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19 January 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202116974

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 30 November 2021. You specifically asked:

> *"Please send to me the COVID-19 Vaccine Technical Advisory Group's (CV TAG) DRAFT & FINAL advice regarding myocarditis in under 30s, and the risk/benefit in that age group. - As per the request above, I would like to make it clear that I would like to see all versions of the above advice, including all DRAFT minutes from these meeting; not just the final advice"*

I have identified four documents within scope of your request. These include relevant excerpts of the COVID-19 Vaccine Technical Advisory Group (CV TAG) final meeting minutes from July 2021, the minutes that went to the committee as the draft, final advice from CV TAG regarding myocarditis and the draft memorandum. All documents are itemised in Appendix 1 and have been released to you in full.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Astrid Koornneef
Director
National Immunisation Programme

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	13 – 27 July 2021	Excerpts of COVID-19 Vaccine Technical Advisory Group draft minutes regarding myocarditis	Information released under section 16(1)(e) of the Act by giving an excerpt or summary of the contents.
2	13 – 27 July 2021	Excerpts of COVID-19 Vaccine Technical Advisory Group minutes regarding myocarditis	
3	14 July 2021	Draft Memo: Myocarditis following vaccination: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine	Released in full.
4	21 July 2021	Memo: Myocarditis following vaccination: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine	

Excerpt from COVID-19 CV TAG Draft Meeting Minutes: 13 July 2021

4.0	**Myocarditis Recommendations** • Draft recommendations on the risk of myocarditis after mRNA vaccination were presented to CV TAG. • It was noted that, this is a developing issue, and there are still several uncertainties in the data. • Based on preliminary US data, the risk of myocarditis after Pfizer vaccination is approximately 1 in 25,000 for males 12-29 years, and 1 in 240,000 for females 12-29 years. For individuals 30 and over, the corresponding risks decrease to approximately 1 in 400,000 for males, and 1 in a million for females. While the risk for females is lower than for males, it is still greater for younger people, and therefore any recommendation should be applied to all people aged under 30. • The New Zealand context of having no community transmission is important to consider, as the risk of COVID-19 is currently low and this effects the benefit:risk calculation.

	• It is also important to consider and review all cardiac-related events post-vaccination, rather than limiting the discussion to myocarditis. CV TAG noted that cardiac-related events after vaccination are being reported to CARM, and the Independent Safety Monitoring Board (ISMB) is reviewing reported cases. The Ministry will follow up on current cases under review.
	• Emerging evidence suggests one dose of the vaccine appears to be highly immunogenic, and provides greater protection in younger compared to older age groups, and therefore may provide sufficient protection in the interim, until further evidence emerges on second dose options.
	• CV TAG recommended that:
	  ○ The second dose of Pfizer vaccination be deferred in individuals aged 29 years and under until further information is available about the risk, long-term outcomes of myocarditis and/or pericarditis, and protection offered by one dose for this age group.
	  ○ People 29 years of age and younger who require regular clinical review by a cardiologist are advised to discuss the risks and benefits of the first dose of COVID-19 vaccine for their specific situation with their healthcare team.
	  ○ People aged 30 years and over should still receive two doses of the vaccine, 21 days apart as the risk of myocarditis and/or pericarditis post vaccination is less than 1 in 400,000 and risks of severe disease and sequelae due to COVID-19, including myocarditis, are substantially higher in this age group compared to people aged 29 years and under.
	  ○ Anyone who develops confirmed myocarditis and/or pericarditis after the first dose should not receive a second dose of the Pfizer COVID-19 vaccine. CV TAG will 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.
	  ○ CV TAG will continue to monitor all relevant effectiveness and safety data closely and advise on the need and options for the second dose for individuals aged 29 years and under at a future date. Options for the second dose may include: 1) proceeding with the second dose of the Pfizer COVID-19 vaccine after a longer interval between doses; 2) not administering a second dose; 3) administering a second dose of an alternative COVID-19 vaccine.
	  ○ If, after discussion with their health care provider, the individual and/or their whānau decides that the benefits and potential risks of vaccination outweigh the risks from COVID-19, then the individual may receive the second dose.
	• A memo with these recommendations is being prepared and will be shared with CV TAG for feedback. Public-facing communications will be drafted for CVIP Communications. Options will need to remain agile as further evidence emerges.
	• Cardiac-related events associated with alternative vaccine schedules will be explored by the Science and Technical Advisory team, as will the use of other options.
	• Given that vaccinating the whānau together is a key approach for delivering the vaccine to Māori, further discussion will be needed on the equity implications of these recommendations.

Excerpt from COVID-19 CV TAG Draft Meeting Minutes: 20 July 2021

5.0	**Myocarditis Recommendations Update**

- A Medsafe alert on myocarditis will be published later this week. The draft communication was shared with CV TAG, and feedback will be collated by the Secretariat to share back to Medsafe.
- CV TAG discussed the background rates of myocarditis, and rates post-Pfizer vaccination, internationally and in Aotearoa New Zealand.
    - It was agreed that the US rates provided the best available baseline for comparisons with Aotearoa New Zealand.
    - The US data is broken down further by gender, age group and follow-up time, and notes a risk of 1 in 25,000 for males aged 12-29 within 7 days of the second dose, and 1 in 238,000 for females aged 12-29 within 7 days of the second dose, for mRNA vaccines.
    - Severity measures should also be incorporated into the presentation of the data, for example hospitalisation and/or ICU admission rates, if data are available.
- Draft recommendations on the risk of myocarditis after Pfizer vaccination were discussed.
    - CV TAG noted that there is some evidence that young people aged 16 to 29 years perform well immunologically after one dose, however that two doses provide the best protection. A delayed schedule for the second dose was discussed. Whether this potentially reduces the risk of myocarditis, in addition to the severity of other adverse events, is unknown.
    - CV TAG recommended that for people aged 16 to 29 years the second dose be administered 8 weeks after the first.
    - It was outlined that this would have practical implications for the booking system, planning mass vaccination events, and public risk communications.
- A memo with these recommendations will be updated and provided to the Director-General and CVIP.

Excerpt from COVID-19 CV TAG Draft Meeting Minutes: 27 July 2021

2.0	**Myocarditis Recommendations Update** The final memo on Myocarditis after Pfizer mRNA vaccination was shared with CV TAG and discussed. • The final memo included input and advice from Medsafe, who the Ministry have been working with to align advice and recommendations. • The Director-General has received the recommendations, and an implementation plan is currently being prepared within the Ministry to update the booking arrangements, planning of mass vaccination events, and public risk communications. • CV TAG discussed the data supporting longer dosing intervals for Pfizer; Data showed higher immunogenicity was associated with an extended dosing interval (median 10 weeks) compared to the usual 3-4 weeks. • Draft messaging and timelines will be shared with CV TAG when available, for sharing with the wider sector. Consultation is needed with the Cardiac Society prior to the announcement. • CV TAG discussed the recommended dosing interval for people under 30 years. CV TAG discussed the while an 8-week interval is recommended for this age group, administering the second dose between 6 and 12 weeks is acceptable, and that the exact timing is a programming decision. It was agreed that the change must communicated in a way to provide clarity.

Excerpt from COVID-19 CV TAG Meeting Minutes: 13 July 2021

4.0	**Myocarditis Recommendations** • Draft recommendations on the risk of myocarditis after mRNA vaccination were presented to CV TAG. • It was noted that, this is a developing issue, and there are still several uncertainties in the data. • Based on preliminary US data, the risk of myocarditis after Pfizer vaccination is approximately 1 in 25,000 for males 12-29 years, and 1 in 240,000 for females 12-29 years. For individuals 30 and over, the corresponding risks decrease to approximately 1 in 400,000 for males, and 1 in a million for females. While the risk for females is lower than for males, it is still greater for younger people, and therefore any recommendation should be applied to all people aged under 30.

	• The New Zealand context of having no community transmission is important to consider, as the risk of COVID-19 is currently low and this effects the benefit:risk assessment.
	• CV TAG noted that cardiac-related events after vaccination are being reported to CARM, and the Independent Safety Monitoring Board (ISMB) is reviewing reported cases.
	• Emerging evidence suggests one dose of the vaccine appears to be highly immunogenic, and provides greater protection in younger compared to older age groups, and therefore may provide sufficient protection in the interim, until further evidence emerges on second dose options.
	• CV TAG progressed to summarise an initial draft of the approach:
	  ○ The second dose of Pfizer vaccination could be deferred in individuals aged 29 years and under until further information is available about the risk, long-term outcomes of myocarditis and/or pericarditis, and protection offered by one dose for this age group.
	  ○ People 29 years of age and younger who require regular clinical re iew by a cardiologist are advised to discuss the risks and benefits of the first dose of COVID-19 vaccine for their specific situation with their healthcare team
	  ○ People aged 30 years and over should still receive two doses of the vaccine, 21 days apart as the risk of myocarditis and/or pericarditis post vaccination is less than 1 in 400,000 and risks of severe disease and sequelae due to COVID-19, including myocarditis, are substantially higher in this age group compared to people aged 29 years and under.
	  ○ Anyone who develops confirmed myocarditis and/or pericarditis after the first dose should not receive a second dose of the Pfizer COVID-19 vaccine. CV TAG will 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.
	  ○ CV TAG will continue to monitor all relevant effectiveness and safety data closely and advise on the need and options for the second dose for individuals aged 29 years and under at a future date. Options for the second dose may include: 1) proceeding with the second dose of the Pfizer COVID-19 vaccine after a longer interval between doses; 2) not administering a second dose; 3) administering a second dose of an alternative COVID-19 vaccine.
	• A memo with these recommendations is being prepared and will be shared with CV TAG for feedback. Public-facing communications will be drafted for CVIP Communications. Options will need to remain agile as further evidence emerges.
	• Cardiac related events associated with alternative vaccine schedules will be explored by the Science and Technical Advisory team, as will the use of other options.
	• Given that vaccinating the whānau together is a key approach for delivering the vaccine to Māori, further discussion will be needed on the equity implications of these recommendations.
	• The Director-General will need to be consulted about the options and the CVIP team will need to consider the implications for the programme.

Excerpt from COVID-19 CV TAG Meeting Minutes: 20 July 2021

5.0	**Myocarditis Recommendations Update**

	• A Medsafe alert on myocarditis will be published later this week. The draft communication was shared with CV TAG, and feedback will be collated by the Secretariat to share back to Medsafe.
	• CV TAG discussed the background rates of myocarditis, and rates post-Pfizer vaccination, internationally and in Aotearoa New Zealand.
	  ○ It was agreed that the US rates provided the best available baseline for comparisons with Aotearoa New Zealand.
	  ○ The US data is broken down further by gender, age group and follow-up time, and notes a risk of 1 in 25,000 for males aged 12-29 within 7 days of the second dose, and 1 in 238,000 for females aged 12-29 within 7 days of the second dose, for mRNA vaccines.
	  ○ Severity measures should also be incorporated into the presentation of the data, for example hospitalisation and/or ICU admission rates, if data are available.
	• Draft recommendations on the risk of myocarditis after Pfizer vaccination were discussed.
	  ○ CV TAG noted that there is some evidence that young people aged 16 to 29 years have a strong immune response after one dose, however that two doses provide the best protection. A delayed schedule for the second dose was discussed. Whether this potentially reduces the risk of myocarditis, in addition to the severity of other adverse events, is unknown.
	  ○ CV TAG recommended that for people aged 16 to 29 years the second dose be administered at least 8 weeks after the first.
	  ○ It was noted that this would have practical implications for the booking system, planning mass vaccination events, and public risk communications.
	• A memo with these recommendations will be updated and provided to the Director-General and CVIP.

Excerpt from COVID-19 CV TAG Meeting Minutes: 27 July 2021

2.0	**Myocarditis Recommendations Update** The final memo on Myocarditis after Pfizer mRNA vaccination was shared with CV TAG and discussed. • The final memo included input and advice from Medsafe. • The Director-General has received the recommendations, and an implementation plan is currently being prepared within the Ministry, once the recommendations have been agreed by Ministers • CV TAG discussed the data supporting longer dosing intervals for Pfizer; Data showed higher immunogenicity was associated with an extended dosing interval (median 10 weeks) compared to the usual 3-4 weeks. • CV TAG discussed the recommended dosing interval for people under 30 years. CV TAG discussed the while an 8-week interval is recommended for this age group, administering the second dose between 6 and 12 weeks is acceptable, and that the exact timing is a programming decision. • It was agreed that all changes must communicated in a way to provide clarity.

Memo

Myocarditis following vaccination: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine

Date:	14 July 2021
To:	Dr Ashley Bloomfield, Director-General of Health
Cc:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme Allison Bennett, Manager, System Enablers, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Information

Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the use of Pfizer mRNA COVID-19 vaccination in the context of the potential risk of myocarditis and/or pericarditis following vaccination.

Context

2. Myocarditis is an inflammation of the heart muscle; pericarditis is an inflammation of the thin tissue surrounding the heart (pericardium); myopericarditis is myocarditis accompanied by pericarditis.
3. Cases of myocarditis and/or pericarditis have been reported following administration of both the Pfizer and Moderna mRNA COVID-19 vaccines.
4. Emerging data from the US and Israel, indicate that there appears to be a risk of myocarditis and/or pericarditis following Pfizer vaccination. The risk appears to be higher following the second dose, in males and in younger age groups.
5. Background rates for myocarditis and/or pericarditis in younger populations should be considered for context, and tend to be age-dependent. Estimated incidence ranges from between 1-2 per 100,000 person years for 0-19 year-olds, which corresponds to a risk of approximately 1 in 100,000 to 1 in 50,000 people over the course of a year. However, the background risk is higher for boys over 12 years. For example, in one national study in Finland, the risk of myocarditis was approximately 2 per 100,000 person-years overall for the 0-15 year-olds. This increased to approximately 5 per 100,000 for 12-13 year-olds, and 14 per 100,000 person-years for 14-15 year-olds, which corresponds to 1 in 20,000 and 1 in 7,000 over the course of a year, respectively. Note that these background estimates are taken for all

causes *annually*, but the risks in the context of vaccination are typically considered with a much shorter time interval, typically within 7-30 days after vaccination.

6. The evidence is still emerging, but in a presentation on 23 June 2021 to the US Advisory Committee on Immunisation Practices (ACIP), the risk of myocarditis and/or pericarditis following vaccination with Pfizer in the US was estimated to be approximately 1 in 36,000 doses, in 12–39 year-old males within 21 days following the second dose. There is limited information on the severity of cases, long-term effects, and it is yet unknown whether the risk may vary by ethnicity. Overall, the US ACIP recommended that the benefits of using mRNA COVID-19 vaccines such as Pfizer and Moderna clearly outweighed the risks in all populations, including adolescents and young adults for the US population, in the context of an ongoing pandemic in the US

7. On 25 June 2021, the United States Food and Drug Administration added a warning for myocarditis and pericarditis to the Pfizer and Moderna COVID-19 vaccine fact sheets after observing cases following vaccination. Although evidence is still emerg ng, data from the US Vaccine Safety Datalink (VSD) active surveillance network supports a causal link to mRNA vaccines.

8. In Israel, the Ministry of Health reported in a press release that 121 cases of myocarditis had been reported within 30 days of a second dose of mRNA vaccine, out of approximately 5 million individuals. This corresponds to an overall popul tion risk after the second dose of approximately 1 in 42,000. Limited information was available in the press release, however, the Israeli Ministry of Health reported that events were mostly reported in young men aged 16-19 years, usually after the second dose. Most cases were hospitalised but 95% of cases were considered to have mild illness that passed within a few days.

9. In Australia, to 27 June 2021, the Therapeutic Goods Administration (TGA) has received reports of 26 cases of suspected myocarditis or pericarditis: "*During this time, approximately 2.9 million Comirnaty doses have been given. Eight of the TGA reports were in men and 18 were in women. One of the men was 18 years old and another was 23 years old, while the others were aged 41–72 years. The women were aged 23–47 years old. At the time of reporting, the majority of individuals had recovered or were recovering*". TGA has sought advice on this issue from the Australian Technical Advisory Group on Immunisation (ATAGI), who are closely monitoring this issue.

10. In Aotearoa New Zealand, as of 01 July 2021, 10 reports of myocarditis or pericarditis occurring in individuals following vaccination with the Pfizer COVID-19 vaccine have been confirmed by Centre for Adverse Reactions Monitoring (CARM). An additional 3 unconfirmed reports of myocarditis or pericarditis have been received by CARM. Of the 10 confirmed cases, 4 were male, 4 were in 15-34 year-olds, and the ages of the individuals ranged from 24-63 years. Reported time from vaccination to onset was up to 18 days, with 2 cases occurring after the first dose and 8 after the second dose. All cases have been medically assessed and follow-up information sought.

11. In Aotearoa New Zealand, as of 01 July 2021, 84,025 individuals aged 15-34 years have received two doses of the Pfizer vaccine, with 31,365 of these being male.

12. It is also important to consider, with regards to benefit-risk, the risks posed by COVID-19 itself. COVID-19 is associated with a range of cardiac complications, the most common of which are heart failure, myocardial injury, and arrhythmias. The magnitude of the risk of myocarditis after COVID-19 is uncertain. One preliminary study estimated the risk to be

approximately 0.01% for COVID-19 patients overall. A US study of young college athletes with a history of COVID-19 reported that between 0.3-2.3% had myocarditis, depending on the diagnostic criteria.

13. In addition, the US CDC reported that another serious complication associated with COVID-19, multisystem inflammatory syndrome in children (MIS-C), occurs at a rate of approximately 2.1 per 100,000 person-years in children and young adults aged 0-21 years. There are a number of unknowns, but emerging evidence suggest that the risk of MIS-C is age-dependent, with a rate of 2-3 per 100,000 person-years in children aged 14 and under, and 0-1.5 in young adults aged 15-20 years.

14. With regards to vaccine hesitancy, younger individuals (i.e., under the age of 30) tend to be more vaccine hesitant than older age groups. Vaccine hesitancy appears to not be differentially associated with ethnicity in Aotearoa New Zealand once age and educational differences are accounted for.

15. The Ministry's Policy team sought clinical and scientific advice from CV TAG on the potential risk of myocarditis following vaccination. This advice will be considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Vaccine and Immunisation Programme.

Recommendations

16. CV TAG met 0n 06 July 2021 and a subgroup of the CV TAG assisted by a paediatric cardiologist met again on 08 July 2021 to discuss the potential risk of myocarditis and/or pericarditis after Pfizer mRNA COVID-19 vaccination.

17. CV TAG noted that:

- In general, two doses of the Pfizer vaccine are recommended for robust protection, as per the provisional Medsafe approval.
- Symptom onset for myocarditis and/or pericarditis following mRNA COVID-19 vaccination is usually within 7 days following vaccination, and can present with chest pain, laboured breathing, and/or racing pulse.
- There have been cases of myocarditis reported in New Zealand, however, at this stage there is limited information to fully characterise the risk of myocarditis.
- Preliminary evidence suggests that the rate of myocarditis appears to be higher after the second dose, in males and younger age groups, particularly in males aged 16-30 years.
- There are no pre-existing conditions or other factors known to be associated with increased risk of myocarditis in children or adults. Although the risks of myocarditis tend to be age- and gender-dependent in the general population, there is not enough evidence to date to recommend a precaution for a particular pre-existing condition or demographic.
- In particular, there is no evidence, to date, to suggest that pre-existing rheumatic heart disease is a risk factor for myocarditis. In Aotearoa New Zealand, rheumatic heart disease is prevalent in several populations who may be particularly vulnerable to COVID-19, including in Māori and Pacific Peoples.

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

18. CV TAG recommends that:

    - Those that are currently under active clinical management for a heart condition are advised to discuss the risks and benefits of COVID-19 vaccination with their healthcare team prior to vaccination.
    - For those that experience myocarditis after the first dose consideration should be given to delaying the second dose. Use of an alternative vaccine be considered when it becomes available.
    - The general population should still be administered two doses of the vaccine at least 21 days apart.

19. The evidence on myocarditis/pericarditis following COVID-19 vaccination is still very preliminary. CV TAG will continue to review information nationally and internationally, and will update their recommendations as further evidence becomes available.

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group

Memo

Myocarditis following vaccination: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine

Date:	21 July 2021
To:	Dr Ashley Bloomfield, Director-General of Health
Cc:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme Maree Roberts, DDG, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Information

Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the use of Pfizer mRNA COVID-19 vaccine in the context of the risk of myocarditis and/or pericarditis following vaccination.

Context

2. Myocarditis is an inflammation of the heart muscle; pericarditis is an inflammation of the thin tissue surrounding the heart (pericardium). Hereafter the risk will be referred to as myocarditis and/or pericarditis.

3. Emerging 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 appears to be higher following the second dose, in males and in younger age groups.

4. Background rates for myocarditis and/or pericarditis in younger populations tend to be age-dependent; based on international data, the estimated incidence rate ranges from 8.4-20 per million person-years for 0-19 year-olds (which corresponds to a risk of approximately 1 in 50,000 to 1 in 119,000 people over the course of a year). However, the background risk for children and young adults (i.e. how often myocarditis and/or pericarditis occurs each year from general observation) is highest for male children and adolescents aged over 12 years (see Table 1).

Table 1. Background rates for myocarditis in Aotearoa New Zealand and internationally

Country	Demographic	Rate per million person-years	Approximate risk over 1 year (to nearest 1000)	Source
New Zealand	Total population	18.1	1 in 55,000	Preliminary results from Dr Helen Petousis-Harris[1]
	Māori	19.5	1 in 51,000	
	Pacific Peoples	17.9	1 in 56,000	
	Males	24.3	1 in 41,000	
	Females	12.1	1 in 83,000	
	0-9 years	2.0	1 in 500,000	
	10-19 years	7.6	1 in 132,000	
	20-19 years	21.3	1 in 47,000	
US	Total population	10-100	1 in 10,000 to 1 in 100,000	Gubernot, D., et al, 2021[2]
UK	0-19 years	20.0	1 in 50,000	ACCESS (based on CPRD GP database)[3]
Italy	0-19 years	8.4	1 in 119,000	ACCESS (based on PediaNET, Italian GP database)[3]
Finland	0-15 years	19.5	1 in 513,000	Arola et al, 2017[4]
	Males, 0-11 years	Approximately 0-20	1 in 50,000 to NE*	
	Males, 12-15 years	Approximately 50 135	1 in 7,400 to 1 in 20,000	
	Females, 0-11 years	Approximately 0-10	1 in 100,000 to NE*	
	Females, 12-15 years	Approximately 10-35	1 in 29,000 to1 in 100,000	

*NE=Not estimable

5. COVID-19 itself is associated with a range of cardiac complications, the most common of which are heart failure, myocardial injury and arrhythmias.[5] The magnitude of the risk of myocarditis after COVID-19 is uncertain. A USA study published in JAMA Cardiology of 1,597 young college athletes with a history of COVID-19 reported that between 0.3-2.3% had myocarditis, depending on the diagnostic criteria.[6]

6. Background rates for 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 (see Table 1). For Māori the rate was 1.95 per 100,000 person-years, and for Pacific Peoples 1.79 per 100,000 person-years. With regards to age, the rates of myocarditis in children and young adults were: 0.20 per 100,000 person-years in 0-9 year-olds, 0.76 per 100,000 person-years in 10-19 year-olds, and 2.13 per 100,000 person-years in 20-29 year-olds. Note that these background rates are for events coded for myocarditis alone; background rates for myocarditis and/or pericarditis for Aotearoa New Zealand are not available.[1]

7. Based on data presented on 23 June 2021 to the United States Centre for Disease Control and Prevention (CDC) Advisory Committee on Immunisation Practices (ACIP) and follow-up data published 06 July 2021, the risk of myocarditis and/or pericarditis over the 7 days after the second dose of the mRNA COVID-19 vaccines was estimated to be approximately 1 in 25,000 for males 12-29 years, and 1 in 240,000 for females 12-29 years (see Table 2). For individuals 30 years and over, the corresponding risks were approximately 1 in 420,000 for males, and 1 in 1,000,000 for females. While the risk for females is lower than for males, it is still greater overall for younger people.[7, 8] In addition, lower rates of myocarditis could in part be due to under-diagnosis in women.[9]

Table 2. Risk of myocarditis after administration of the second dose of Pfizer and/or Moderna mRNA COVID-19 vaccines

Country	Demographic, follow-up time, dose, vaccine type	Incidence per million second doses	Approximate risk within 7 days of dose 2 (to nearest 1000)	Source
US	Males, 12-29 years, within 7 days post dose 2 of mRNA vaccine	40.6	1 in 25,000	Gargano et al, 2021[7] based on confirmed and unconfirmed cases after administration of an mRNA COVID-19 vaccine (Pfizer or Moderna), reported to VAERS.
	Males, 30 years and over, within 7 days post dose 2 of mRNA vaccine	2.4	1 in 417,000	
	Females, 12-29 years, within 7 days post dose 2 of mRNA vaccine	4.2	1 in 238,000	
	Females, 30 years and over, within 7 days post dose 2 of mRNA	1.0	1 in 1,000,000	
	12-39 year-olds, within 21 days following dose 2 of an mRNA vaccine	12.6	1 in 79,000	Chart confirmed cases following dose 2 of Pfizer, reported to Vaccine Safety Datalink (VSD), US CDC ACIP, 23 June 2021[8]
	12-39 year olds, within 21 days following dose 2 of Pfizer COVID-19 vaccine	8.0	1 in 125,000	
	Males, 12-39 years, within 21 days post dose 2 of Pfizer COVID-19 vaccine	23.0	1 in 43,000	ICD-10 coded cases following dose 2 of Pfizer, reported to Vaccine Safety Datalink (VSD), US CDC ACIP, 23 June 2021[8]
	Females, 12-39 years, within 21 days post dose 2 of Pfizer COVID-19 vaccine	NE*	NE	

*NE=not estimable

8. There is limited information on the long-term effects of myocarditis after vaccination and it is yet unknown whether the risk may vary by ethnicity. Overall, the USA ACIP recommended that the benefits of using mRNA COVID-19 vaccines such as Pfizer and Moderna clearly outweighed the risks in all populations, including adolescents and young adults for the USA population, **in the context of an ongoing pandemic in the USA.**

9. On 25 June 2021, the United States Food and Drug Administration (FDA) added a warning for myocarditis and pericarditis to the Pfizer and Moderna COVID-19 vaccine fact sheets after

observing cases following vaccination.[10] Although evidence is still emerging, data presented to the US CDC's ACIP support a causal link to mRNA vaccines.

10. On 09 July 2021, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) recommended adding myocarditis and/or pericarditis as a side effect for the Pfizer and Moderna vaccines, and added a warning for myocarditis to both vaccines. The PRAC reviewed 145 cases of myocarditis that were reported in the European Economic Area (EEA) among people who received Pfizer, and 19 cases among people who received Moderna. Separately, the PRAC also reviewed reports of 138 cases of pericarditis following the use of Pfizer and 19 cases following the use of Moderna. As of 04 July 2021 approximately 276 million doses of Pfizer and 20 million doses of Moderna had been administered in the European Union/EEA.

11. In Israel, the Ministry of Health reported in a press release that 121 cases of myocarditis had been reported within 30 days of a second dose of mRNA vaccine, out of approximately 5 million vaccinated individuals. This corresponds to an overall population risk after the second dose of approximately 1 in 42,000. Limited information was available in the press release, however, the Israeli Ministry of Health reported that events were mostly reported in young men aged 16-19 years, usually after the second dose. It was also reported that most cases were hospitalised but 95% of cases were considered to have mild illness with recovery over a few days.

12. In Canada, up to 09 July 2021, 111 cases of myocarditis and/or pericarditis have been reported to the Public Health Agency of Canada (PHAC) or Health Canada following administration of the Pfizer COVID-19 vaccine. Of those, 26 cases followed the second dose.[13] Through 10 July 2021, approximately 7.8 million second doses of the Pfizer COVID-19 vaccine have been administered in Canada.[14] This corresponds to an approximate rate for myocarditis and/or pericarditis of 3.3 per million second doses, or 1 in 303,000. Of note, in Canada the immunisation schedule for the Pfizer COVID-19 vaccine allows an interval of up to 16 weeks (4 months).

13. In Australia, to 04 July 2021, the Therapeutic Goods Administration (TGA) has received reports of 38 cases of suspected myocarditis and/or pericarditis following vaccination (note that the vaccine type was not specified in TGA's Weekly Safety Report for 08 July 2021). Approximately 3.2 million doses have been administered in Australia to the 08 July 2021, which corresponds to a risk of approximately 1 in 84,000 doses (this includes first and second doses). TGA stated that, of the 38 reports, "*…13 reports were in men and 25 were in women. Of the men, five were aged 17–23 years, while the others were aged 41–72 years. The women were aged 22–65 years old with the most aged in their 20s and 30s. At the time of reporting, the majority of individuals had recovered or were recovering*". TGA has sought advice on this issue from the Australian Technical Advisory Group on Immunisation (ATAGI), who are closely monitoring this issue. As of 08 July 2021, the TGA states that it plans to add a warning to the Product Information regarding myocarditis and/or pericarditis.

14. In Aotearoa New Zealand, as of 01 July 2021, 10 reports of myocarditis and/or pericarditis occurring in individuals following vaccination with the Pfizer COVID-19 vaccine have been received by Centre for Adverse Reactions Monitoring (CARM). Of the 10 cases, 4 were male, 2 were in individuals less than 30 years old (1 male, 1 female), and the ages of the individuals ranged from 24-63 years. Reported time from vaccination to onset was up to 18 days, with 2 cases occurring after the first dose and 8 after the second dose. All cases have been medically assessed by CARM and follow-up information sought.

15. In Aotearoa New Zealand, Medsafe has been monitoring this emerging signal for some time with data provided by CARM and regulators internationally. Medsafe has briefed the Independent Safety Monitoring Board (ISMB) frequently with updates on data and received advice including the need to communicate early to consumers and healthcare professionals. Medsafe issued a monitoring communication on 9 June 2021 to highlight this potential adverse reaction of myocarditis and seeking further information from healthcare professionals to help with our assessment of the signal. Whilst the New Zealand data do not currently indicate an association between the Pfizer COVID-19 vaccine (Comirnaty) and myocarditis, the international data does. Therefore, Medsafe has confirmed that Pfizer will update the data sheet for the Pfizer COVID-19 vaccine. The wording will be similar to the recent United Kingdom update: *There have been very rare reports of myocarditis and pericarditis occurring after vaccination with Comirnaty often in younger men and shortly after the second dose of the vaccine. These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. Health care professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should also seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrythmias.*

16. In Aotearoa New Zealand, Medsafe intends to publish an updated communication on myocarditis/pericarditis associated with Comirnaty. The communication is an update to the June communication and will provide the proposed wording above, with advice to healthcare professionals and consumers. The communication confirms that, after assessing the data currently available on myocarditis, the benefits of vaccination with Comirnaty continue to outweigh the risk of experiencing a side effect for people of all ages in the approved indication. The communication has been shared for comment with the ISMB, the CVTAG, and Medicines Adverse Reactions Committee (MARC). Medsafe will publish this information to ensure advice based on the current evidence is available to healthcare professionals and the public.

17. Medsafe has discussed the signal of myocarditis with its international regulatory partners on a number of occasions, most recently on 21 July 2021. All regulatory partners who were present on 21 July 2021 (US FDA, Health Canada, Singapore, Australia, Israel, European Medicines Agency) agree that the product information should be updated in line with the wording above (or similar). All agree that the benefits of vaccination with Comirnaty continue to outweigh the risks for people of all ages in the approved indication and no changes to the dosing schedule have been put in place or recommended.

18. Medsafe will continue to monitor local and international reports of myocarditis and/or pericarditis with support from CARM and the ISMB. Medsafe will also be taking a review of myocarditis and/or pericarditis reports associated with Comirnaty to the next meeting of the Medicines Adverse Reactions Committee (MARC). The MARC is an independent, Ministerial appointed, expert advisory committee who provides expert advice to Medsafe on the regulation of medicines.

19. In Aotearoa New Zealand, as of 14 July 2021, 64,298 individuals aged 15-29 years have received two doses of the Pfizer vaccine, including 5,922 Māori and 5,196 Pacific Peoples.

20. With regards to vaccine hesitancy, younger individuals (i.e., under the age of 30) tend to be more vaccine hesitant than older age groups. Vaccine hesitancy appears to not be differentially associated with ethnicity in Aotearoa New Zealand once age and educational differences are accounted for.

21. The Ministry's Policy team sought clinical and scientific advice from CV TAG on the potential risk of myocarditis following vaccination. This advice will be considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Vaccine and Immunisation Programme.

Recommendations

22. CV TAG met on 06 July 2021 and 20 July 2021, assisted by a paediatric cardiologist, to consider recommendations regarding the potential risk of myocarditis and/or pericarditis after Pfizer mRNA COVID-19 vaccination.

23. **CV TAG noted that:**

    a) Two doses of the Pfizer vaccine are recommended to achieve the maximum level of protection, as per the provisional Medsafe approval. This is true for people of all ages and is particularly important for those 30 years and over who are more at risk of severe disease from COVID-19.

    b) Symptom onset for myocarditis and/or pericarditis following mRNA COVID-19 vaccination is usually within 7 days following the second dose, and can present with chest pain, breathlessness, and/or racing pulse.

    c) There have been a small number of cases of myocarditis reported in Aotearoa New Zealand. There is limited information to fully characterise the risk of myocarditis after vaccination in Aotearoa New Zealand.

    d) There are no pre-existing conditions or other factors known to be associated with increased risk of myocarditis in children or adults. Although the risks of myocarditis tend to be age and gender-dependent in the general population, there is not enough evidence to date to recommend a precaution for any pre-existing conditions.

    e) There is no evidence, to date, to suggest that pre-existing rheumatic heart disease is a risk factor for myocarditis. In Aotearoa New Zealand, rheumatic heart disease is prevalent in several populations who may be particularly vulnerable to COVID-19, including in Māori and Pacific Peoples.

    f) 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.

24. **CV TAG recommends that:**

    a) People aged 16-29 years receive their second dose of the Pfizer COVID-19 vaccine at least 8 weeks after the first dose. A longer interval between doses may reduce the frequency of some side effects while conferring robust protection from COVID-19.

    b) People aged 12-29 years who require regular clinical review by a cardiologist are advised to discuss the risks and benefits of the COVID-19 vaccine with their healthcare team in order to plan a vaccination schedule that best supports their needs.

    c) People aged 30 years and over should still receive two doses of the vaccine, at least 21 days apart. Myocarditis and/or pericarditis after vaccination in this group is rare,

and the risks of severe disease and sequelae due to COVID-19 are substantially higher in older compared to younger age groups.

d) Anyone who develops confirmed myocarditis and/or pericarditis after the first dose should not receive a second dose of the Pfizer COVID-19 vaccine. CV TAG will 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.

e) 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.

25. The evidence on myocarditis and/or pericarditis following COVID-19 vaccination is still preliminary. CV TAG will continue to monitor all relevant information and will update their recommendations as further evidence becomes available.

Ian G Town

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