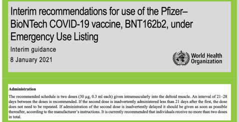
ANNEX B

12–15 YEAR OLD REGULATORY APPROVAL AND ROLL-OUT ADVICE

TIMELINE

Body	Role
Medsafe	Regulatory approval (safety/efficacy for use)
Covid-19 Vaccine Technical Advisory Group. (CV-TAG)	Vaccine policy advice (who to vaccinate, dosing, intervals, boosters etc.)
COVID-19 Vaccine Independent Safety Monitoring Board. (CV-ISMB)	Independent safety monitoring
Strategic Technical Advisory Group	– Internal science and technical advice / analysis
Ministry of Health	Policy advice to Ministers
Cabinet	Final decisions
Vaccine Ministers	**Chair:** **Hon Chris Hipkins**, Minister for COVID-19 Response **Rt Hon Jacinda Ardern**, Prime Minister **Hon Grant Robertson**, Minister of Finance; Minister of Infrastructure **Hon Andrew Little**, Minister of Health **Hon Dr Ayesha Verrall**, Associate Minister of Health **Hon Aupito William Sio**, Associate Minister of Health **Hon Peeni Henare**, Associate Minister of Health

8 January 2021
Pfizer's recommended dosing schedule: A three-week interval based on the initial study to provide 95% protection against symptomatic COVID-19.



Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing

Interim guidance

8 January 2021

World Health Organization

Administration

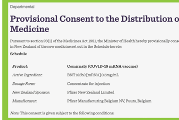
The recommended schedule is two doses (30 µg, 0.3 ml each) given intramuscularly into the deltoid muscle. An interval of 21–28 days between the doses is recommended. If the second dose is inadvertently administered less than 21 days after the first, the dose does not need to be repeated. If administration of the second dose is inadvertently delayed it should be given as soon as possible thereafter, according to the manufacturer's instructions. It is currently recommended that individuals receive no more than two doses in total.

https://iris.who.int/server/api/core/bitstreams/461c4424-5d1c-4dd6-a510-6230a0ca15f5/content

!

Claimed effectiveness of 95% was based on the relative risk reduction. Actual effectiveness was approximately **0.84%,** representing the absolute risk reduction.

3 February 2021
Medsafe grants provisional consent for the Pfize
subject to 58 conditions, for those 16 years and
Noting that protection had only been assessed
months, evidence of protection against severe
was limited, long-term safety data were unava
prevention of asymptomatic infection and tran
had not been established.



Departmental

Provisional Consent to the Distribution o
Medicine

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally cons
in New Zealand of the new medicine set out in the Schedule hereto:

Schedule

Product:	**Comirnaty (COVID-19 mRNA vaccine)**
Active Ingredient:	BNT162b2 [mRNA] 0.5mg/mL
Dosage Form:	Concentrate for injection
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturer:	Pfizer Manufacturing Belgium NV, Puurs, Belgium

Note: This consent is given subject to the following conditions:

https://gazette.govt.nz/notice/id/2021-go338

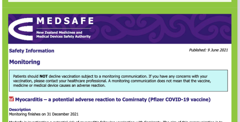
er vaccine,
above.
to two
disease
ilable, and
smission

f a New

ents to the sale, supply or use

9 June 2021

Medsafe issues public safety information monitoring of myocarditis as a potential risk following the Pfizer vaccine and encourages further adverse event reporting.



MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Safety Information *Published: 9 June 2021*

Monitoring

Patients should **NOT** decline vaccination subject to a monitoring communication. If you have any concerns with your vaccination, please contact your healthcare professional. A monitoring communication does not mean that the vaccine, medicine or medical device causes an adverse reaction.

Myocarditis – a potential adverse reaction to Comirnaty (Pfizer COVID-19 vaccine)

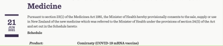
Description
Monitoring finishes on 31 December 2021

Medsafe is investigating a potential risk of myocarditis following vaccination with Comirnaty. The aim of this communication is to encourage further reports to obtain more information on this potential safety concern.

https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis.asp

21 June 2021

Medsafe grants provisional approval for use in 12 to 15-year-olds at the adult dose.



Provisional Consent to the Distribution of a New Medicine

21 JUN 2021

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicine which was referred to the Minister of Health under the provisions of section 24(5) of the Act and set out in the Schedule hereto:

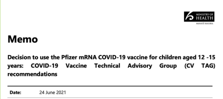
Schedule

Product: **Comirnaty (COVID-19 mRNA vaccine)**

https://gazette.govt.nz/notice/id/2021-go2440

24 June 2021

CV-TAG minutes record that vaccination priority should remain focused on those over 16, noting limited clinical trial data for 12–15 year olds, and **identifies emerging concerns regarding myocarditis risk in people under 30.**

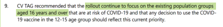


MINISTRY OF HEALTH

Memo

Decision to use the Pfizer mRNA COVID-19 vaccine for children aged 12 -15 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date: 24 June 2021

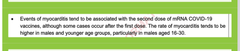


9. CV TAG recommended that the rollout continue to focus on the existing population groups aged 16 years and over that are at risk of COVID-19 and that any decision to use the COVID-19 vaccine in the 12-15 age group should reflect this current priority.

https://web.archive.org/web/20220528063514/https://www.health.govt.nz/system/files/documents/pages/20210624_-_cv_tag_recommendations_for_decision_to_use_pfizer_for_12-15_years.pdf

6 July 2021

CV-TAG reviewed international myocarditis data showing higher risk after the second dose in younger males and discussed whether longer dosing intervals could reduce risk.

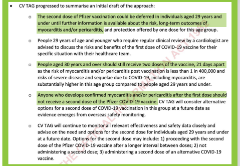


- Events of myocarditis tend to be associated with the second dose of mRNA COVID-19 vaccines, although some cases occur after the first dose. The rate of myocarditis tends to be higher in males and younger age groups, particularly in males aged 16-30.

https://www.health.govt.nz/system/files/2022-06/h202116357_response.pdf

13 July 2021

CV-TAG recommends two doses for those aged 30 and over, but advises that the second dose for those aged 29 and under could be deferred pending further data on myocarditis risk and single-dose protection.



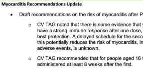
- CV TAG progressed to summarise an initial draft of the approach:
  - The second dose of Pfizer vaccination could be deferred in individuals aged 29 years and under until further information is available about the risk, long-term outcomes of myocarditis and/or pericarditis, and protection offered by one dose for this age group.
  - People 29 years of age and younger who require regular clinical 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.

THE OFFICIAL INFORMATION ACT 1982

https://www.health.govt.nz/system/files/2022-06/h202116357_response.pdf

20 July 2021

CV-TAG notes that young people aged
immune responses after one dose but
doses, with the second dose delayed t
potentially reduce myocarditis risk.

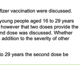


Myocarditis Recommendations Update

- Draft recommendations on the risk of myocarditis after P
  - CV TAG noted that there is some evidence that
    have a strong immune response after one dose,
    best protection. A delayed schedule for the seco
    this potentially reduces the risk of myocarditis, in
    adverse events, is unknown.
  - CV TAG recommended that for people aged 16
    administered at least 8 weeks after the first.

https://www.health.govt.nz/system/files/2022-06/h20

16–29 have strong
recommends two
at least 8 weeks to


fizer vaccination were discussed.

young people aged 16 to 29 years
however that two doses provide the
nd dose was discussed. Whether
addition to the severity of other

to 29 years the second dose be

2116357_response.pdf

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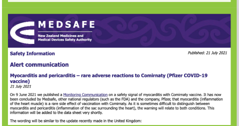
21 July 2021

Medsafe issues a second safety alert investigating myocarditis and pericarditis as potential adverse reactions to the Pfizer vaccine, particularly after the second dose and in younger males.


MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Safety Information *Published: 21 July 2021*

Alert communication

Myocarditis and pericarditis – rare adverse reactions to Comirnaty (Pfizer COVID-19 vaccine)
21 July 2021

On 9 June 2021 we published a Monitoring Communication on a safety signal of myocarditis with Comirnaty vaccine. It has now been concluded by Medsafe, other national regulators (such as the FDA) and the company, Pfizer, that myocarditis (inflammation of the heart muscle) is a rare side effect of vaccination with Comirnaty. As it is sometimes difficult to distinguish between myocarditis and pericarditis (inflammation of the sac surrounding the heart), the warning will relate to both conditions. This information will be added to the data sheet very shortly.

The wording will be similar to the update recently made in the United Kingdom:

https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-alert.htm

Despite this warning appearing on the Medsafe website, most New Zealanders remained unaware of the risk, and it was not highlighted during government media briefings.

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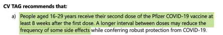
21 July 2021

A CV-TAG memo records emerging international data linking mRNA vaccination to myocarditis, including cases in New Zealand, particularly among younger males. It RECOMMENDS longer dosing intervals for younger people, while maintaining the standard three-week schedule for those aged 30 and over.


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.

https://web.archive.org/web/20221003112843/https://www.health.govt.nz/system/files/documents/pages/20210721_-_cv_tag_myocarditis_following_vaccination.pdf

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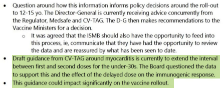
21 July 2021

CV-ISMB noted that extending the dosing interval to reduce myocarditis risk could significantly impact the rollout and questioned the data supporting the interval extension.


- Question around how this information informs policy decisions around the roll-out to 12-15 yo. The Director-General is currently receiving advice concurrently from the Regulator, Medsafe and CV-TAG. The D-G then makes recommendations to the Vaccine Ministers for a decision.
    - It was agreed that the ISMB should also have the opportunity to feed into this process, ie, communicate that they have had the opportunity to review the data and are reassured by what has been seen to date.
- Draft guidance from CV-TAG around myocarditis is currently to extend the interval between first and second doses for the under-30s. The Board questioned the data to support this and the effect of the delayed dose on the immunogenic response.
- This guidance could impact significantly on the vaccine rollout.

https://www.brashandmitchell.com/post/thomas-cranmer-covid-and-our-kiwi-kids-part-1

This highlighted tensions between Government experts, safety considerations and the goal of accelerating vaccination coverage.

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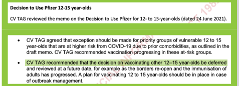
27 July 2021

CV-TAG recommends vaccinating high-risk 12–15 year olds but deferring vaccination of the wider age group.


Decision to Use Pfizer 12-15 year-olds

CV TAG reviewed the memo on the Decision to Use Pfizer for 12- to 15-year-olds (dated 24 June 2021).

- CV TAG agreed that exception should be made for priority groups of vulnerable 12 to 15 year-olds that are at higher risk from COVID-19 due to prior comorbidities, as outlined in the draft memo. CV TAG recommended vaccination progressing in these at-risk groups.
- CV TAG recommended that the decision on vaccinating other 12–15 year-olds be deferred and reviewed at a future date, for example as the borders re-open and the immunisation of adults has progressed. A plan for vaccinating 12 to 15 year-olds should be in place in case of outbreak management.

https://www.health.govt.nz/system/files/2022-06/h202116357_response.pdf

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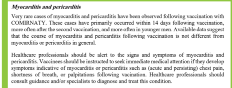
28 July 2021

Pfizer's Datasheet v3 is updated to include myocarditis and pericarditis as a rare adverse reaction to the Pfizer vaccine, particularly in adolescents and young adults. The Pfizer data sheet is updated to include a warning.


Myocarditis and pericarditis

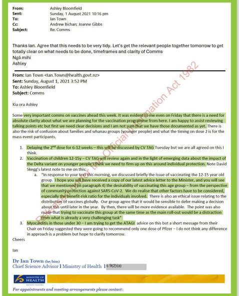
Very rare cases of myocarditis and pericarditis have been observed following vaccination with COMIRNATY. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vacination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

https://drive.google.com/file/d/1SNH38mtyUsPq8hMPovPUQwFCX0HCWBOw/view?usp=share_link

1 August 2021

Dr Ian Town advised the Director-General that vaccination of 12–15 year olds remained under active consideration, noting concerns about the individual benefit–risk balance and that there may be merit in deferring a decision until more evidence was available.



From: Ashley Bloomfield
Sent: Sunday, 1 August 2021 10:16 pm
To: Ian Town
Cc: Andrew Bichan; Joanne Gibbs
Subject: Re: Comms

Thanks Ian. Agree that this needs to be very tidy. Let's get the relevant people together tomorrow to get totally clear on what needs to be done, timeframes and clarity of Comms
Ngā mihi
Ashley

From: Ian Town <Ian.Town@health.govt.nz>
Sent: Sunday, August 1, 2021 3:52 PM
To: Ashley Bloomfield
Subject: Comms

Kia ora Ashley

Some very important comms on vaccines ahead this week. It was evident to me even on Friday that there is a need for absolute clarity about what we are planning for the vaccination programme from here. I am happy to assist reviewing talking points etc but first we need clear decisions and I am not sure that we have those documented as yet. There is also the risk of confusion about families and whanau groups (younger people) and what the timing on dose 2 is for the mass event participants.

1. Delaying the 2nd dose for 6-12 weeks – this will be discussed by CV TAG Tuesday but we are all agreed on this I think.
2. Vaccination of children 12-15y – CV TAG will review again and in the light of emerging data about the impact of the Delta variant on younger people I think we need to firm up on this around individual protection. Note David Skegg's latest note to me on this:
    a. "In response to your text this morning, we discussed briefly the issue of vaccinating the 12-15 year old group. I hope you will have received a copy of our latest advice letter to the Minister, and you will see that we mentioned (in paragraph 4) the desirability of vaccinating this age group – from the perspective of community protection against SARS-CoV-2. We do realise that other factors have to be considered, especially the benefit-risk ratio for the individuals involved. There is also an ethical issue relating to the distribution of vaccines globally. Our group agree that it would be sensible to defer making a decision about this until later in the year. By then, there will be more evidence available. The point was also made that trying to vaccinate this group at the same time as the main roll-out would be a distraction from what is already a very challenging task"
3. Myocarditis in those under 30 – I am trying to get the ATAGI advice on this but a short message from their Chair on Friday suggested they were going to recommend only one dose of Pfizer – I do not think any difference in approach is a problem but hope to clarify tomorrow.

Cheers

Ian

Dr Ian Town (he/him)
Chief Science Advisor I Ministry of Health I s 9(2)(a)

For appointments and meeting arrangements please contact:

Released under the Official Information Act 1982

https://drive.google.com/file/d/1706uizCeUNxlHLbbyQ_XNfpOC0LPLoVG/view?usp=share_link

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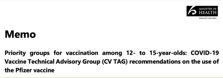
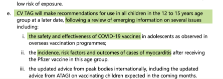
4 August 2021

CV-TAG advises that routine administration in 12 to 15-year-olds should be deferred pending further review of emerging safety and effectiveness data, particularly regarding the incidence, risk factors and outcomes of myocarditis.



Memo

Priority groups for vaccination among 12- to 15-year-olds: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine



d. The COVID-19 vaccine should not be routinely administered to children and young people aged 12 to 15 years of age, at this time. Children and young people have a low risk of severe disease or death due to COVID-19 compared to adults, and, given the low prevalence of SARS-CoV-2 infection in Aotearoa New Zealand, there is currently a low risk of exposure.

e. CV TAG will make recommendations for use in all children in the 12 to 15 years age group at a later date, following a review of emerging information on several issues including:

  i. the safety and effectiveness of COVID-19 vaccines in adolescents as observed in overseas vaccination programmes;

  ii. the incidence, risk factors and outcomes of cases of myocarditis after receiving the Pfizer vaccine in this age group.

  iii. the updated advice from peak bodies internationally, including the updated advice from ATAGI on vaccinating children expected in the coming months.

https://web.archive.org/web/20230115180058/https://www.health.govt.nz/system/files/documents/pages/20210804_-_cv_tag_children_priority_groups.pdf

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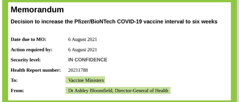
6 August 2021

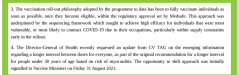
Description Memorandum from Director-General to vaccine ministers notes CV-TAG advice about dosing interval increases for myocarditis risk in under 30s.



Memorandum

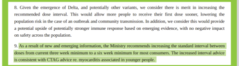
Decision to increase the Pfizer/BioNTech COVID-19 vaccine interval to six weeks

Date due to MO: 6 August 2021
Action required by: 6 August 2021
Security level: IN CONFIDENCE
Health Report number: 20211788
To: Vaccine Ministers
From: Dr Ashley Bloomfield, Director-General of Health



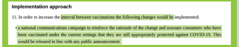
3. The vaccination roll-out philosophy adopted by the programme to date has been to fully vaccinate individuals as soon as possible, once they become eligible, within the regulatory approval set by Medsafe. This approach was underpinned by the sequencing framework which sought to achieve high efficacy for individuals that were most vulnerable, or most likely to contract COVID-19 due to their occupations, particularly within supply constraints early in the rollout.

4. The Director-General of Health recently requested an update from CV TAG on the emerging information regarding a longer interval between doses for everyone, as part of the original recommendation for a longer interval for people under 30 years of age based on risk of myocarditis. The opportunity to shift approach was initially signalled to Vaccine Ministers on Friday 31 August 2021.



8. Given the emergence of Delta, and potentially other variants, we consider there is merit in increasing the recommended dose interval. This would allow more people to receive their first dose sooner, lowering the population risk in the case of an outbreak and community transmission. In addition, we consider this would provide a potential upside of potentially stronger immune response based on emerging evidence, with no negative impact on safety across the population.

9. As a result of new and emerging information, the Ministry recommends increasing the standard interval between doses from current three week minimum to a six week minimum for most consumers. The increased interval advice is consistent with CTAG advice re. myocarditis associated in younger people.



Implementation approach

11. In order to increase the interval between vaccinations the following changes would be implemented:

- a national communications campaign to reinforce the rationale of the change and reassure consumers who have been vaccinated under the current settings that they are still appropriately protected against COVID-19. This would be released in line with any public announcement

https://drive.google.com/file/d/1i1lEFexXgaxDuCN41OWtQtArixh1-lof/view?usp=share_link

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11–12 August 2021

Press releases:

1. Prime Minister announces move to 6 weeks between doses to ensure more NZers at least partially vaccinated as soon as possible in face of Delta risk, **no mention of myocarditis risk or advice from experts.**
2. Director-General of Health announces the Pfizer dosing interval would be extended from three to six weeks, citing studies showing an equally robust immune response and **no additional safety concerns.**
3. An identical NZ government press release on the same date is identical but notes "the larger interval is also consistent with the advice from the COVID Technical Advisory Group (CVTAG) for an extended interval between doses to **reduce the likelihood of rare side effects of myocarditis or pericarditis."**

1. https://www.beehive.govt.nz/release/government-sets-out-plan-reconnect-new-zealanders-world
2. https://www.brashandmitchell.com/post/thomas-cranmer-covid-and-our-kiwi-kids-part-1
3. https://centralapp.nz/NewsStory/time-between-covid-19-vaccine-doses-extended/611464ed5c4fad002b7078c7

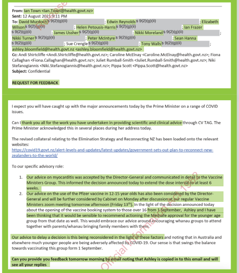
Most public communications announcing the extended dosing interval did not refer to myocarditis risk. The CV-TAG minutes of 17 August 2021 (across) record that a request had been made to remove reference to myocarditis as a reason for extending the dosing interval.

12–13 August 2021

CV-TAG members were advised:

- That their advice on myocarditis risk had been accepted by the Director-General, communicated in detail to Vaccine Ministers, and had informed the decision to extend the dosing interval to at least six weeks.
- Their recommendation to defer routine vaccination of 12–15 year olds was being reconsidered by the Director-General, Vaccine Ministers and Cabinet.

Members were asked to provide urgent feedback overnight on whether CV-TAG should reverse its earlier advice and support vaccination of all 12–15 year olds from 1 September 2021.



From: Ian Town <Ian.Town@health.govt.nz>
Sent: 12 August 2021 9:11 PM
To: David Murdoch s 9(2)(g)(ii); Edwin Reynolds s 9(2)(g)(ii); Elizabeth Wilson s 9(2)(g)(ii); Helen Petousis-Harris s 9(2)(g)(ii); Ian Frazer s 9(2)(g)(ii); James Ussher s 9(2)(g)(ii); Nikki Moreland s 9(2)(g)(ii); Nikki Turner s 9(2)(g)(ii); Peter McIntyre s 9(2)(g)(ii); Sean Hanna s 9(2)(g)(ii); Sue Crengle s 9(2)(g)(ii); Tony Walls s 9(2)(g)(ii); ashley.bloomfield@health.govt.nz <ashley.bloomfield@health.govt.nz>
Cc: Andi Shirtcliffe <Andi.Shirtcliffe@health.govt.nz>; Caroline McElnay <Caroline.McElnay@health.govt.nz>; Fiona Callaghan <Fiona.Callaghan@health.govt.nz>; Juliet Rumball-Smith <Juliet.Rumball-Smith@health.govt.nz>; Niki Stefanogiannis <Niki.Stefanogiannis@health.govt.nz>; Pippa Scott <Pippa.Scott@health.govt.nz>
Subject: Confidential

REQUEST FOR FEEDBACK

I expect you will have caught up with the major announcements today by the Prime Minister on a range of COVID issues.

Can I thank you all for the work you have undertaken in providing scientific and clinical advice through CV TAG. The Prime Minister acknowledged this in several places during her address today.

The revised collateral relating to the Elimination Strategy and Reconnecting NZ has been loaded onto the relevant websites:
https://covid19.govt.nz/alert-levels-and-updates/latest-updates/government-sets-out-plan-to-reconnect-new-zealanders-to-the-world/

To our specific advisory role:

1. Our advice on myocarditis was accepted by the Director-General and communicated in detail to the Vaccine Ministers Group. This informed the decision announced today to extend the dose interval to at least 6 weeks.
2. Our advice on the use of the Pfizer vaccine in 12-15 year olds has also been considered by the Director-General and will be further considered by Cabinet on Monday after discussion at our regular Vaccine Ministers zoom meeting tomorrow afternoon (Friday 13th). In the light of the decision announced today about the opening of the vaccine booking system to those over 16 from 1 September, Ashley and I have been thinking that it would be sensible to recommend actioning the Medsafe approval for the younger age group from that date as well. This would embrace our advice around encouraging whanau groups to attend together with parents/whanau bringing family members with them.

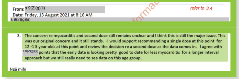
Our advice to delay a decision is this being reconsidered in the light of these factors and noting that in Australia and elsewhere much younger people are being adversely affected by COVID-19. Our sense is that swings the balance towards vaccinating this group form 1 September.

Can you provide you feedback tomorrow morning by email noting that Ashley is copied in to this email and will see all your replies

https://drive.google.com/file/d/1QT2gJaaYNOv0BeXRTuWqq3PogTrrG6rF/view

Expert Advisors' replies

Expert 1



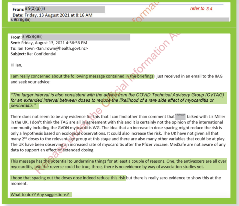
From: s 9(2)(g)(ii)
Date: Friday, 13 August 2021 at 8:16 AM
s 9(2)(g)(ii)

refer to 3.4

3. The concern re myocarditis and second dose still remains unclear and I think this is still the major issue. This was our original concern and it still stands. -I would support recommending a single dose at this point for 12 -1 5 year olds at this point and review the decision re a second dose as the data comes in. I agree with [redacted] points that the early data is looking pretty good to date for less myocarditis for a longer interval approach but we still really need to see data on this age group.

Ngā mihi

Expert 2



From: s 9(2)(g)(ii)
Date: Friday, 13 August 2021 at 8:16 AM
s 9(2)(g)(ii)

refer to 3.4

From: s 9(2)(g)(ii)
Sent: Friday, August 13, 2021 4:56:56 PM
To: Ian Town <Ian.Town@health.govt.nz>
Subject: Re: Confidential

Hi Ian,

I am really concerned about the following message contained in the briefings I just received in an email to the IIAG and seek your advice:

"The larger interval is also consistent with the advice from the COVID Technical Advisory Group (CVTAG) for an extended interval between doses to reduce the likelihood of a rare side effect of myocarditis or pericarditis."

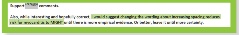
There does not seem to be any evidence for this that I can find other than comment that [redacted] talked with Liz Miller in the UK. I don't think the TAG are all in agreement with this and it is certainly not the opinion of the international community including the GVDN myocarditis WG. The idea that an increase in dose spacing might reduce the risk is only a hypothesis based on ecological observations. It could also increase the risk. The UK have not given all that many 2nd doses to the relevant age group at this stage and there are also many other variables that could be at play. The UK have been observing an increased rate of myocarditis after the Pfizer vaccine. MedSafe are not aware of any data to support an effect of extended dosing.

This message has the potential to undermine things for at least a couple of reasons. One, the antivaxxers are all over myocarditis, two the reverse could be true, three, there is no evidence by way of association studies yet.

I hope that spacing out the doses dose indeed reduce this risk but there is really zero evidence to show this at the moment.

What to do?? Any suggestions?

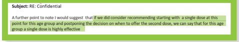
Expert 3



Support [redacted] comments.

Also, while interesting and hopefully correct, I would suggest changing the wording about increasing spacing reduces risk for myocarditis to MIGHT until there is more empirical evidence. Or better, leave it until more certainty.

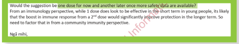
Expert 4



Subject: RE: Confidential

A further point to note I would suggest that if we did consider recommending starting with a single dose at this point for this age group and postponing the decision on when to offer the second dose, we can say that for this age group a single dose is highly effective

Expert 5

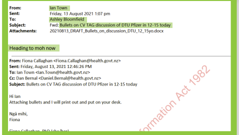


Would the suggestion be one dose for now and another later once more safety data are available?
From an immunology perspective, while 1 dose does look to be effective in the short term in young people, its likely that the boost in immune response from a 2nd dose would significantly improve protection in the longer term. So need to factor that in from a community immunity perspective.

Ngā mihi,

13 August 2021

CV-TAG bullet points sent to the Director-General ahead of a Vaccine Ministers Meeting recorded agreement that 12–15 year olds should be vaccinated, noted that a one-dose schedule could provide good protection while reducing pressure on vaccine capacity, and suggested that references to the potential myocarditis benefit of an extended dosing interval be removed or re-worded in communications.



From: Ian Town
Sent: Friday, 13 August 2021 1:07 pm
To: Ashley Bloomfield
Subject: Fwd: Bullets on CV TAG discussion of DTU Pfizer in 12-15 today
Attachments: 20210813_DRAFT_Bullets_on_discussion_DTU_12_15yo.docx

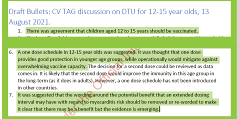
Heading to moh now

From: Fiona Callaghan <Fiona.Callaghan@health.govt.nz>
Sent: Friday, August 13, 2021 12:46:26 PM
To: Ian Town <Ian.Town@health.govt.nz>
Cc: Dan Bernal <Daniel.Bernal@health.govt.nz>
Subject: Bullets on CV TAG discussion of DTU Pfizer in 12-15 today

Hi Ian
Attaching bullets and I will print out and put on your desk.

Ngā mihi,
Fiona

Fiona Callaghan, PhD (she/her)



Draft Bullets: CV TAG discussion on DTU for 12-15 year olds, 13 August 2021.

1. There was agreement that children aged 12 to 15 years should be vaccinated.

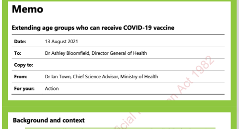
6. A one dose schedule in 12-15 year olds was suggested. It was thought that one dose provides good protection in younger age groups, while operationally would mitigate against overwhelming vaccine capacity. The decision for a second dose could be reviewed as data comes in. It is likely that the second dose would improve the immunity in this age group in the long-term (as it does in adults). However, a one dose schedule has not been introduced in other countries.
7. It was suggested that the wording around the potential benefit that an extended dosing interval may have with regard to myocarditis risk should be removed or re-worded to make it clear that there may be a benefit but the evidence is emerging.

https://drive.google.com/file/d/1706uizCeUNxIHLbbyO_XNfpOC0LPLoVG/view?usp=share_link

Was the experts' recommendation to remove the myocarditis risk from messaging shared with and decided by the Vaccine Ministers?

13 August 2021

CV-TAG reverses its earlier position and recommends universal vaccination of 12–15 year olds, with the change recorded in the 13 August minutes without further safety or effectiveness review being recorded (as per 4 August 2021 memo).



Memo

Extending age groups who can receive COVID-19 vaccine

Date:	13 August 2021
To:	Dr Ashley Bloomfield, Director General of Health
Copy to:	
From:	Dr Ian Town, Chief Science Advisor, Ministry of Health
For your:	Action

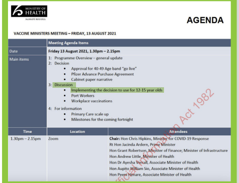
Background and context

2. CV TAG convened by email on 12 August to discuss extending eligibility for the vaccine.
3. There was agreement that children aged 12 to 15 years should be vaccinated.

https://www.health.govt.nz/system/files/2022-06/h202115654_response.pdf

13 August 2021

A Vaccine Ministers Meeting agenda recorded that Ministers were to discuss and agree the narrative, vaccine uptake strategies, and implementation considerations for the vaccination of 12–15 year olds, indicating a focus on communication and rollout planning alongside the policy decision..



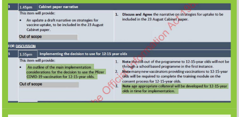
MINISTRY OF HEALTH
MANATŪ HAUORA

AGENDA

VACCINE MINISTERS MEETING – FRIDAY, 13 AUGUST 2021

	Meeting Agenda Items
Date	**Friday 13 August 2021, 1.30pm – 2.15pm**
Main items	1: Programme Overview – general update 2: Decision • Approval for 40-49 Age band "go live" • Pfizer Advance Purchase Agreement • Cabinet paper narrative 3: Discussion • Implementing the decision to use for 12-15 year olds • Port Workers • Workplace vaccinations 4: For information • Primary Care scale up • Milestones for the coming fortnight

Time	Location	Attendees
1.30pm – 2.15pm	Zoom	**Chair:** Hon Chris Hipkins, Minister for COVID-19 Response Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance; Minister of Infrastructure Hon Andrew Little, Minister of Health Hon Dr Ayesha Verrall, Associate Minister of Health Hon Aupito William Sio, Associate Minister of Health Hon Peeni Henare, Associate Minister of Health



3	1.45pm	**Cabinet paper narrative**	
		This item will provide: • An update a draft narrative on strategies for vaccine uptake, to be included in the 23 August Cabinet paper. Out of scope	1. **Discuss and Agree** the narrative on strategies for uptake to be included in the 23 August Cabinet paper.
FOR DISCUSSION			
3	1.55pm	**Implementing the decision to use for 12-15 year olds**	
		This item will provide: • An outline of the main implementation considerations for the decision to use the Pfizer COVID-19 vaccination for 12-15-year olds. Out of scope	1. **Note** the roll-out of the programme to 12-15-year olds will not be through a school based programme in the first instance. 2. **Note** many new vaccinators providing vaccinations to 12-15-year olds will be required to complete the training module on the consent process for 12-15-year olds. 3. **Note** age appropriate collateral will be developed for 12-15-year olds in time for implementation.

https://drive.google.com/file/d/1bxSVx2B3sJNRuqS1JtTAkxrYu0f0u6ME/view?usp=share_link

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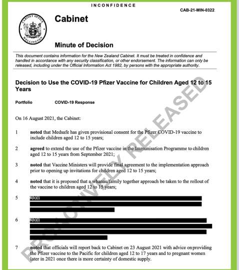
16 August 2021

Cabinet agrees that all children 12-15 can be vaccinated, no mention of dosing schedule, on adult dose and presumed adult dosing schedule.



IN CONFIDENCE

CAB-21-MIN-0322

Cabinet

Minute of Decision

This document contains information for the New Zealand Cabinet. It must be treated in confidence and handled in accordance with any security classification, or other endorsement. The information can only be released, including under the Official Information Act 1982, by persons with the appropriate authority.

Decision to Use the COVID-19 Pfizer Vaccine for Children Aged 12 to 15 Years

Portfolio **COVID-19 Response**

On 16 August 2021, the Cabinet:

1 **noted** that Medsafe has given provisional consent for the Pfizer COVID-19 vaccine to include children aged 12 to 15 years;

2 **agreed** to extend the use of the Pfizer vaccine in the Immunisation Programme to children aged 12 to 15 years from September 2021;

3 **noted** that Vaccine Ministers will provide final agreement to the implementation approach prior to opening up invitations for children aged 12 to 15 years;

4 **noted** that it is proposed that a whanau/family together approach be taken to the rollout of the vaccine to children aged 12 to 15 years;

5 6(b)(i) [redacted]

6 6(b)(i) [redacted]

7 **noted** that officials will report back to Cabinet on 23 August 2021 with advice on providing the Pfizer vaccine to the Pacific for children aged 12 to 17 years and to pregnant women later in 2021 once there is more certainty of domestic supply.

PROACTIVELY RELEASED

https://www.health.govt.nz/system/files/2022-04/cabinet-minute-decision-to-use-the-covid-19-pfizer-vaccine-for-children-aged-12-to-15-years.pdf

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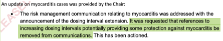
17 August 2021

CV-TAG memo records an update on myocarditis and a request that the reference to "increasing dosing intervals potentially providing some protection against myocarditis" be removed from communications, which had been actioned.



An update on myocarditis cases was provided by the Chair:

- The risk management communication relating to myocarditis was addressed with the announcement of the dosing interval extension. It was requested that references to increasing dosing intervals potentially providing some protection against myocarditis be removed from communications. This has been actioned.

https://www.health.govt.nz/system/files/2022-06/h202116357_response.pdf

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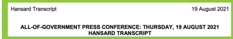
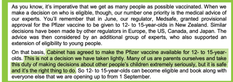
19 August 2021

The Prime Minister announces that Cabinet had agreed to extend Pfizer vaccination eligibility to all 12–15 year olds, stating the decision follows advice from Medsafe and an additional group of experts. "This is not a decision we have taken lightly. Many of us are parents ourselves and take this duty of making decisions about other people's children extremely seriously, but it is safe, and it's the right thing to do. So 12 to 15 year olds can become eligible and book, along with everyone else that we are opening up to from the 1st of September."



Hansard Transcript 19 August 2021

ALL-OF-GOVERNMENT PRESS CONFERENCE: THURSDAY, 19 AUGUST 2021
HANSARD TRANSCRIPT



As you know, it's imperative that we get as many people as possible vaccinated. When we make a decision on who is eligible, though, our number one priority is the medical advice of our experts. You'll remember that in June, our regulator, Medsafe, granted provisional approval for the Pfizer vaccine to be given to 12- to 15-year-olds in New Zealand. Similar decisions have been made by other regulators in Europe, the US, Canada, and Japan. The advice was then considered by an additional group of experts, who also supported an extension of eligibility to young people.

On that basis, Cabinet has agreed to make the Pfizer vaccine available for 12- to 15-year-olds. This is not a decision we have taken lightly. Many of us are parents ourselves and take this duty of making decisions about other people's children extremely seriously, but it is safe and it's the right thing to do. So 12- to 15-year-olds can become eligible and book along with everyone else that we are opening up to from 1 September.

https://www.beehive.govt.nz/sites/default/files/2021-08/Press%20Conference%2019%20August%202021%20-%20Final.pdf

https://www.rnz.co.nz/news/national/449517/covid-19-cabinet-grants-vaccine-approval-for-12-15-year-olds

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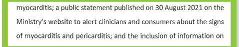
?

Prime Minister, how can you say it is safe when the Government's experts are discussing the increased risk of myocarditis in under 30s?

30 August 2021

Alert on Ministry of Health's website to clinicians and consumers about the signs of myocarditis and pericarditis.



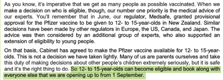
myocarditis; a public statement published on 30 August 2021 on the Ministry's website to alert clinicians and consumers about the signs of myocarditis and pericarditis; and the inclusion of information on

Bloomfield's second affidavit in the Kiwi Kids' Case
https://drive.google.com/file/d/1o7F14Ef32xg5J7E00yY0YIXFehQsz__u/view?usp=sharing

While the Ministry formally noted myocarditis risk, between June-December 2021 this safety signal was not meaningfully reflected in public communications. The issue remained largely absent from the messaging shaping public understanding at the time.

1 September 2021

12 to 15 year olds become eligible and able to book vaccination appointments, including without parental consent.



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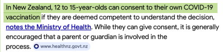
On that basis, Cabinet has agreed to make the Pfizer vaccine available for 12- to 15-year-olds. This is not a decision we have taken lightly. Many of us are parents ourselves and take this duty of making decisions about other people's children extremely seriously, but it is safe and it's the right thing to do. So 12- to 15-year-olds can become eligible and book along with everyone else that we are opening up to from 1 September.



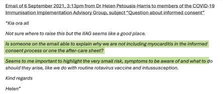
In New Zealand, 12 to 15-year-olds can consent to their own COVID-19 vaccination if they are deemed competent to understand the decision, notes the Ministry of Health. While they can give consent, it is generally encouraged that a parent or guardian is involved in the process. www.healthnz.govt.nz

https://www.beehive.govt.nz/sites/default/files/2021-08/Press%20Conference%2019%20August%202021%20-%20Final.pdf

https://www.healthnz.govt.nz/health-topics/immunisations/vaccines-aotearoa/covid-19-vaccines/getting-covid-19-vaccines#

6 September 2021

CV-TAG member, Helen Petousis-Harris, raises concerns by email that myocarditis risk was not being included in informed consent materials or after-care sheets and emphasises the importance of informing recipients about symptoms and when to seek medical care.



Email of 6 September 2021, 3:13pm from Dr Helen Petousis-Harris to members of the COVID-19 Immunisation Implementation Advisory Group, subject "Question about informed consent"

"Kia ora all

Not sure where to raise this but the IIAG seems like a good place.

Is someone on the email able to explain why we are not including myocarditis in the informed consent process or one the after-care sheet?

Seems to me important to highlight the very small risk, symptoms to be aware of and what to do should they arise, like we do with routine rotavirus vaccine and intussusception.

Kind regards

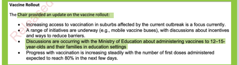
Helen"

https://drive.google.com/file/d/1U2xWhqZOXjyRRSEj6cK-Nj6uNSckbwb4/view

Myocarditis risk missing from the informed consent process a week after vaccination started in 5 to 12 year-olds, and over a month after Pfizer updated its datasheet with the risk on 28 July 2021 (above).

21 September 2021

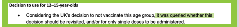
CV-TAG query whether they revisit the decision to vaccinate 12 to 15-year-olds given the UK's decision not to.



Vaccine Rollout

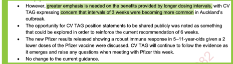
The Chair provided an update on the vaccine rollout:

- Increasing access to vaccination in suburbs affected by the current outbreak is a focus currently.
- A range of initiatives are underway (e.g., mobile vaccine buses), with discussions about incentives and ways to reduce barriers.
- Discussions are occurring with the Ministry of Education about administering vaccines to 12–15-year-olds and their families in education settings
- Progress with vaccination is increasing steadily with the number of first doses administered expected to reach 80% in the next few days.



Decision to use for 12–15-year-olds

- Considering the UK's decision to not vaccinate this age group, it was queried whether this decision should be revisited, and/or for only single doses to be administered.



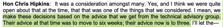
- However, greater emphasis is needed on the benefits provided by longer dosing intervals, with CV TAG expressing concern that intervals of 3 weeks were becoming more common in Auckland's outbreak.
- The opportunity for CV TAG position statements to be shared publicly was noted as something that could be explored in order to reinforce the current recommendation of 6 weeks.
- The new Pfizer results released showing a robust immune response in 5–11-year-olds given a 2 lower doses of the Pfizer vaccine were discussed. CV TAG will continue to follow the evidence as it emerges and raise any questions when meeting with Pfizer this week.
- No change to the current guidance.

https://www.health.govt.nz/system/files/2022-06/h202115654_response.pdf

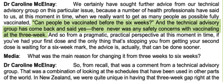
CV-TAG queried revisiting the decision to vaccinate 5-12 year olds and separately noticed concerns about 3 week dosing schedule.

6 October 2021

Government reverses its earlier decision and returned to a three-week dosing interval to accelerate full vaccination. Press Conference with Minister Hipkins and Dr McElnay:



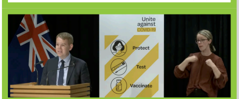
Hon Chris Hipkins: It was a consideration amongst many. Yes, and I think we were quite open about that at the time, that that was one of the things that we considered. I mean, we make these decisions based on the advice that we get from the technical advisory group. Their advice at that time was to move to six weeks; their advice now is to three. I'll let the—



Dr Caroline McElnay: We certainly have sought further advice from our technical advisory group on this particular issue, because a number of health professionals have said to us, at this moment in time, when we really want to get as many people as possible fully vaccinated, "Can people be vaccinated before the six weeks?" And the technical advisory group has come back and said yes—there never was any safety concerns with vaccinating at the three-week. And so from a pragmatic, practical perspective at this moment in time, if you've had your first dose and the only thing that's stopping you from getting your second dose is waiting for a six-week mark, the advice is, actually, that can be done sooner.

Media: What was the main reason for changing it from three weeks to six weeks?

Dr Caroline McElnay: So, from recall, that was a comment from a technical advisory group. That was a combination of looking at the schedules that have been used in other parts of the world. In New Zealand, we were quite unique in having that three-week gap right at the



https://www.beehive.govt.nz/sites/default/files/2021-10/Hipkins%2C%20Dr%20McElnay%20Press%20Conference%206%20October.pdf

https://www.youtube.com/watch?v=og4E7pl_EOQ

22 October 202

Government anno
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22 OCTOBER 2021

New COVID-19
greater freedor

Rt Hon Jacinda Ardern

https://www.beehive.gov
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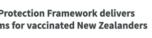


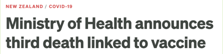
**Protection Framework delivers
ms for vaccinated New Zealanders**

t.nz/release/new-covid-19-protection-framework-
ns-vaccinated-new-zealanders

The Vaccine Pass was
ced when myocarditis risk in
r people was known, severe
19 risk for younger people was
, and vaccine effectiveness
infection was already waning.

28 October 2021

13 year old dies of myocarditis 10 days following second Pfizer vaccine.



NEW ZEALAND / COVID-19

Ministry of Health announces third death linked to vaccine

https://www.rnz.co.nz/news/national/465103/ministry-of-health-announces-third-death-linked-to-vaccine

https://www.rnz.co.nz/news/national/513266/cause-of-teen-s-death-unable-to-be-satisfactorily-determined-coroner

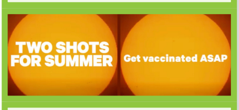
Chris James' affidavit in the Kiwi Kids' Case
https://drive.google.com/file/d/1rvk29GSLhmbMsZyLNFSqrleZ5THYbsYo/view?usp=share_link page 19 paragraph 54

!

This is misinformation, CV-TAG had advised that shorter dosing intervals could increase myocarditis risk in younger people, yet the public was told there were no safety concerns with bringing the second dose forward. This was not an accurate representation of the advice provided to Government.

2 November 2021

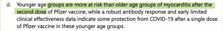
NZ Government commences its Two Shots For Summer Campaign



https://www.facebook.com/reel/223208129881681

5 November 2021

CV-TAG advises the Director-General on the definition of fully vaccinated. In that advice CV-Tag NOTES that younger age groups ARE at higher risk of myocarditis after the second Pfizer dose. IT ADDS that some protection is provided after a single dose, raising concerns about requiring two doses for younger people under vaccine mandates.

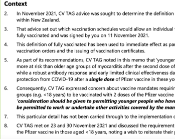


d. Younger age groups are more at risk than older age groups of myocarditis after the second dose of Pfizer vaccine, while a robust antibody response and early limited clinical effectiveness data indicate some protection from COVID-19 after a single dose of Pfizer vaccine in these younger age groups.

https://www.tewhatuora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/New-Zealand-definition-of-fully-vaccinated-for-use-inside-the-New-Zealand.pdf

11 November 2021

Director-General signed advice from CV-TAG on t
of "fully vaccinated". That advice noted younger g
more at risk of myocarditis and recommended a s
consideration should be given to those mandatec
with one dose.



Context

2. In November 2021, CV TAG advice was sought to determine the definition
within New Zealand.
3. That advice set out which vaccination schedules would allow an individual
fully vaccinated and was signed by you on 11 November 2021.
4. This definition of fully vaccinated has been used to immediate effect as par
vaccination orders and the issuing of vaccination certificates.
5. As part of its recommendations, CV TAG noted in this memo that 'younger
more at risk than older age groups of myocarditis after the second dose of
while a robust antibody response and early limited clinical effectiveness da
protection from COVID-19 after a ***single dose*** of Pfizer vaccine in these yo
6. Consequently, CV TAG expressed concern about vaccine mandates requirin
groups (e.g. <18 years) to be vaccinated with 2 doses of the Pfizer vaccine
***'consideration should be given to permitting younger people who have
be permitted to work or undertake other activities covered by the man***
7. This particular detail has not been carried through to the implementation c
8. CV TAG met on 23 and 30 November 2021 and discussed the requirement
the Pfizer vaccine in those aged <18 years, noting a wish to reiterate their

https://www.tewhatuora.govt.nz/assets/About-us/Who-we-are/Ex
COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Vaccinatio
in-those-under-18-years-of-age.pdf

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Misinformation, Chris Hipkins how can you say this when CV-TAG were recommending one dose or longer dosing intervals because of the risk of myocarditis?

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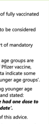
of fully vaccinated
to be considered
rt of mandatory
age groups are
Pfizer vaccine,
ta indicate some
unger age groups'.
g younger age
and stated:
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date'.
of this advice.
for two doses of
previous position.

pert-groups/
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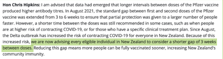
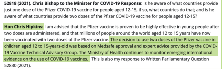
15 November 2021

1. In response to a Parliamentary question about CV-TAG concerns regarding three-week dosing intervals (raised in CVTAG memo 21 September 2021), the Minister states the shorter interval was being encouraged to increase full vaccination coverage more quickly during the Delta outbreak.
2. In a Written Parliamentary Question response, the Minister states that the decision to require two doses for 12–15 year olds was based on Medsafe approval and advice from the COVID-19 Vaccine Technical Advisory Group.


Hon Chris Hipkins: I am advised that data had emerged that longer intervals between doses of the Pfizer vaccine produced higher antibody titres. In August 2021, the standard gap between first and second doses of the Pfizer vaccine was extended from 3 to 6 weeks to ensure that partial protection was given to a larger number of people faster. However, a shorter time between the doses was still recommended in some cases, such as when people are at higher risk of contracting COVID-19, or for those who have a specific clinical treatment plan. Since August, the Delta outbreak has increased the risk of contracting COVID-19 for everyone in New Zealand. Because of this increased risk, we are now advising every eligible individual in New Zealand to consider a shorter gap of 3 weeks between doses. Reducing this gap means more people can be fully vaccinated sooner, increasing New Zealand's community immunity.

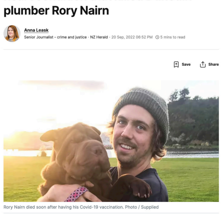

52818 (2021). Chris Bishop to the Minister for COVID-19 Response: Is he aware of what countries provide just one dose of the Pfizer COVID-19 vaccine for people aged 12-15, if so, what countries do that; and is he aware of what countries provide two doses of the Pfizer COVID-19 vaccine for people aged 12-15?

Hon Chris Hipkins: I am advised that the Pfizer vaccine is proven to be highly effective in young people after two doses are administered, and that millions of people around the world aged 12 to 15 years have now been vaccinated with two doses of the Pfizer vaccine. The decision to use two doses of the Pfizer vaccine in children aged 12 to 15-years-old was based on Medsafe approval and expert advice provided by the COVID-19 Vaccine Technical Advisory Group. The Ministry of Health continues to monitor emerging international evidence on the use of COVID-19 vaccines. This is also my response to Written Parliamentary Question 52830 (2021).

https://questions.parliament.nz/written-questions/question/WQ_52800_2021?lang=en
https://questions.parliament.nz/written-questions/question/WQ_52818_2021?lang=en

17 November 2021

26 year old Rory Nairn dies of a heart attack from myocarditis, 12 days after his first vaccination dose.


Covid-19 vaccine ruled as cause of heart condition that killed Dunedin plumber Rory Nairn

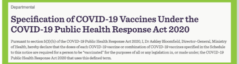
Anna Leask
Senior Journalist - crime and justice · NZ Herald · 20 Sep, 2022 06:52 PM · 5 mins to read

Rory Nairn died soon after having his Covid-19 vaccination. Photo / Supplied

https://www.nzherald.co.nz/nz/covid-19-vaccine-ruled-as-cause-of-heart-condition-that-killed-dunedin-plumber-rory-nairn/SLY2ZNPU53IBGAE6HA4AQE4JA4/

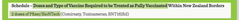
26 November 2021

The Director-General of Health determines by legal notice the number of doses required for a person to be considered "vaccinated" for the purposes of legislation, mandates and the Vaccine Pass system. This notice did not differentiate from 12-15 year olds.


Departmental

Specification of COVID-19 Vaccines Under the COVID-19 Public Health Response Act 2020

Pursuant to section 5(3)(b) of the COVID-19 Public Health Response Act 2020, I, Dr Ashley Bloomfield, Director-General, Ministry of Health, hereby declare that the doses of each COVID-19 vaccine or combination of COVID-19 vaccines specified in the Schedule to this notice are required for a person to be "vaccinated" for the purposes of all or any legislation in, or made under, the COVID-19 Public Health Response Act 2020 that uses this defined term.


Schedule – Doses and Type of Vaccine Required to be Treated as Fully Vaccinated Within New Zealand Borders

2 doses of Pfizer/BioNTech (Comirnaty, Tozinameran, BNT162b2)

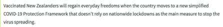
https://gazette.govt.nz/notice/id/2021-go5122

Despite receiving CV-TAG advice about a single-dose approach or longer dosing intervals for 12–15 year olds, the Director-General defined "vaccinated" for the purposes of mandates and the Vaccine Pass as two doses.

2 December 2021

Traffic Light System (Vaccine Pass) comes into effect.

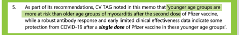
My Vaccine Pass
NEW ZEALAND
My Vaccine Pass
NAME
DATE OF BIRTH
Exp: 17-05-2022

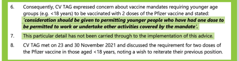

Vaccinated New Zealanders will regain everyday freedoms when the country moves to a new simplified COVID-19 Protection Framework that doesn't rely on nationwide lockdowns as the main measure to stop the virus spreading.

https://www.beehive.govt.nz/release/new-covid-19-protection-framework-delivers-greater-freedoms-vaccinated-new-zealanders

9 December 2021

CV-TAG raises concern that its earlier advice supporting a single-dose approach for 12 to 15-year-olds is not reflected in the 26 November 2021 notice defining "vaccinated". The group again notes protection after one dose and increased myocarditis risk following a second dose.

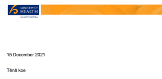

5. As part of its recommendations, CV TAG noted in this memo that 'younger age groups are more at risk than older age groups of myocarditis after the second dose of Pfizer vaccine, while a robust antibody response and early limited clinical effectiveness data indicate some protection from COVID-19 after a ***single dose*** of Pfizer vaccine in these younger age groups'.


6. Consequently, CV TAG expressed concern about vaccine mandates requiring younger age groups (e.g. <18 years) to be vaccinated with 2 doses of the Pfizer vaccine and stated: ***'consideration should be given to permitting younger people who have had one dose to be permitted to work or undertake other activities covered by the mandate'.***
7. This particular detail has not been carried through to the implementation of this advice.
8. CV TAG met on 23 and 30 November 2021 and discussed the requirement for two doses of the Pfizer vaccine in those aged <18 years, noting a wish to reiterate their previous position.

https://www.tewhatuora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Vaccination-mandates-in-those-under-18-years-of-age.pdf

15 December 2021

The Director-General of Health Issues a letter
warning of myocarditis risk following Pfizer va
advising clinicians to monitor for symptoms.
the risk saying: "the overall rate of this event i
is reported to be around 3 per 100,000 vaccin


MINISTRY OF HEALTH
MANATŪ HAUORA

15 December 2021

Tēnā koe

Urgent update on COVID-19 Vaccine-associated Myocarditis and Pericar

https://www.rnzcgp.org.nz/gpdocs/new-website/membership
associated-myocarditis-and-pericarditis_MOH%2015122l.pdf

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133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

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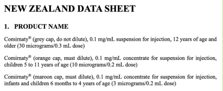
16 December 2021

Medsafe grants provisional approval for Pfizer for ages 5–11, child’s two dose regiment at 3 week interval. The datasheet lists Myocarditis as a special warning.

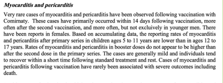

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Comirnaty® (grey cap, do not dilute), 0.1 mg/mL suspension for injection, 12 years of age and older (30 micrograms/0.3 mL dose)

Comirnaty® (orange cap, must dilute), 0.1 mg/mL concentrate for suspension for injection, children 5 to 11 years of age (10 micrograms/0.2 mL dose)

Comirnaty® (maroon cap, must dilute), 0.1 mg/mL concentrate for suspension for injection, infants and children 6 months to 4 years of age (3 micrograms/0.2 mL dose)


Myocarditis and pericarditis

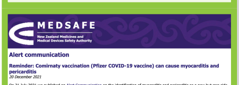
Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often, but not excliuvely in younger men. There have been reports in females. Based on accumulating data, the reporting rates of myocarditis and pericarditis after primary series in children ages 5 to 11 years are lower than in ages 12 to 17 years. Rates of myocarditis and pericarditis in booster doses do not appear to be higher than after the second dose in the primary series. The cases are generally mild and individuals tend to recover within a short time following standard treatment and rest. Cases of myocarditis and pericarditis following vaccination have rarely been associated with severe outcomes including death.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis, including atypical presentations. Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following

https://www.medsafe.govt.nz/profs/Datasheet/c/Comirnaty0.2mlOrangeCapinj.pdf

20 December 2021

Medsafe Issues a third warning - a reminder to healthcare professionals about the risk of myocarditis and pericarditis following the Pfizer vaccine, particularly after the second dose in younger males. It advises monitoring for symptoms such as chest pain and shortness of breath.


MEDSAFE
New Zealand Medicines and
Medical Devices Safety Authority

Alert communication

Reminder: Comirnaty vaccination (Pfizer COVID-19 vaccine) can cause myocarditis and pericarditis
20 December 2021

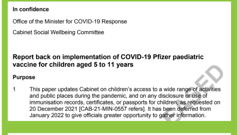
On 21 July 2021 we published an Alert Communication on the identification of myocarditis and pericarditis as a new but rare side effect of vaccination with Comirnaty vaccine (Pfizer COVID-19 vaccine). We are reminding everyone that myocarditis and pericarditis can occur after any dose of the Comirnaty vaccine, including after a booster dose. Children can also experience myocarditis and pericarditis after vaccination with Comirnaty. We have received reports for children aged 12 to 16 years.

Myocarditis also occurs after COVID-19 infection at a higher rate than after vaccination with Comirnaty[1,2].

https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-reminder.htm

20 December 2021

Cabinet agrees that 5–11 year olds are eligible for paediatric vaccination available from 17 January 2022. Memo mentions CV TAG 9 December 2021 myocarditis concern with single and short dose in under 30s.


In confidence

Office of the Minister for COVID-19 Response

Cabinet Social Wellbeing Committee

Report back on implementation of COVID-19 Pfizer paediatric vaccine for children aged 5 to 11 years

Purpose

1 This paper updates Cabinet on children’s access to a wide range of activities and public places during the pandemic, and on any disclosure or use of immunisation records, certificates, or passports for children, as requested on 20 December 2021 [CAB-21-MIN-0557 refers]. It has been deferred from January 2022 to give officials greater opportunity to gather information.

https://www.health.govt.nz/system/files/2022-05/implementation_of_covid-19_pfizer_paediatric_vaccine_for_children_aged_5_to_11_years_report_back.pdf

17 January 2022

Vaccination rollout begins for 5 to 11-year-olds.

January-June 2022

5 to 11-year-olds judicial review. Dr Town from CV-TAG, Dr Bloomfield, and Minister Hipkins all give two affidavits each in the Kiwi Kids case, **none ever provide or mention the 9 December 2021 CV-TAG memorandum warning of myocarditis in under 18s.**