership Boards (IMPBs), Māori Health and Pacific Health groups within Health New Zealand, and Disability groups could work more closely together to ensure that clear pathways are developed, and safety information is disseminated to healthcare professionals and the public. This will help to build awareness about the frequency and expectations of common and rare reactions, in addition to what support is available for people who experience serious adverse reactions. Support may be physical, psychological, or financial, and should be tailored to the specific needs of an individual. In addition, the inclusion of the consumer voice when developing processes, or setting up panels or committees, will aid in the development of pathways that suit users.

   The Australian Technical Advisory Group on Immunisation (ATAGI) worked with the Cardiac Society of Australia and Aotearoa New Zealand, among other medical organisations, to develop guidance on myocarditis and pericarditis after COVID-19 vaccines for healthcare professionals in Australia [35]. ATAGI is a National Immunisation Technical Advisory Group (NITAG); NITAGs are multidisciplinary bodies of national experts that provide evidence-based advice and recommendations. The Global Vaccine Action Plan, a World Health Organisation framework, recommended all countries develop a NITAG [36]. During the COVID-19 Response several different groups fulfilled parts of the role of a NITAG, including the COVID-19 Vaccine Independent Safety Monitoring Board, the COVID-19 Vaccine Technical Advisory Group, and the Medicines Adverse Reactions Committee. A NITAG has been established by the Public Health Agency within the Ministry of Health, which will bring several of these functions together.

2. **Ensure that guidance and information materials provide clear information on both the risks and benefits of vaccines, and that this information is communicated with healthcare professionals and consumers.**

   Participants raised that they were not aware of the potential risk of myocarditis and pericarditis at the time they were vaccinated. It is imperative that people are aware of serious adverse reactions following vaccination, but that they are complications of COVID-19 infection as well. This would enable them to make an informed decision on the risks versus benefits and know where to seek help if they experience symptoms after vaccination. Doing so increases trust and combats misinformation. This is particularly important when trust in the government is low,

especially among ethnicities that have been historically disadvantaged. It is suggested that this is done by:

a) Ensuring that guidance and information materials provide clear and balanced information on both the risks and benefits of vaccines.

b) Ensuring that vaccinators are given practical training on how to discuss risks and are well-supported by the programme in prioritising informed consent over vaccination targets or fears of suboptimal uptake. Additionally, ensuring that consumers are provided with accurate information about potential risks and benefits of vaccination as part of the informed consent process.

c) Assisting the newly established Immunisation Outcomes Collective (a cross-agency group to exercise operational governance) to improve community engagement in promoting and communicating advice relating to vaccine safety.

3. Continue to expand our knowledge of rare and serious reactions to vaccines and ensure that clinical practice is guided by the latest evidence.

People diagnosed with myocarditis or pericarditis following vaccination with Comirnaty may continue to experience symptoms such as chest pain and fatigue, and other impacts several months after the initial diagnosis. Healthcare providers should be aware of this to ensure that appropriate follow-up and support are arranged. Further research comparing outcomes for serious reactions following vaccination, compared to other forms of the conditions, will help guide clinical practice and follow-up care.

Additionally, as Māori were less likely to participate in this study, kaupapa Māori research methods and engaging with Māori Health and Pacific Health would provide further insights into the impact of rare serious reactions among Māori and Pacific peoples. An example of this currently underway is investigating IFNAR1 deficiency with the measles, mumps, and rubella (MMR) vaccination.

In future mass vaccination campaigns of novel vaccines, adverse reactions should be considered during the resource allocation phase of the campaign. Adverse reactions are an expected part of all medicines and should be planned for accordingly. Some consumers will inevitably experience a serious reaction and support pathways should be planned for, in advance of vaccine distribution.

4. Reporting of suspected adverse reactions.

In our study, recruitment through CARM allowed the study team to efficiently recruit participants. However, eligible consumers who did not have a CARM report were unable to be invited using this method. Encouraging reporting to CARM builds a greater knowledge base about adverse reactions and feeds into research that can help inform future practices. This can be done by:

a) Developing and disseminating consumer information materials (e.g., information leaflets, web pages, advertisements) that encourage consumers to submit CARM reports.

b) Investigating reasons that healthcare providers do not report to CARM and engaging with healthcare providers to encourage reporting of incidences to CARM (even if there may be concerns around dissuading consumers or where it is not confirmed that the symptoms are related to the vaccine).

Additionally, the National Public Health Service conducts active monitoring campaigns such as the Post Vaccine Symptom Check. More information on active monitoring can be found on the vaccine safety monitoring page on the Health New Zealand website. Continuing to strengthen active safety monitoring will aid in the early detection of vaccine adverse reactions and assist with communicating to the public. Consumer safety is a key priority in any Aotearoa New Zealand vaccination campaign.

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Appendix 1: Research Oversight Committee (ROC)

Member Biographies

**Note: biographies were written at the time the ROC was formed, and thus may not reflect current roles, responsibilities, or titles.*

ROC chair

Chris James *(BPharm, PGCertClinPharm, DPH, MRPharmS)*

Mr James is the Group Manager of the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). He has worked for Medsafe for 14 years. He is a professional member of the Royal Pharmaceutical Society of Great Britain, the Pharmaceutical Society of New Zealand, and the Pharmacy Council of New Zealand, and holds a current practising certificate. Mr James has a background as a clinical pharmacist. Prior to working for the Ministry of Health, he worked as a clinical pharmacist (predominantly in hospital settings) in New Zealand and the United Kingdom. This included specialising in paediatric and neonatal clinical pharmacy. He also has experience working in community pharmacy. He has expertise in granting consent for new and changed medicines, approval of clinical trials, and medicines adverse reactions.

ROC Members

Professor Chris Frampton *(BSc Hons, PhD)*

Professor Frampton is a part-time biostatistician within the departments of Psychological Medicine and Medicine at the University of Otago, Christchurch. He is a member of the Standing Committee on Therapeutic Trials (SCOTT) and the Pharmac Cancer Treatments Subcommittee (CaTSoP). Professor Frampton is a member of the invited faculty for the Australasian Clinical Oncology Research Development (ACORD) and the international Collaboration for Research Development in Oncology (CREDO) workshops, run biennially in Australia, and annually in India. His specific research focus is on the design, conduct, and analysis of randomised controlled trials (RCTs) and he serves on many international data safety monitoring committees overseeing multi-national RCTs. Professor Frampton provides expertise in the field of biostatistics.

Dr Tim Hanlon *(BSc Hons, MSc, DPharm, FRPharmS)*

Dr Hanlon is a pharmacist who heads the Vaccine Safety Surveillance and Research Group within the National Public Health Service (National Immunisation Programme), Health New Zealand. His background is in hospital pharmacy, having most recently held the appointment of Chief Pharmacist and Clinical Director of Pharmacy and Medicines Optimisation at Guy's and St Thomas' NHS Foundation Trust (GSTT) in London, United Kingdom. GSTT is one of the largest tertiary hospital groups in the UK National Health Service. In addition to holding this appointment as a member of the Trust Management Executive, Dr Hanlon also held the appointment of Visiting Professor at the School of Cancer and Pharmaceutical Sciences, King's College, London. Dr Hanlon was the inaugural Chair of the Shelford Group of Leading Hospital Trusts Chief Pharmacists' Board. The Shelford Group represents a collaborative of 10 of the English National Health Service's largest teaching and research hospital groups. He was a member of the Royal Pharmaceutical Society's Hospital Expert Advisory Group for a number of years, and was a member of several key national

reviews into hospital pharmacy services and the management of controlled drugs in hospitals. Dr Hanlon is the Principal Investigator (PI) providing overall management and leadership for this project.

Peter Himona

Mr Himona has been in the Māori Health team at the Ministry of Health for 14 years, working in the area of Māori health statistics, statistical methods and methodology, and monitoring of Māori health action plans and frameworks. Prior to that, he worked at Te Puni Kōkiri in the statistical monitoring team, profiling and reporting on Māori outcomes across sectors including health, education and employment, and indicators of Māori wellbeing such as te reo Māori, Māori housing, whānau, and connectiveness.

Saskia Schuitemaker *(MSocSc, PGDipPsych(Comm))*

Ms Schuitemaker is the Programme Coordinator, Child and Youth Mortality. She was previously employed as a Health Consumer Service Facilitator of health consumer complaints. Ms Schuitemaker served as a lay member representing consumer interests on the Waikato Medical Ethics Committee for six years. She is also informed by her work as a Community Magistrate and Community Development Advisor. Ms Schuitemaker is a lay member (non-health professional) who provides a consumer lens.

Honorary Professor Ralph Stewart *(MD, FRACP, FCSANZ, FESC)*

Dr Stewart is a cardiologist at Auckland City Hospital and the Auckland Heart Group, and an Honorary Professor of Medicine at the University of Auckland. He is past Chairman of the New Zealand Division of the Cardiac Society of Australia and New Zealand, and of the National Cardiac Clinical Network. He is a member of several national and international cardiology and research organisations. Dr Stewart provides expertise in the field of cardiology.

Professor Michael Tatley *(MBChB, BBusSci(Hon), FFCH(SA), FAFPHM, FNZCPHM)*

Professor Tatley is Director of the New Zealand Pharmacovigilance Centre (NZPhvC) at the University of Otago. The NZPhvC provides pharmacovigilance services on contract to Medsafe. He has several years of experience in drug safety surveillance and the evaluation of adverse events attributed to medicines. He has a particular interest in vaccine adverse events and vaccinology.

ROC committee meeting summaries

Table A1.1: ROC committee meeting summaries

Date of meeting	Meeting Agenda/ topics to discuss	Presentations/ discussions	Issues to address/ recommendations to review/ points raised	Outcomes of the meeting
01 December 2021	• Overview of ROC committee functions • Overview of the myocarditis/pericarditis follow up study. • Equity focus. • Presentations and discussions. • Outcomes.	**Presentations:** • Study design and objectives. • Draft protocol. • Modification of original CDC protocol. **Discussions:** • Possible choice of surveyors for the study. • Expected number of participants. • Project ownership by Medsafe and support by CVIP. • Multiple ways of contacting participants to alleviate access issues. • Decision regarding not collecting information about supplement consumption, considering length of survey.	• IMAC to report to CARM for capturing of all cases. • Terms of reference to be outlined. • Requirements of minimum sample size to be discussed outside of the meeting. • Participants to consent about additional information from healthcare provider. • In-depth review of questions regarding medicines use to be considered by Ministry of Health. • Adjustments to be made to the survey questions to make it optimal length to ensure participation is not hindered. • Present revised questions to the committee again for further review.	• Committee purpose and function understood and agreed upon by members. • Robust study design to ensure key outcomes are met. • Equity to remain a key priority and principle of Te Tiriti o Waitangi to embedded through delivery of the study. **Study to address:** • Primary focus: current health physical functioning, mental health, school/university/work attendance. • Secondary focus of hospitalisations: cardiac recovery. • Proposed timeline to include consumers diagnosed up to 31 December. • To consider and investigate possibility of incentives to increase participation.
Date of meeting	Meeting Agenda/ topics to discuss	Presentations/ discussions	Issues to address/ recommendations to review/ points raised	Outcomes of the meeting

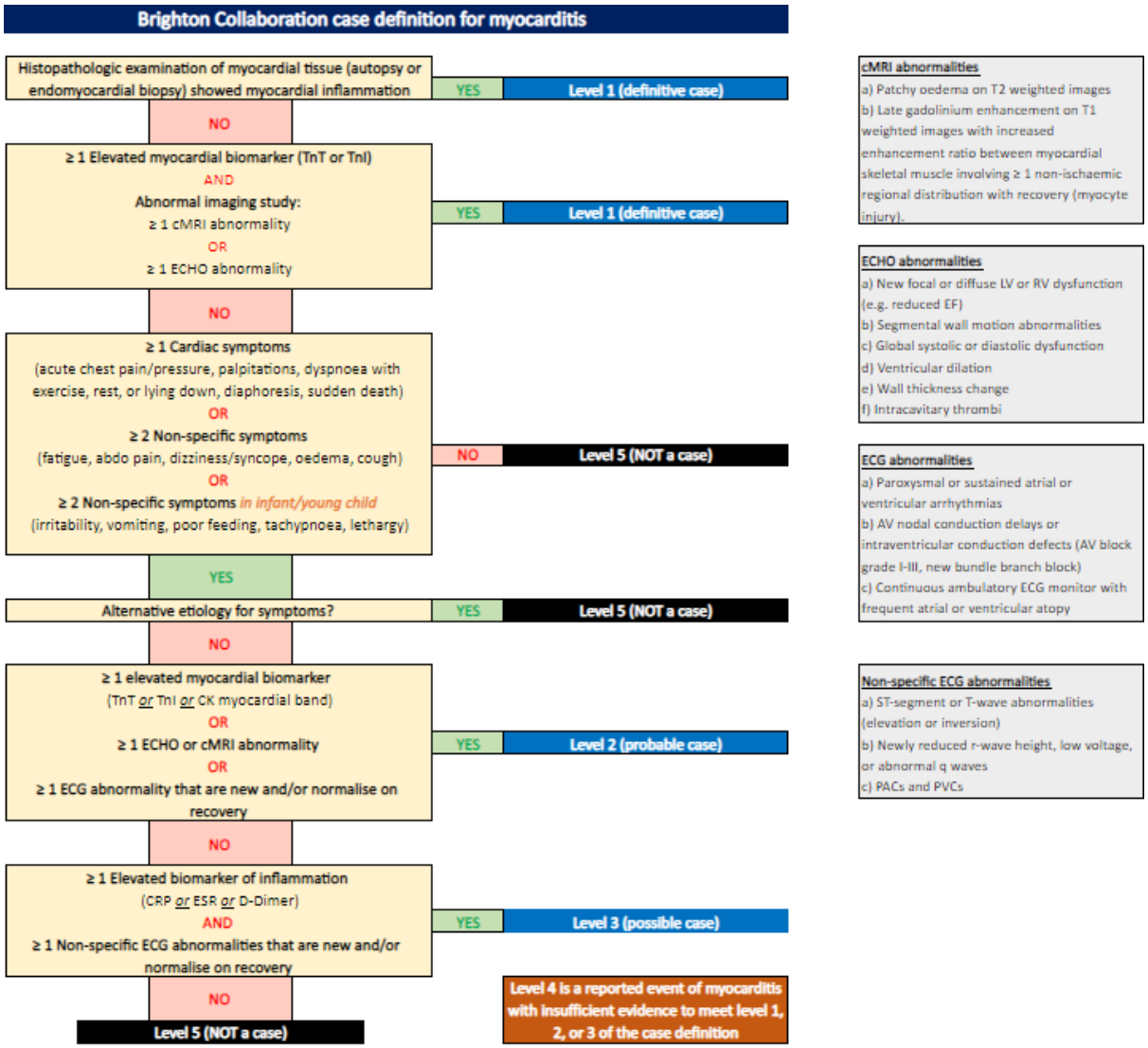
21 March 2022	• Overview of key study parameters. • Update on status of study. • Any changes that have occurred. • Actions that have taken place.	**Presentations:** • International studies. • CDC study and preliminary results. **Discussions:** • Changes in the study design since last meeting. • Brighton criteria. • Data linking through Conporto Platform. • Current available data in CARM. • Update on international research.	• Early review of preliminary data (first 10-20 surveys) strongly recommended. • Status updates of how study is progressing to be provided to ROC and issues raised as soon as enough samples are gathered. • Due to COVID-19 also circulating, current COVID-19 status needs to be captured. • Issue of low rate of reporting by some ethnic groups and part of the comms plan to encourage retrospective reporting to capture more Māori and Pacific people reporting. • Recruitment rates for Māori and Pacific people to be monitored.	• To feedback committee recommendation to CBG regarding capturing of ethnicity data. • Latest versions of survey to be shared to the committee via Teams channel; healthcare provider survey could still be tweaked. • Myocarditis and pericarditis incidence by ethnicity and age data in the community before commencement of vaccination, to be shared with ROC.

Date of meeting	Meeting Agenda/ topics to discuss	Presentations/ discussions	Issues to address/ recommendations to review/ points raised	Outcomes of the meeting
25 May 2022	• Status update of current study. • Status update of consumer and healthcare provider surveys. • Discussion of problems encountered in survey collection and possible solutions.	**Presentations:** • Overview of study status and current study population. • Preliminary data of survey responses. **Discussions:** • Survey delivery methods, ways to improve engagement. • Types of possible incentives and their pros and cons. • Results of literature review regarding improvement of healthcare provider response rates. • Value of extending cut-off date and including Comirnaty booster vaccinations.	• Point raised that healthcare provider low response rate already had an escalation protocol in place, but more needed to be done. • Paper-based method could be useful, clearly communicating that some parts could be done by nurses. • Paper-based survey to be trialled over incentives, due to incentives requiring further ethics approval and some forms of incentives have no data to back them up in terms of effectiveness. • If outcomes of study find myocarditis and pericarditis to be prolonged event(s), this should be communicated to ACC since it can be a claimable event.	• Suggestion made to raise awareness of the study through Royal College of General Practice, Facebook groups, ePulse e-newsletter, New Zealand Doctor. • Article to be published in New Zealand Doctor. Unanimous agreement (as a result of vote) to: • Extend study population to include Comirnaty booster vaccinations. • Extending study date up to 28 February 2022.

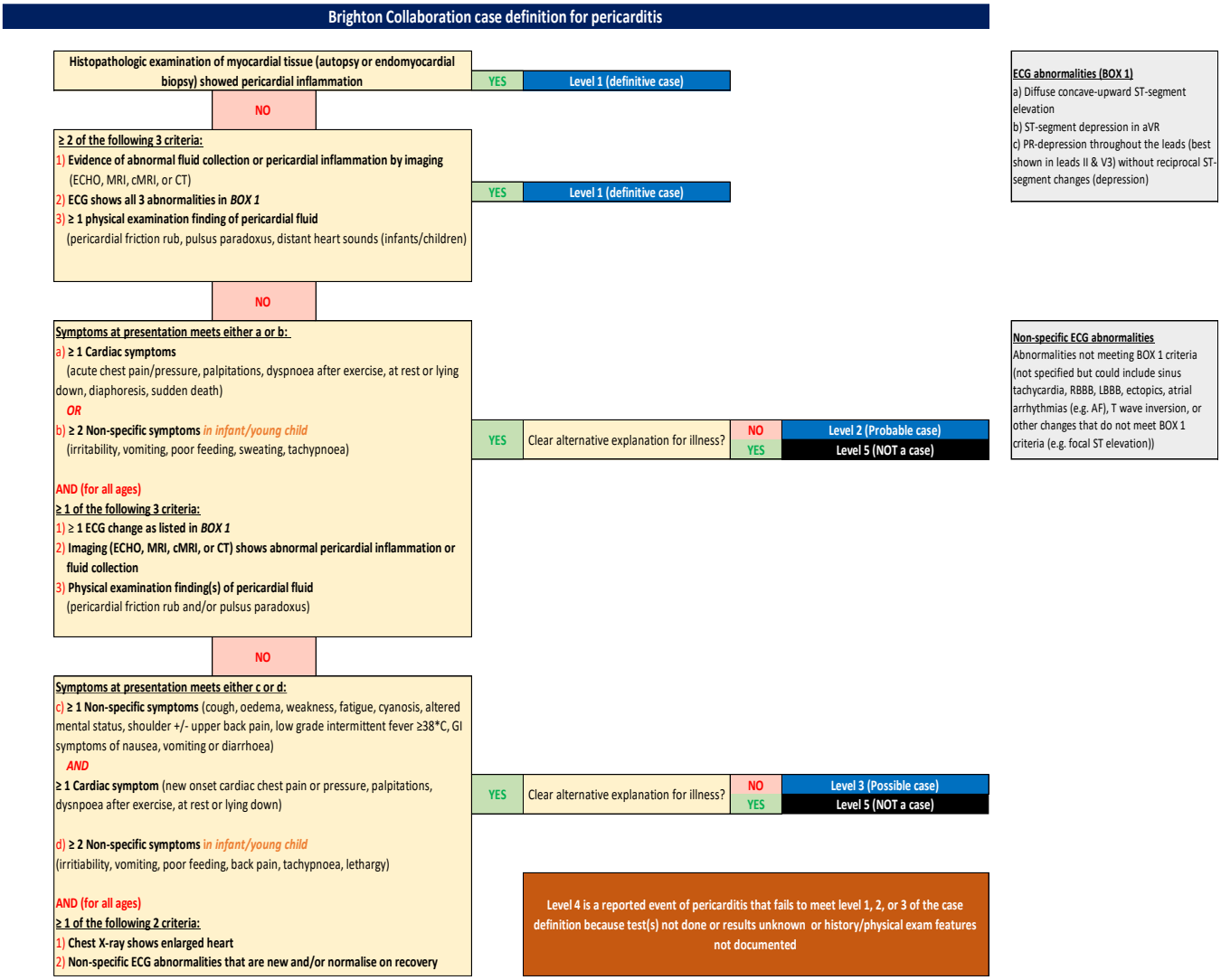
Date of the meeting	Meeting Agenda/ topics to discuss	Presentations/ discussions	Issues to address/ recommendations to review/ points raised	Outcomes of the meeting
28 November 2022	• Update on current literature. • Overview of data analysis. • Update on results and analysis. • Plan for publication and dissemination of results.	**Presentations:** • CDC study and AusVaxSafety. • Overview of statistical methods and Brighton criteria. • Overview of preliminary results. **Discussions:** • Brighton criteria and its application, decision regarding inclusion of Level 1-3. • Diagnosis, Aetiology, and results examples. • Overview of dissemination of results plan.	• Breakdown of Brighton criteria could be provided initially before grouping 1-2 and 3 for analysis. • In case of high burden of symptoms, it would be interesting to see if this is supported by objective evidence. • Multivariate analysis to be considered when analysing results. • CDC work vs New Zealand study difference to be analysed to note the difference.	**Publication and dissemination work to consider following:** • Key results. • Presentation of data. • Potential difference vs CDC work. **Results of the study to be included in:** • Internal report. • Lay summary for consumers. • Overview to be published on Health New Zealand website.

Appendix 2: Case definition flowcharts

Myocarditis



Pericarditis



Appendix 3: Non-participant vs Participant tests of association

Table A3.1: Testing association between survey participation and diagnosis, Brighton criteria, age, gender, and ethnicity

	Non-participant n=183 (%)	Participant n=312 (%)	Total N = 495	P-value[1] (5% level of significance)
Diagnosis				
Myocarditis	59 (36)	105 (64)	164	
Pericarditis	101 (33)	206 (67)	307	0.569
Brighton Criteria Level				
1-3	88 (31)	198 (69)	286	
4-5	73 (39)	113 (61)	186	0.072
Age group				
12-19	24 (52)	22 (48)	46	
20-29	53 (42)	74 (58)	127	
30-39	49 (40)	75 (60)	124	
40-49	24 (32)	51 (68)	75	
50-59	16 (25)	47 (75)	63	
60-69	5 (20)	20 (80)	25	
70-79	5 (23)	17 (77)	22	
≥80	4 (44)	5 (56)	9	0.027**
Gender				
Female	64 (35)	120 (65)	184	
Male	116 (38)	191 (62)	307	0.568
Ethnicity				
Māori	26 (52)	24 (48)	50	
Non-Māori	157 (35)	287 (65)	444	0.031**

[1]P-value from a Chi-square test.

**Statistically significant.

Appendix 4: Dictionaries and summary of responses for the adult and child consumer survey and healthcare provider survey

The following files contain the survey questions for each survey administered and redacted deidentified data (counts of responses to multiple choice, non-open-ended questions) among those included in the analysis:

- Adult consumer survey dictionary and responses.xlsx
- Child consumer survey dictionary.xlsx
- HCP survey dictionary and responses.xlsx

The child consumer survey responses have not been published due to having only 10 participants aged 12-15 years old. In order to protect privacy, child participant response counts to individual questions have been removed from the spreadsheet. These files can be found on the Health Zealand website: COVID-19 vaccine: myocarditis and pericarditis study.

Appendix 5: Diagnosis, gender, and ethnicity of participants by age

Table A5.1: Diagnosis, gender and ethnicity stratified by 10-year age groups

	Diagnosis		Gender		Ethnicity	
Age range	Myocarditis N=100 n (%)	Pericarditis N=198 n (%)	Female N=113 n (%)	Male N=185 n (%)	Māori N=23 n (%)	Non-Māori N=275 n (%)
12-19	12 (12.0)	14 (7.1)	6 (5.3)	20 (10.8)	4 (17.4)	22 (8.0)
20-29	25 (25.0)	46 (23.2)	18 (15.9)	53 (28.6)	7 (30.4)	64 (23.3)
30-39	15 (15.0)	59 (29.8)	26 (23.0)	48 (25.9)	5 (21.7)	69 (25.1)
40-49	20 (20.0)	34 (17.2)	28 (24.8)	26 (14.1)	3 (13.0)	51 (18.5)
50-59	13 (13.0)	21 (10.6)	17 (15.0)	17 (9.2)	3 (13.0)	31 (11.3)
60-69	7 (7.0)	12 (6.1)	7 (6.2)	12 (6.5)	0 (0.0)	19 (6.9)
70-79	5 (5.0)	11 (5.6)	9 (8.0)	7 (3.8)	0 (0.0)	16 (5.8)
80+	3 (3.0)	1 (0.5)	2 (1.8)	2 (1.1)	1 (4.3)	3 (1.1)

Appendix 6: Participant self-reported clinical information

Table A6.1: Participant self-reported clinical information, by diagnosis

	Myocarditis, n=100 (%)	Pericarditis, n=198 (%)	Total, n=298 (%)
Prescribed medication at diagnosis			
Yes	91 (91.0)	194 (98.0)	285 (95.6)
No	9 (9.0)	4 (2.0)	13 (4.4)
Still prescribed medication at time of survey			
Yes	16 (16.0)	33 (16.7)	49 (16.4)
No	84 (84.0)	165 (83.3)	249 (83.6)
Previous COVID-19 infection*			
Yes	25 (25.0)	71 (35.9)	96 (32.2)
No	74 (74.0)	126 (63.6)	200 (67.1)
Unknown	1 (1.0)	1 (0.5)	2 (0.7)
History of non-myocarditis/ pericarditis heart disease			
Yes	19 (19.0)	32 (16.2)	51 (17.1)
No	81 (81.0)	166 (83.8)	247 (82.9)
History of cancer			
Yes	5 (5.0)	6 (3.0)	11 (3.7)
No	95 (95.0)	192 (97.0)	287 (96.3)
History of an autoimmune condition			
Yes	14 (14.0)	17 (8.6)	31 (10.4)
No	86 (86.0)	181 (91.4)	267 (89.6)
History of diabetes			
Yes	4 (4.0)	8 (4.0)	12 (4.0)
No	96 (96.0)	190 (96.0)	286 (96.0)
History of other long-term medical condition(s)			
Yes	31 (31.0)	55 (27.8)	86 (28.9)
No	69 (69.0)	143 (72.2)	212 (71.1)

*Includes self-reported COVID-19 results by participants using rapid antigen tests

Appendix 7: Resolution of physical symptoms as reported by study participants

Table A7.1: Resolution of physical symptoms as reported by study participants, by diagnosis

	Myocarditis, n=100 (%)	Pericarditis, n=198 (%)	Total, n=298 (%)
Chest pain			
Resolved <4 weeks	19 (19.0)	41 (20.7)	60 (20.1)
Resolved >4 weeks	23 (23.0)	28 (14.1)	51 (17.1)
Unresolved	52 (52.0)	124 (62.6)	176 (59.1)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Did not experience	6 (6.0)	5 (2.5)	11 (3.7)
Shortness of breath			
Resolved <4 weeks	22 (22.0)	42 (21.2)	64 (21.5)
Resolved >4 weeks	14 (14.0)	35 (17.7)	49 (16.4)
Unresolved	42 (42.0)	81 (40.9)	123 (41.3)
Unknown	1 (1.0)	8 (4.0)	9 (3.0)
Did not experience	21 (21.0)	32 (16.2)	53 (17.8)
Palpitations			
Resolved <4 weeks	10 (10.0)	39 (19.7)	49 (16.4)
Resolved >4 weeks	16 (16.0)	36 (18.2)	52 (17.4)
Unresolved	43 (43.0)	87 (43.9)	130 (43.6)
Unknown	1 (1.0)	2 (1.0)	3 (1.0)
Did not experience	30 (30.0)	34 (17.2)	64 (21.5)
Fatigue			
Resolved <4 weeks	10 (10.0)	21 (10.6)	31 (10.4)
Resolved >4 weeks	25 (25.0)	35 (17.7)	60 (20.1)
Unresolved	53 (53.0)	109 (55.1)	162 (54.4)
Unknown	1 (1.0)	2 (1.0)	3 (1.0)
Did not experience	11 (11.0)	31 (15.7)	42 (14.1)
Dizziness			
Resolved <4 weeks	15 (15.0)	41 (20.7)	56 (18.8)
Resolved >4 weeks	14 (14.0)	34 (17.2)	48 (16.1)
Unresolved	26 (26.0)	57 (28.8)	83 (27.9)
Unknown	0 (0.0)	2 (1.0)	2 (0.7)
Did not experience	45 (45.0)	64 (32.3)	109 (36.6)
Fainting			
Resolved <4 weeks	2 (2.0)	12 (6.1)	14 (4.7)
Resolved >4 weeks	1 (1.0)	3 (1.5)	4 (1.3)
Unresolved	2 (2.0)	2 (1.0)	4 (1.3)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Did not experience	95 (95.0)	181 (91.4)	276 (2.6)