# Memo

## Booster doses after myocarditis/pericarditis: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

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| **Date:** | 30 March 2022 |
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| **From:** | Dr Ian Town, Chief Science Advisor |
| **For your:** | Consideration |

## Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) advice on the use of COVID-19 vaccines in those who have experienced vaccine-associated myocarditis and/or pericarditis after a second (or subsequent) dose.

## Background and context

2. Myocarditis is an inflammation of the heart muscle; pericarditis is an inflammation of the thin tissue surrounding the heart (pericardium).
3. Data from countries such as the United States of America (USA) and Israel, indicate that there is a risk of myocarditis and/or pericarditis following Pfizer and Moderna mRNA COVID-19 vaccination. The risk is well documented following the second dose (compared to the first), in age groups younger than 40 years and in males.
4. In July 2021, the Ministry's Policy team sought clinical and scientific advice from CV TAG on the potential risk of myocarditis and/or pericarditis following vaccination. This advice was considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Vaccine and Immunisation Programme. It was recommended that a longer interval between first and second doses be operationalised for peopled aged 16-29, and that those under regular clinical review by a cardiologist discuss the risks and benefits of the COVID-19 vaccine with their healthcare team. It was recommended that anyone who develops confirmed myocarditis and/or pericarditis after the first dose should not receive a second dose of the Pfizer COVID-19 vaccine, and that CV TAG would consider alternative options for a second dose of COVID-19 vaccination in this group at a future date as evidence emerges from overseas safety monitoring sources. CV TAG noted that if, after discussion with their health care provider, the individual and/or their whānau decides that the benefits of receiving two doses and gaining robust protection against COVID-19

sooner, outweigh the potential risks, then the individual may receive the second dose as per the current indication. CV TAG recommended on 27 October 2022 the use of AstraZeneca in people who have a contraindication to the Pfizer vaccine.

5. The Government currently requires certain sectors and professions to have received COVID-19 booster doses as part of their employment requirements as directed by the COVID-19 Public Health Response (Vaccinations) Order 2021. There is an exemption process to this order which enables individuals without a booster to continue in employment.

6. On 3 February 2022, the Immunisation Advisory Centre (IMAC) wrote to the COVID-19 Vaccine Temporary Medical Exemption Panel requesting reconsideration of the use of boosters for people who developed myocarditis or pericarditis following the second dose of Pfizer vaccine, particularly for workers mandated to receive a booster dose. Advice was offered on the risk associated with different COVID-19 vaccines, and the best clinical pathway for these individuals.

7. IMAC also expressed concern about a uniform approach requiring mandated workers to receive the AstraZeneca vaccine as a booster for the reasons outlined below:
    a. AstraZeneca adenovirus vectored vaccine carries a risk of Thrombosis with Thrombocytopaenia Syndrome (TTS), which although rare overall is greatest among people aged under 50 years. They also noted that a large epidemiological analysis of linked vaccination and hospitalisation data reported significantly increased risk of myocarditis after first but not subsequent doses of AstraZeneca in people <40 years.
    b. In the context of Omicron, vaccine booster doses are substantially less effective at reducing transmission than for previous variants, and likely to reduce further over time. This makes incremental benefit of a booster dose over standard infection control measures to reduce work-related transmission more difficult to justify for a person who has had documented myocarditis following the second dose of Pfizer vaccine.

## Evidence on myocarditis/pericarditis risk

8. Background rates for hospitalisations coded as myocarditis in Aotearoa New Zealand are consistent with international data. The rate of myocarditis in the overall population from 2011-2019 was 1.81 per 100,000 person-years. For Māori the rate was 1.95 per 100,000 person-years, and for Pacific peoples 1.79 per 100,000 person-years. There was a steady increase in incidence per 100,000 person-years from 0.20 in 0–9-years, to 0.76 10-19 years, and 2.13 in 20-29 year-olds [1-3].

*Risk from the Pfizer vaccine*

9. *Primary course:* There is an established link between the Pfizer vaccine and the risk of myocarditis, greatest within 7 days of administration of the second dose. The age group at greatest risk are adolescent and younger males. Approximately 90% recover with conservative management.

10. A report from Israel found an overall risk difference between the first and second doses of 1.76 per 100,000 persons (95%CI, 1.33-2.19), largest among males between the ages of 16 and 19 years (difference, 13.73 per 100,000 persons; 95%CI, 8.11-19.46). As compared with the expected incidence based on historical data, there was five-fold increase for all ages (standardised incidence ratio for the second dose was 5.34 (95%CI, 4.48-6.40), highest after the second dose in males between 16 and 19 years (13.60; 95% CI, 9.30 to 19.20). The rate

ratio for myocarditis within 30 days of receipt of the second vaccine dose in the general population compared with unvaccinated was 2.35 (95% CI, 1.10 to 5.02); highest in males between the ages of 16 and 19 years (8.96; 95% CI, 4.50 to 17.83), translating to an absolute risk of 1 in 6637 [4].

11. *New Zealand data:* Up to 13 March, 707 reports of myocarditis and/or pericarditis as adverse events following immunisation (AEFI) have been received for the Pfizer vaccine. All these reports are evaluated by a medical assessor at the Centre for Adverse Reactions Monitoring (CARM) and staff at Medsafe. Of the 649 reported cases, 263 (40%) have a recorded clinical diagnosis (e.g., diagnosed by a doctor or relevant healthcare professional). Other cases are still under follow-up or a clinical diagnosis was unable to be verified (e.g. self-diagnosis or occurred before the clinical syndrome was identified and were not seen). A number of the reported cases which were not verified have since gone on to receive a further dose of the Pfizer vaccine. From available CARM reports, there have been at least 21 people who had a clinical diagnosis of myocarditis or pericarditis (mostly pericarditis) after dose 1 who went on to receive dose 2, with no subsequent reported recurrence or other problems. There were at least 10 reports of people who had a clinical diagnosis of myocarditis or pericarditis after dose 2 who received dose 3 with no further reports received. However, it should be noted that less time has passed for people to have boosters and this number is likely to increase.

12. *Recurrent myocarditis/pericarditis:* It is not possible to quantify the risk of recurrent myocarditis or pericarditis. Case reports exist of individuals who have experienced documented or probable myocarditis after sequential COVID-19 vaccinations [5] or after a previous episode of myocarditis unrelated to vaccination [6]. As the majority of cases occur after the second dose of a primary course, there will be a considerable delay before a further, booster dose, is required.

13. *Risk from a booster dose:* The estimated risk of myocarditis following mRNA vaccines based on reporting to the VAERS database at the US CDC is reproduced below (Table 1) [7].

*Table 1: Cases and rates of myocarditis reported to the Vaccine Adverse Event Reporting System following receipt of an mRNA COVID-19 booster dose among adults aged ≥18 years (N = 37), by age, sex, and vaccine product received [7]*

| | No. of cases (rates)*,§ | | | |
|---|---|---|---|---|
| | Pfizer-BioNTech (n = 18) | | Moderna (n = 18) | |
| Age group, yrs | Men (n = 16) | Women (n<5) | Men (n = 10) | Women (n = 8) |
| 18–24 | 5 (4.1) | <5 (<1.0) | 6 (8.7) | <5 (1.1) |
| 25–29 | <5 (1.1) | 0 (—) | <5 (3.2) | <5 (1.2) |
| 30–39 | <5 (1.7) | <5 (<1.0) | <5 (<1.0) | <5 (1.5) |
| 40–49 | 0 (—) | 0 (—) | 0 (—) | <5 (<1.0) |
| 50–64 | <5 (<1.0) | 0 (—) | 0 (—) | <5 (<1.0) |
| ≥65¶ | 5 (<1.0) | 0 (—) | <5 (<1.0) | 0 (—) |

14. Israel published second dose and booster dose safety data for Pfizer vaccination on 15 December 2021. It is unclear whether anyone receiving a booster had had an episode of myocarditis after a previous dose. Local and systemic reactions in the 30 days following Pfizer booster were less frequent than after the second dose across all age groups. Myocarditis rates following Pfizer booster were also lower than after the second dose across all age groups (Figure 1). While the trend of fewer side effects following the booster dose relative to the second dose is congruous with the CDC data, the raw frequency of events differs greatly, likely due to the use of different data collection methods (phone app-based reporting vs. reporting to Israel Ministry of Health) and varying surveillance times (7 days vs. 30 days). These data were interpreted as supporting continued use of boosters in these age groups [8].

15. A pre-print from the UK evaluated the association between COVID-19 vaccination and myocarditis, stratified by age and sex, including 10,978,507 people receiving a third vaccine dose. Myocarditis risk was increased during 1-28 days following a third dose of Pfizer (IRR 2.02, 95%CI 1.40, 2.91). While they observed an increase in myocarditis events following a third dose of Pfizer, the risk remained small in the overall population with an estimated 2 additional cases of myocarditis per million following a booster dose of Pfizer [9].

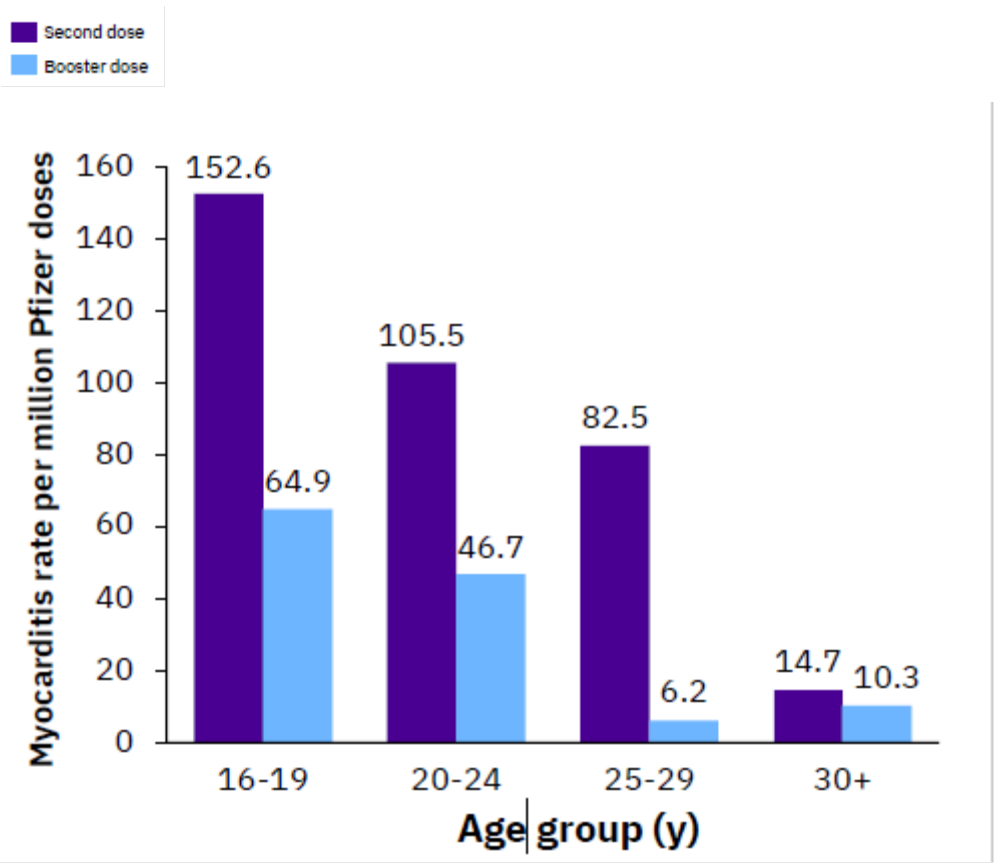


*Figure 1: Israel's myocarditis rates following second and booster dose of Pfizer in males. Source: Airfinity*

*Risk of myocarditis/pericarditis from the AstraZeneca vaccine*

16. *International data, risk of myocarditis after a primary course:* While there has been a consistent pattern of higher reporting of myocarditis after mRNA vaccines, the association between myocarditis and vaccination with AstraZeneca is less clear, although an increased risk of myocarditis after a first dose has been reported by one study [10, 11]. In particular, the pattern of reported myocarditis after AstraZeneca vaccination does not display the age or sex

characteristics seen with the mRNA vaccines, though notably this data reports all (suspected or confirmed) cases and therefore is not directly comparable to New Zealand's data (Tables 2 and 3) [10].

*Table 2 Number of UK ADR reports associated with suspected myocarditis, pericarditis and other related terms received for the COVID-19 Vaccine AstraZeneca, COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna by patient age to 23 Feb 2022 [10]*

| Age range (years) | COVID-19 Pfizer/BioNTech Vaccine | COVID-19 Vaccine Moderna | COVID-19 Vaccine AstraZeneca |
|---|---|---|---|
| Under 18 | 65 | 0 | 0 |
| 18-29 | 360 | 113 | 31 |
| 30-39 | 285 | 87 | 47 |
| 40-49 | 132 | 47 | 115 |
| 50-59 | 88 | 21 | 100 |
| 60+ | 140 | 15 | 100 |
| Unknown | 142 | 35 | 44 |
| Total | 1212 | 318 | 437 |

*Table 3 Number of UK ADR reports associated with suspected myocarditis, pericarditis and other related terms received for the COVID-19 Vaccine AstraZeneca, COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna by patient sex to 23 Feb 2022 [10]*

| Sex | COVID-19 Vaccine Pfizer/BioNTech | COVID-19 Vaccine Moderna | COVID-19 Vaccine AstraZeneca |
|---|---|---|---|
| Female | 477 | 105 | 198 |
| Male | 698 | 202 | 229 |
| Unknown | 37 | 11 | 10 |
| Total | 1212 | 318 | 437 |

17. *New Zealand data, risk of myocarditis after a primary course of AstraZeneca:* Up to 28 February, 262 AEFI reports have been received for the AstraZeneca COVID-19 vaccine, of which 17 have currently been classified as serious. The majority of serious reports have been allergic type reactions. There has been one reported case of a pulmonary embolism occurring in a consumer approximately two weeks after their first dose of the AstraZeneca vaccine. No cases of thrombosis with thrombocytopenia syndrome have been reported. There are currently two cases of reported pericarditis after the AstraZeneca vaccine under investigation:

    a. A consumer who developed pericarditis after their first dose of the Pfizer vaccine and it is unclear whether the report relates to this or a new onset of symptoms.
    b. A report of pericarditis in a consumer, who had a history of pericarditis prior to vaccination, after their AstraZeneca booster. The person received the Pfizer vaccine for their primary course and no AEFI reports were received associated with those doses.

    The COVID-19 Vaccine Independent Safety Monitoring Board reviewed the available safety data for the AstraZeneca vaccine at their meeting on 26th January 2022, with no concerns noted and the Board supported the recommendation for Medsafe to continue to monitor the safety of the AstraZeneca vaccine through routine pharmacovigilance.

18. *Risk from a booster dose:* In general, no additional safety concerns have been identified when AstraZeneca has been administered as a booster dose. In the UK, due to this limited usage and very small numbers of reports of suspected myocarditis and pericarditis after booster doses, the MHRA report states it is not possible to calculate a reliable reporting rate for

AstraZeneca when used as a booster; no association has been established between myocarditis or pericarditis and AstraZeneca [10].

*Risk from the Novavax vaccine*

19. *Risk from a primary course:* In the UK phase III trial, one case of myocarditis occurred three days after the second dose. It was adjudicated to most likely be viral myocarditis [12].

20. This vaccine has not been widely rolled-out and therefore does not have the breadth of safety data that is available for other vaccines in the portfolio. However, recombinant protein vaccines have previously been widely used against viruses and bacteria, therefore the long-term safety profile of this platform is generally well established. Continued safety monitoring is essential.

21. *Risk from a booster dose:* A phase II randomised controlled trial investigated a booster dose of Novavax administered 6 months after a primary series of Novavax in healthy adults aged 18-84 years, compared with placebo (n=383 total participants). The likelihood of short-term adverse reactions increased with each subsequent dose of this vaccine. Local and systemic adverse events were reported more frequently after the booster dose compared with after the second primary dose (local: 82.5% vs. 70.0%; systemic: 76.5% vs. 52.8%) [13].

22. Another phase II randomised controlled trial in adults aged 30 years or older (N=2,878) investigated a booster dose of Novavax administered approximately 2.5 months after a two dose primary series of AstraZeneca, or approximately 3 months after a two dose primary series of Pfizer in a heterologous vaccine schedule. Local and systemic adverse events following a Novavax booster dose were not frequently reported compared to the other booster vaccines investigated. However, they were more common in participants who had received an AstraZeneca primary series compared with those who received a Pfizer primary series. Overall, reactogenicity was greater in people aged 30 to 69 years compared to those aged 70 years and older [14].

*Vaccination after vaccine-related myocarditis/pericarditis and infection*

23. Data are scarce or absent about the safety of, and additional protection from, a booster dose after infection following vaccine-related myocarditis or pericarditis. The protection gained from infection alone has been shown to be inferior compared to protection conferred by COVID-19 vaccination after infection [15]. However, the extent of additional protection provided by a booster dose after infection remains unclear. COVID-19 vaccination after infection is generally well-tolerated. Previous COVID-19 infection is associated with a slight increase in side effects after subsequent vaccination, particularly fatigue (29% vs 20%), myalgia (30% vs 15%), fever (8% vs 2%) and lymphadenopathy (4% vs 1%) [16]. However, once again, it is not clear if this extends to those who experienced vaccine-related myocarditis during their primary course.

## International guidance on vaccination after myocarditis

24. ***The Australian Technical Advisory Group on Immunisation (ATAGI):*** ATAGI updated guidance on myocarditis and pericarditis after mRNA vaccination on 2 December 2021 (link).

    a. They state there is a small increased risk after Pfizer and Moderna, however COVID-19 itself is associated with a substantially higher risk. Vaxzevria (AstraZeneca) is not associated with an increased risk of myocarditis and/or pericarditis. While cases have

been reported after this vaccine, they have not been reported more frequently than what is expected in the absence of vaccination (the 'background rate') within Australia. People with a history of any of the following conditions can receive an mRNA vaccine but should consult a GP, immunisation specialist service or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:
    i. Recent (i.e., within the last 3 months) myocarditis or pericarditis
    ii. Acute rheumatic fever or acute rheumatic heart disease (i.e., with evidence of active inflammation)
    iii. Acute decompensated heart failure
b. ATAGI also state that 'Further doses of an mRNA COVID-9 vaccine can be given to people who have been investigated for pericarditis but who had normal ECG, troponin and inflammatory markers, and who have been symptom-free for at least 6 weeks. This includes people with a clinical diagnosis of pericarditis despite normal investigations.'
c. For people with suspected or proven pericarditis and abnormal investigation results, the need and choice of further doses is informed by age and sex.
d. **People who have had confirmed myocarditis attributed to a dose of Comirnaty (Pfizer) or Spikevax (Moderna) should defer further doses of an mRNA COVID-19 vaccine and if they are >18 years can consider Vaxzevria (AstraZeneca) on a case-by-case basis, after they have recovered from their symptoms.**

25. ***The UK's Joint Committee on Immunisation (JCVI):*** The JCVI has not issued specific guidance on the administration further vaccine doses if myocarditis has occurred after COVID-19 vaccination. However, the UK's "Green Book" (link, government-provided information for public health professionals on immunisation) currently provides advice:

    a. An individual's second or subsequent doses should be deferred pending further investigation and careful consideration of the risks and benefits.
    b. For those that experience myocarditis or pericarditis within two weeks of the first dose of an mRNA vaccine, testing for "N-antibody" may indicate prior exposure to COVID-19. These individuals are likely to be well protected and therefore the benefit from a second or subsequent dose is likely to be more limited.
    c. Where N antibody is negative or in other circumstances where a further dose is considered necessary, for example in those higher risk of the complications of COVID-19 infection**, a second or booster dose of Pfizer BioNTech vaccine should be considered once the patient has fully recovered.** Emerging evidence suggests that an interval of at least 12 weeks should be observed from the previous dose. Pfizer BioNTech is preferred over Moderna due to a slightly higher rate of myocarditis reported after the latter vaccine; AstraZeneca should not be offered to those who have previously received an mRNA vaccine given the more serious nature of thrombosis and thrombocytopenia syndrome.

26. ***The US Advisory Committee on Immunization Practices (ACIP):*** ACIP state that development of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided (link). ACIP recommend:
    a. Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive a subsequent dose of any COVID-19 vaccine. If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until at least after their episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by

patient's clinical team). For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise the use of Janssen COVID-19 Vaccine be considered instead of mRNA COVID-19 vaccines. These people should be aware of the risk of TTS. Considerations for subsequent vaccination may include:

i. The myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine
ii. Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
iii. Level of COVID-19 community transmission and personal risk of infection
iv. Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information.

27. ***The National Advisory Committee on Immunization (NACI), Canada***: On January 14, 2022, the Public Health Agency of Canada (PHAC) released updated guidance from the National Advisory Committee on Immunization (NACI) in the COVID-19 vaccine chapter of the Canadian Immunization Guide, on the topic vaccination following myocarditis and pericarditis. Notably, boosters continue to be recommended from six months after a primary series in Canada.

a. This chapter includes NACI's recommendations on the use of COVID-19 vaccines up to and including January 14, 2022. Rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the heart lining) following vaccination with COVID-19 mRNA vaccines have been reported in Canada and internationally. Most cases have occurred in males 12 to 29 years of age after a second dose of an mRNA vaccine. Most cases have been mild and resolved quickly. Following review of the latest evidence and consultation with Canadian cardiologists, NACI has issued updated guidance on re-vaccination with COVID-19 vaccines for those who experienced myocarditis and/or pericarditis after a previous dose of an mRNA COVID-19 vaccine.
b. Since June 2021, NACI has recommended that people who experienced myocarditis and/or pericarditis after a first dose of an mRNA COVID-19 vaccine should wait to get their second dose until more information was available. NACI continues to recommend that:
    **i.** In most circumstances, and as a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated troponins, echocardiogram, or cardiac MRI after a dose of an mRNA vaccine.
c. NACI now recommends that:
    i. Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next dose once they are symptom free and at least 90 days has passed since vaccination.
d. Some people with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider. If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30 mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt

of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.

## Recommendations

28. CV TAG met on 8 March 2022 to discuss advice for administering boosters after myocarditis and/or pericarditis.

29. **CV TAG noted that:**

    a. Currently only the Pfizer and AstraZeneca vaccines are approved for use as a booster. Novavax has been approved as a booster vaccine by the TGA in Australia and an application is expected to be submitted to Medsafe in the near future. However, it can currently only be used as a booster based on specific individual need by prescription for off-label use.

    b. Myocarditis and pericarditis are listed as a rare adverse events on the Pfizer data sheet [17]. However, they are not listed as being rare adverse events or contraindications for the AstraZeneca vaccine or Novavax vaccine.

    c. There have been a small number of cases of myocarditis and pericarditis reported in Aotearoa New Zealand, and there is limited information to fully characterise the risk of myocarditis after vaccination in Aotearoa New Zealand. Of the cases of myocarditis and/or pericarditis after COVID-19 vaccination in New Zealand (with a clinical diagnosis), 72% are European, 12% Asian, 11% Māori, 2% Pacific peoples, and 4% other/unknown ethnicity. The ethnicity distribution is very similar for all reported cases (including verified and unverified cases).

    d. There have been reports of myocarditis after AstraZeneca vaccine through adverse event monitoring systems in New Zealand and internationally. However, this has not occurred more frequently than the background rate. In Aotearoa New Zealand, usage has been too limited (8,376 doses administered since the end of November 2021) for separate estimates.

    e. The risk of thrombosis with thrombocytopaenia syndrome (TTS) has been shown to be linked to the AstraZeneca vaccine in post-marketing roll-out, and the relative risk of TTS compared with COVID complications while low is substantially higher for younger age groups.

    f. Earlier advice from CV TAG recommended that anyone who develops confirmed myocarditis and/or pericarditis after the first dose should not receive a second dose of the Pfizer COVID-19 vaccine, and CV TAG recommended AstraZeneca in people who have a contraindication to the Pfizer vaccine. CV TAG noted that if, after discussion with their health care provider, the individual and/or their whānau decides that the benefits of receiving two doses and gaining robust protection against COVID-19 sooner, outweigh the potential risks, then the individual may receive the second dose as per the current indication.

    g. International guidance from peak bodies states that after confirmed myocarditis and/or pericarditis, further doses should be deferred until symptoms resolve. The need for and choice of further doses is informed by age and sex after individual-level discussion of

risks and benefits with their healthcare provider. In Australia, AstraZeneca can be given on a case-by-case basis to people aged over 18. NACI and JCVI recommend further mRNA doses can be given if deemed appropriate after individual risk-benefit discussions.

h. COVID-19 itself is associated with a range of cardiac complications, the most common of which are heart failure, myocardial injury and arrhythmias. One UK study found an association between COVID-19 infection and myocarditis in all ages for all sexes, substantially higher in those older than 40 years. In people less than 40 years of age, the risk of myocarditis from COVID-19 was comparable to the risk from mRNA vaccination [18]. There are limited data about the safety of, and additional protection from, a booster dose after infection following vaccine-related myocarditis

i. CARM and the COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB) will continue to monitor closely and review any reports of myocarditis and/or pericarditis following COVID-19 vaccination in Aotearoa New Zealand.

30. **CV TAG recommended that**

a. For those who have had myocarditis and/or pericarditis after their second dose of the Pfizer vaccine, further doses of Pfizer should not be given, and any further COVID-19 vaccines should be deferred for at least 3 months.

b. Advice on the need for and type of booster given on recovery should be sought from a clinician caring for the individual (e.g. their cardiologist or primary care physician) on a case-by-case basis, with individualised support plans developed which take into account previous infection, sex, age, and previous symptoms as well as risk of exposure to SARS-CoV-2 and severe COVID-19.

c. If considered appropriate by the clinician, the Vaxzevria (AstraZeneca) vaccine or Nuvaxovid (Novavax) vaccine could be offered to people aged 50 years and over.

d. If considered appropriate by the clinician, the Nuvaxovid (Novavax) vaccine could be offered to people aged 18 to 49 (under prescription unless approved as a booster by Medsafe).

31. CV TAG will continue to monitor all relevant information and will update their recommendations as further evidence becomes available.

Ian G Town

Dr Ian Town

**Chief Science Advisor and**

**Chair of the COVID-19 Vaccine Technical Advisory Group**

## References


1. Petousis-Harris, H., *Background rates of myocarditis in New Zealand*. 2021: Confidential report, unpublished.
2. Medsafe. *Myocarditis and pericarditis – rare adverse reactions to Comirnaty (Pfizer COVID-19 vaccine)*. 21 July 2021; Available from: https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-alert.htm.
3. Global Vaccine Data Network. *GVDN*. 2022; Available from: https://gvdn.shinyapps.io/gvdn/.
4. Mevorach, D., et al., *Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel.* New England Journal of Medicine, 2021.
5. Minocha, P.K., et al., *Recurrence of Acute Myocarditis Temporally Associated with Receipt of the mRNA Coronavirus Disease 2019 (COVID-19) Vaccine in a Male Adolescent.* The Journal of pediatrics, 2021. **238**: p. 321-323.
6. Giuseppe Di Tano, et al., *Recurrent Myocarditis after the First Dose of SARS-CoV-2 mRNA-1273 Vaccine.* Annals of Clinical Case Reports, 2021.
7. Hause, A., Baggs, J., Marquez, P., et al. , *Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults — United States, September 22, 2021–February 6, 2022.* MMWR Morb Mortal Wkly Rep, 2022. **71**: p. 249–254.
8. Israel Ministry of Health. *Vaccine Safety Follow-Up*. 2021; Available from: https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_vaccine-safty-15122021.pdf.
9. Patone, M., et al., *Risk of myocarditis following sequential COVID-19 vaccinations by age and sex.* medRxiv, 2021: p. 2021.12.23.21268276.
10. UK MHRA. *Coronavirus vaccine - weekly summary of Yellow Card reporting 24 February 2022*. 2022; Available from: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting.
11. Patone, M., et al., *Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection.* Nature Medicine, 2021.
12. Heath, P.T., et al., *Efficacy of the NVX-CoV2373 Covid-19 Vaccine Against the B.1.1.7 Variant*. 2021, Cold Spring Harbor Laboratory.
13. Mallory, R., et al. *Immunogenicity and Safety Following a Homologous Booster Dose of a SARS-CoV-2 recombinant spike protein vaccine (NVX-CoV2373): A Phase 2 Randomized Placebo-Controlled Trial*. medRxiv 2021; 2021.12.23.21267374]. Available from: http://medrxiv.org/content/early/2021/12/24/2021.12.23.21267374.abstract.
14. Munro, A.P.S., et al., *Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial.* The Lancet, 2021. **398**(10318): p. 2258-2276.
15. Cavanaugh, A.M., et al., *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021.* MMWR. Morbidity and Mortality Weekly Report, 2021. **70**(32): p. 1081-1083.
16. Raw, R.K., et al., *Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination.* The Journal of infection, 2021. **83**(3): p. 381-412.
17. Medsafe - New Zealand Medicines and Medical Devices Safety Authority. *New Zealand Data Sheet, Comirnaty Covid-19 Vaccine*. 2021; Available from: https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.
18. Hurwitz, B. and O. Issa, *Management and Treatment of Myocarditis in Athletes.* Current Treatment Options in Cardiovascular Medicine, 2020. **22**(12): p. 65.