Memo

New Zealand definition of fully vaccinated for use inside the New Zealand border

Date:	5 November 2021
To:	Maree Roberts, Deputy Director General, System Strategy and Policy
Cc:	Alison Cossar, Manager, Public Health Policy, Systems Strategy and Policy Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme Niki Stefanogiannis, Deputy Director Public Health, Population Health and Prevention
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 definition of fully vaccinated for use in settings inside the New Zealand border.

Context

2. As New Zealand begins to introduce guidance and legislation based on COVID-19 vaccination status, there is a need for a uniform definition of what constitutes being fully vaccinated (from a legal perspective) that can be applied to all situations inside the New Zealand border ("***New Zealand definition for fully vaccinated for use inside the border (October 2021)***").

3. Recommendations about vaccination requirements for entry to New Zealand (i.e., being granted permission to cross the New Zealand border) are subject to different legal and equity considerations to requirements inside the New Zealand Border. Recommendations about "*minimum vaccine requirements to enter New Zealand*" should therefore be considered separately and are not the subject of this document. Previous CV TAG recommendations about "*minimum vaccine requirements to enter New Zealand*" are given in Appendix 1 (non-New-Zealand citizens entering 14 days of MIQ) and Appendix 2 (Recognised Seasonal Employees).

4. It is likely that the COVID-19 management strategy for inbound travellers will move away from a universal pathway through managed isolation and quarantine (MIQ). New COVID-19 management strategies for travellers are likely to be based, in part, on their vaccination status. As inbound travellers will be inside the New Zealand border while completing their COVID-19 management pathway (e.g., MIQ, self-isolation or other requirements) it is intended that the "***New Zealand definition for fully vaccinated for use inside the border***

(October 2021)" would apply in any decisions around COVID-19 management strategies for inbound travellers.

5. In addition to the context of inbound travellers, there are other settings within New Zealand borders in which the "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" are likely to be applied. These include, but are not limited to, the issuing of vaccination certificates (both domestic and international), and in the implementation of vaccine mandates.

6. In New Zealand, the majority of individuals will have received 2 doses of the Pfizer COVID-19 vaccine as their primary schedule. However, other vaccines may be used in the future in New Zealand, and individuals vaccinated overseas will have received a variety of vaccines. The "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" therefore needs to cover the range of vaccines available worldwide.

7. For schedules using vaccines not approved by Medsafe, the key consideration for inclusion in the "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" is the extent of protection they provide, rather than other aspects considered for licensure such as reactogenicity, safety, and populations groups it should be administered to. This is because the schedule has already been administered to the individual, so New Zealand's position on whether the vaccine should have been administered is not relevant in this context.

8. There are currently 23 COVID-19 vaccines worldwide approved for use by at least one government or other authority. This number is likely to increase with time (https://covid19.trackvaccines.org/vaccines/approved/#vaccine-list).

9. There are currently 3 COVID-19 vaccines provisionally approved by Medsafe for use in New Zealand are Pfizer, Janssen, and AstraZeneca.

10. The World Health Organization (WHO) has an Emergency Use Listing Procedure (EUL) that is being used to assess COVID-19 vaccines. It is a risk-based procedure for assessing and listing unlicensed vaccines with the aim of expediting vaccine availability to people affected by the pandemic. This process is to assist agencies and Member States in determining the acceptability of using specific products, based on an essential set of available quality, safety, and efficacy and performance data. To be approved for WHO emergency use listing, vaccines are required to have an efficacy (not specified against which outcome, but likely symptomatic disease) of 50% or above. There are currently 8 COVID-19 vaccines approved for Emergency Use by the WHO: Pfizer, Janssen, AstraZeneca (counted as 2 vaccines as includes the Serum Institute of India product), Moderna, Sinopharm, Sinovac and Bharat Biotech.

11. A rapid assessment of the 23 vaccines approved by at least one government (or other authority) worldwide identified 1 vaccine (in addition to the WHO approved vaccines) which was approved in at least 5 countries (as of 27th October 2021), and had publicly available (published or pre-print) phase 3 clinical trial data indicating greater than 80% vaccine efficacy (VE) against severe disease. This was Gamaleya (Sputnik V), which showed VE against moderate or severe COVID-19 of 100% (94.4–100%) in its phase 3 trial.[1]

12. Immunological principles would suggest that the development of a humoral immune response (neutralising antibody) after a second dose of a vaccine is not immediate but would be achieved within approximately a week. This is supported by data showing that the neutralising antibody response to Pfizer vaccine peaks between day 4 and day 30 after the second dose in one study,[3] and that the highest neutralising antibody levels were recorded 7 days after the second dose (when measured at day 0, 7 and 14 after second dose) in

another.[4] Similar results have been shown for AstraZeneca, with neutralising antibody response rising to a peak between days 7 and 14 after the second dose.[5]

13. There is some evidence that a single dose of the Janssen vaccine may not be as effective against infection as other Medsafe approved vaccines. A US study from General Massachusetts Hospital compared immune responses in ambulatory adults vaccinated with Pfizer, Moderna or Janssen vaccines and found lower antibody concentrations and neutralisation titres for the Janssen vaccine. However, administering a second dose of either Pfizer or Moderna vaccines boosted the immune response.[6]

14. Adolescents and young adults are at a higher risk of myocarditis than older adults after a second dose of Pfizer vaccine (particularly males under the age of 30 years). However, it is still a rare event in the younger age groups and less frequent than myocarditis after COVID-19 infection.[7, 8] The immune response is robust after each dose of vaccine in adolescents and young adults,[9] but data remain scarce about the clinical effectiveness after a single dose in this group to date. A study of Israeli 12–17-year-olds showed vaccine effectiveness against documented SARS-CoV-2 infection to be 66% (95% CI, 59-72%) 21-27 days after the first dose, and 90% (95% CI, 88-92) 7-21 days after the second dose,[10] and effectiveness against symptomatic Delta COVID-19 to be 82% (95% CI, 73 to 91) 21-27 days after the first dose compared to 93% (95% CI, 88-97%) 7-21 days after the second dose. There were no cases of severe disease in either the vaccinated or unvaccinated in this study.

15. The COVID-19 Policy team have sought CV TAG advice on the definition fully vaccinated for use within the New Zealand border.

Recommendations

16. CV TAG met to consider the "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" on 2nd November 2021.

17. **CV TAG noted that:**

    a. Recommendations around "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" have been considered in the context of use in the COVID-19 management strategy.

    b. "*Minimum vaccination requirements to enter New Zealand*" (i.e. to cross the border) should not be based on the "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***", and are not the subject of this document.

    c. Exemption processes for requirements for vaccination will be put in place for different settings and do not form part of these recommendations.

    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.

18. **CV TAG recommends that:**

    a. The "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" should be 7 or more days after the last dose in an accepted primary vaccination schedule, where accepted primary vaccination schedules are:

        i. The approved number of doses of any Medsafe or WHO approved vaccine

ii. 2 doses of any combination of the Medsafe or WHO approved vaccines (heterologous schedules)

iii. 2 doses of the Gamaleya Sputnik V vaccine

iv. A complete primary course of any other COVID-19 vaccines authorised by at least one government or authority PLUS a single dose of a Medsafe approved vaccine (the Moderna COVID-19 vaccine is also acceptable as the additional dose in the case that it was administered outside of New Zealand).

v. A single dose of any of the COVID-19 vaccines authorised by at least one government or authority PLUS a single dose of a Medsafe approved vaccine (the Moderna COVID-19 vaccine is also acceptable as the additional dose in the case that it was administered outside of New Zealand).

b. CV TAG is concerned about vaccine mandates requiring younger age groups (e.g., ≤18 years) to be fully vaccinated. 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.

c. Those participating in a registered COVID-19 vaccine trial (https://trialsearch.who.int) should be provided with a temporary exemption from being fully vaccinated. Their subsequent pathway to becoming fully vaccinated should be based on the accepted primary schedules described in 18.a. For example, if an individual received a full course of a trial COVID-19 vaccine that was later approved by WHO then they would be considered fully vaccinated; whereas an individual in a control group who received no COVID-19 vaccine would require a full primary course of Pfizer. CV TAG will update the list of acceptable vaccines as data becomes available.

d. For those given a single additional dose of vaccine in New Zealand as described under 18.a.iv and 18.a.v, this dose should be given at least 28 days after the previous COVID-19 vaccine dose.

e. Although not required to meet the definition of fully vaccinated, CV TAG recommends offering another dose of a vaccine approved by Medsafe to those who have had a single dose of the Janssen vaccine, particularly those at high risk of serious disease or occupational exposure.

f. The "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" should be used in all contexts in New Zealand (except for crossing New Zealand's border as stated above) including, but not limited to, the issuing of vaccination certificates (both domestic and international), vaccine mandates and establishing COVID-19 management pathways for those entering New Zealand.

g. The "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" should only consider and individual's status in relation to the primary course of COVID-19 vaccination, without stipulating a maximum time since last dose. As booster doses become more common, requirements for booster doses and maximum time since last vaccination could be added to future definitions.

h. Pathways for inbound travellers for COVID-19 management (e.g. MIQ, self-isolation or other requirements) should be based on the traveller's status according to the "***New Zealand definition for fully vaccinated for use inside the border (October 2021)***" on the day and time they cross the New Zealand border.

19. CV TAG will continue to monitor all relevant information 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

Appendix 1

COVID-19 vaccines for arrivals to Aotearoa New Zealand: COVID-19 Vaccine Technical Advisory Group (CV TAG) Recommendations

Memo dated 29 September 2021

Recommendations

20. CV TAG met on 7, 14 and 21 September 2021 to consider recommendations regarding COVID-19 vaccines for people arriving to Aotearoa New Zealand.

21. CV TAG noted that:

    a. officials are preparing a proposal for the Minister for COVID-19 Response to take to Cabinet that would impose a pre-entry requirement from 1 November 2021, that all (non-New Zealand citizen) arrivals by air are fully vaccinated.

    b. under this proposal all arrivals would still undergo testing and 14 days MIQ, which will continue to be the key line of defence.

    c. this is being proposed as an additional precautionary measure to further reduce the risk of COVID-19 entering the New Zealand community (and until New Zealand achieves high vaccination coverage).

    d. there are significant ethical and equity issues given that most people have no choice about which vaccine they receive, and many countries still have poor access to vaccines and low vaccination rates.

    e. while the effectiveness varies across the different vaccine products, any vaccine is better than no vaccine.

    f. new recommendations will be needed if requirements around MIQ on entry to Aotearoa New Zealand change. This is due to different considerations around requirements of vaccines without MIQ as the key line of defence.

    g. updated recommendations will likely be needed if there are changes to the approved COVID-19 vaccination schedules in New Zealand.

22. CV TAG recommends that:

    a. a complete primary course of vaccination with any of the 22 COVID-19 vaccines approved by at least one government or authority (or an approved combination of those vaccines in their origin country) with the last dose at least 14 days before arrival would be acceptable for entering MIQ for 14 days, given that testing and MIQ would provide the key line of defence. Vaccination should be documented in the manner that the origin country provides.

    b. an exemption process should be put in place for those who require an exemption on humanitarian grounds, because they are below the approved age for COVID-19 vaccination in their origin country, or for other similar reasons.

    c. those aged 12 years or over who enter the country with a full primary course of vaccination, but with a vaccine that is NOT one of those approved by a Medsafe-

recognised authority should be offered an additional dose of Pfizer vaccine as soon as possible after entry to New Zealand (and at the latest as they leave MIQ). This should occur at least 28 days after the last dose, with no upper limit on time since the last dose.

d. those who enter the country, are aged 12 years or over, and have received no doses of any of the 22 COVID-19 vaccines, should be offered a full course of Pfizer vaccine as soon as possible after entry to New Zealand (and at the latest receiving the first dose as they leave MIQ).

e. those who enter the country, are aged 12 years or over and have received an incomplete primary course of any of the 22 COVID-19 vaccines (whether approved by a Medsafe-recognised authority or not), should be offered an additional dose of Pfizer vaccine as soon as possible after entry to New Zealand.

    i. This should occur at least 28 days after the most recent dose of COVID-19 vaccine, with no upper limit on time since the last dose.

    ii. If the interval since the most recent dose allows, vaccination with Pfizer should be offered to people while in MIQ or at the latest as they leave MIQ.

    iii. If the interval since most recent dose does not allow vaccination on or before leaving MIQ, a future vaccination booking should be offered as they leave MIQ at the latest.

23. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

Appendix 2

COVID-19 vaccines for arrivals to Aotearoa New Zealand (Recognised Seasonal Employer, RSE, scheme): COVID-19 Vaccine Technical Advisory Group (CV TAG) Recommendations

Memo dated 1 October 2021

Recommendations

24. CV TAG met on 21 September 2021 to consider recommendations regarding COVID-19 vaccines for arrivals to Aotearoa New Zealand.

25. CV TAG noted that:

    a. There have been no cases of COVID-19 in Samoa, Tonga, and Vanuatu in the last 6 months. Therefore, the purpose of these entry requirements for RSE workers is to ensure they are protected from COVID-19 while in New Zealand with a similar level of protection as others in New Zealand.

    b. Data are still emerging on the efficacy of heterologous vaccine schedules from approved and recognised vaccines in New Zealand's portfolio. Initial results show that mixing doses of mRNA and adenovirus-vectored vaccines is associated with an acceptable reactogenicity profile and generates levels of anti-spike neutralising antibody titres shown to provide high levels of protection in primary efficacy trials.[11-13]

    c. Because receiving vaccines for COVID-19 are free to all within New Zealand, no cost will be associated with administration of any additional doses to RSE workers.

26. CV TAG recommends that:

For RSE workers who have received	Recommendation
a. 2 doses of the AstraZeneca vaccine	This is a full primary course of vaccination approved by Medsafe. Considered 'fully vaccinated'.
b. 2 doses of the Sinopharm vaccine	This vaccine is NOT approved by Medsafe and/or Medsafe recognised authorities. These RSE workers should receive one dose of the Pfizer vaccine.
c. 1 dose of the AstraZeneca vaccine	These RSE workers should receive one dose of the Pfizer vaccine.
d. 1 dose of the Sinopharm vaccine	

e. Regarding timing, administration of any additional doses should occur:

   i. At least 28 days after the most recent dose of COVID-19 vaccine, with no upper limit on time since the last dose.

   ii. If the interval since the most recent dose allows, the Pfizer dose should be offered to people on entry, while in self-isolation or at the latest as they leave self-isolation.

   iii. If the interval since the most recent dose does not allow vaccination before leaving self-isolation, a vaccination booking at the earliest available opportunity will be made before leaving self-isolation.

27. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

Appendix 3

COVID-19 vaccines recognised for work at the Aotearoa New Zealand Border: COVID-19 Vaccine Technical Advisory Group (CV TAG) Recommendations

Memo dated 6 September 2021

Recommendations

1. CV TAG met on 17 and 31 August 2021 to consider recommendations regarding which COVID-19 vaccines can be recognised for Border work, and how to approach incomplete and complete vaccination with non-recognised COVID-19 vaccines.
2. **CV TAG noted that:**
    a) Data are still emerging on the efficacy of heterologous vaccine schedules from approved and recognised vaccines in New Zealand's portfolio, however initial results show that mixing vaccine doses is associated with a low incidence of adverse effects and could provide an improved immune response through increased anti-spike antibody titres and neutralising antibodies.[11-13]
    b) Protection against symptomatic infection is of enhanced importance for work at the Border. Extensive data has emerged showing high efficacy and effectiveness against symptomatic infection after two doses of the Pfizer, AstraZeneca, or Moderna vaccines in Phase 3 clinical trials and large post-marketing studies. There is strong evidence that the Janssen vaccine (the single-dose, adenovirus vector vaccine) provides a high degree of protection against moderate and severe disease from COVID-19, however there are less data on the efficacy or effectiveness against symptomatic infection, especially in the context of the Delta variant of SARS-CoV-2, and the immune response appears to be lower.
3. **CV TAG recommends that:**
    a) A full course of vaccination with a COVID-19 vaccine recognised by Medsafe (or a Medsafe recognised authority) provides sufficient protection from COVID-19 for work at the Border, with the exception of the Janssen vaccine as a single dose schedule.
    b) A 'booster' dose of the Pfizer vaccine should be administered for Border Workers who have only received a single dose of the Janssen vaccine, due to the higher risk of SARS-CoV-2 infection for Border work, and the need for enhanced protection against infection among Border Workers.
    c) If a worker is in New Zealand and has an incomplete vaccination with a vaccine recognised by Medsafe (or a Medsafe recognised authority) they should complete their vaccination by receiving one dose of the Pfizer vaccine. This should occur at least 21 days after the first dose of the non-Pfizer vaccine, or at least 28 days after the first dose if this was AstraZeneca or Moderna. There is no upper time limit on time for when that dose can be administered.
    d) Workers who have received a partial or complete course of vaccine with a non-recognised COVID-19 vaccine, should also receive one dose of the Pfizer vaccine.

4. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

References

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12. Borobia, A.M., et al., *Reactogenicity and Immunogenicity of BNT162b2 in Subjects Having Received a First Dose of ChAdOx1s: Initial Results of a Randomised, Adaptive, Phase 2 Trial (CombiVacS).* SSRN, 2021.
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Document 2

Memo

Date:	10 November 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
Copy:	Dr Ashley Bloomfield, Director-General of Health Allison Bennett, Manager, System Enablers, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
Subject:	Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations
For your:	Consideration

Purpose

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations about COVID-19 booster vaccinations.

Context

2. Current evidence shows that antibody levels against SARS-CoV-2 wane over time following the second Pfizer COVID-19 vaccine dose, and that there is a reduction in protection against infection, particularly from 6 months after a primary vaccination course.[1-3] The reduction in protection is similar for Delta and other virus variants.[2, 4] Protection against transmission from vaccinated individuals who are infected also appears to wane over time.[5] However, evidence suggests that protection against severe disease remains high, including for the Delta variant, though follow-up times varied between studies.[1-4, 6-8]
3. Booster doses are now being given in several countries, including but not limited to the United Kingdom, the United States, Germany, Israel, Singapore, and Malaysia.
4. Medsafe has assessed an application submitted by Pfizer for the use of booster vaccines within New Zealand. On 8 November 2021 Medsafe updated the provisional approval for the Pfizer vaccine to state "a booster dose of Comirnaty may be administered intramuscularly at least 6 months after completion of the primary course in individuals aged 18 years of age and older".
5. *Reactogenicity of a Pfizer booster dose:* Amongst 306 participants aged 18-55 years old receiving a third dose in Pfizer's phase III trial, reactogenicity was largely in line with findings after the second dose, with the exception of lymphadenopathy which occurred at a rate of 5.2% compared to 0.4% post-second dose.[9] Other studies also suggest that the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses.[10-14]
6. *Safety of a Pfizer booster dose:* Data from Israel shows that after more than 2.8 million administered third doses, 19 serious adverse events have been reported, of which 2 have been confirmed as linked, though there is likely underreporting in this data.[15] Only one case of

myocarditis has been reported and is under investigation, in a male older than 30 years, however most younger individuals have had limited follow up time.[15] Israeli data suggests that the risk of myocarditis with the booster dose is not increased when compared with the risk after second doses of vaccine.[16] However, there remain limited data on the incidence of myocarditis after second doses of the mRNA vaccines in younger people.[16-22]

7. *Immunogenicity and effectiveness of a Pfizer booster dose:* A COVID-19 vaccine booster dose administered at 6 months or more after completion of the primary vaccine course has been demonstrated to boost the immune response and is expected to increase protection against infection and disease, particularly in older people where waning appears more marked.[9-12] Data from Israel, where booster doses have been administered to large numbers of people, show reductions in all eligible age groups in the rate of infection, as well as severe disease in those aged ≥40 years, and deaths in those ≥60 years, after the booster dose.[16, 23, 24]

8. *AstraZeneca booster dose:* A small study suggests that AstraZeneca, when used as a booster following a full primary course of Pfizer or Moderna, augments humoral and T cell immune responses, and is well tolerated.[7]

9. *Prioritisation:* The UK's Joint Committee on Immunisation (JCVI) advised on 14 September 2021 that booster vaccines be offered to those more at risk from serious disease, and who were vaccinated during Phase 1 of the vaccine programme (priority groups 1 to 9). This was seen as needed in order to maintain a high level of protection against hospitalisation or death from the virus through winter 2021/2 (while acknowledging that insufficient time has passed to know what levels of protection might be expected 6 to 12 months after the primary course). Those to be offered boosters in the UK include:

    a) those living in residential care homes for older adults

    b) all adults aged 50 years or over

    c) frontline health and social care workers

    d) all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19, and adult carers

    e) adult household contacts of immunosuppressed individuals

    The JCVI advised that the booster vaccine dose is offered no earlier than 6 months after completion of the primary vaccine course, in the same order as during Phase 1. They also indicated a preference for the Pfizer vaccine for the booster programme, regardless of which vaccine brand someone received for their primary doses.

10. The Australian Technical Advisory Group on Immunisation (ATAGI) advised on 27 October 2021 that the highest priority groups to receive booster doses should be those with risk factors for severe COVID-19 and/or those at increased occupational risk of COVID-19, notably:

    a) People at greater risk of severe COVID-19: individuals aged 50 years and older, those with underlying medical conditions, residents of aged care and disability facilities, and Aboriginal and Torres Strait Islander adults. In these groups the benefit of a booster dose is primarily to reduce the risk of severe COVID-19.

    b) People at increased occupational risk of COVID-19: a booster dose for individuals in this group is expected to reduce their likelihood of SARS-CoV-2 infection and associated occupation-related impacts, acknowledging that infection will be mostly mild in these individuals due to prior vaccination and younger age. Booster doses may also reduce the potential for infected individuals to transmit SARS-CoV-2, although evidence for this is currently limited.

11. ATAGI supports the use of a single booster dose for those who completed their primary COVID-19 vaccine course ≥6 months ago. This will initially include, but not be limited to, the groups who were prioritised in the rollout of the vaccine programme from early 2021. This recommendation will be reviewed by ATAGI in January 2022, as groups other than the high-risk groups listed above will become eligible in larger numbers. Pfizer is recommended as a single booster dose, irrespective of the primary COVID-19 vaccine used. Although not preferred, ATAGI recommended that AstraZeneca can also be used as a booster dose in the following situations:
    a) For individuals who have received AstraZeneca for their first two doses if there are no contraindications or precautions for use.
    b) If a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g., anaphylaxis, myocarditis).
12. ATAGI does not currently recommended boosters for those aged <18 years. In this age group, severe COVID-19 is uncommon, and the primary course of COVID-19 vaccines generates a strong immune response, and therefore the benefit from additional doses of vaccine is thought to be to be small. In addition, there are currently only very limited data on the safety of repeated mRNA vaccine doses in this age group.
13. The Ministry of Health's Policy team requested CV TAG's clinical guidance on which groups should be prioritised for booster vaccines, and when these vaccinations should start.

Recommendations

14. CV TAG met on 2 and 9 November 2021 to consider recommendations regarding priority groups for COVID-19 booster vaccinations.
15. **CV TAG noted that:**
    a) Data are still accumulating about waning of protective vaccination effects after primary vaccination and the benefits of a booster dose.
    b) The goal of offering booster doses in New Zealand is to prevent severe disease caused by SARS-CoV-2, to reduce burden on hospitals and other healthcare providers, and to protect those at high occupational risk of exposure.
    c) The current situation in New Zealand is different to the situation at the start of vaccine roll-out (starting in late February 2021, priority groups listed in Appendix 1). There is now greater availability of Pfizer vaccine and effective infrastructure for administering the vaccine, but there is also a higher risk of healthcare workers being exposed to SARS-CoV-2 with the virus now in the community in New Zealand, especially in Auckland.
    d) There is limited data on the safety profile for booster doses in people younger than 30 years of age from the published trials. Concern was noted around vaccine mandates requiring booster doses in this age group before further data are available
    e) There is insufficient data on the safety profile for booster doses in pregnant people.
    f) Māori and Pacific People are at an increased risk of severe disease and hospitalisation,[25] and therefore having a universal age-criteria for prioritisation is inequitable. A lower age band for Māori and Pacific People would be needed to provide equitable protection.
    g) It is now approximately 8 months since the first doses of COVID-19 vaccine were administered in New Zealand.

16. **CV TAG recommends that:**

    a) Increasing the vaccination coverage of first and second doses, particularly for Māori and Pacific People, should remain the first priority of the COVID-19 vaccination programme in New Zealand.

    b) The Pfizer vaccine is recommended as a single booster dose.

    c) COVID-19 vaccine booster doses should be offered to those 18 years of age and older, who have completed their full primary vaccination course 6 or more months prior.

    d) Those aged over 18 who are immunocompromised and have received a third primary dose of a COVID-19 vaccine as described in previous CV TAG recommendations, should only receive a booster dose 6 months after completion of their primary course (i.e., 6 months after their third dose).

    e) Any future vaccine mandates should not require booster doses in younger age groups (<30 years) until further data are available.

    f) When considering prioritisation, priority groups for a booster dose (at least 6 months after completion of the primary course) are those most at risk of exposure to SARS-CoV-2, and those most at risk from serious COVID-19 disease. In particular, these are:

        i. Frontline healthcare workers, particularly in regions where there is COVID-19 in the community (or regions that are at high risk of further spread of COVID-19),

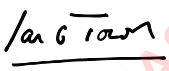
        ii. All those who are aged 65 years or over,

        iii. Māori and Pacific People aged 50 years and over,

        iv. Anyone over the age of 18 with comorbidities, as specified in Group 3 in Appendix 1, with the exception of pregnant people, who completed a full primary course of vaccination in early pregnancy.

    g) AstraZeneca can also be used as a booster dose if available for specific situations including if an individual has had a significant adverse reaction after a previous Pfizer vaccine dose (e.g., anaphylaxis, myocarditis), and if AstraZeneca is not contraindicated.

17. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.



Dr Ian Town

Chief Science Advisor

Chair, CV TAG

Appendix 1: Groups 1- 4 in New Zealand's Pfizer primary vaccination roll-out (as at 30th October 2021)

Group 1

Group 1 includes people working at the border or in MIQ, and the people they live with (household contacts).

Group 2

The Government is expanding the list of Alert Level 4 workers who can get early access to a COVID-19 vaccination. These people will be included in Group 2.

Group 2 will now also include frontline staff who interact with customers and transport and logistic services directly supporting the vaccination programme.

You are also in Group 2 if you:

- are a high-risk frontline healthcare worker (public or private)
- work in a long-term residential environment
- live in long-term residential care and are 12 or over
- are an older Māori or Pacific person being cared for by whānau
- live with or care for an older Māori or Pacific person
- live in the Counties Manukau DHB area and are 65 or over, have an underlying health condition or disability, are pregnant, or are in a custodial setting.

Group 3

People who are at risk of getting very sick from COVID-19. You are in this group if you:

- are aged 65 or over
- are eligible for a publicly funded influenza vaccine
- are pregnant
- are disabled, or are caring for a person with a disability
- are severely obese (defined as a BMI ≥40)
- have high blood pressure requiring 2 or more medications for control
- are an adult in a custodial setting
- have been diagnosed with a severe mental illness (which includes schizophrenia, major depressive disorder, bipolar disorder or schizoaffective disorder, and adults currently accessing secondary and tertiary mental health and addiction services).

Group 4

Everyone aged 12 and over

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Document 3

Memo

Date:	17 December 2021
To:	Dr Ashley Bloomfield, Director-General of Health
Copy:	Astrid Koornneef, Director of National 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
Subject:	COVID-19 booster vaccinations in specific situations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations
For your:	Consideration

Purpose

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations about booster doses of the Pfizer vaccine.

Context

2. On 8 November 2021 Medsafe updated the provisional approval for the Pfizer vaccine to state: ***"a booster dose of Comirnaty may be administered intramuscularly at least 6 months after completion of the primary course in individuals aged 18 years of age and older".***
3. CV TAG has previously made recommendation about booster vaccinations in the memo "Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations", dated 10 November 2021 (Appendix 1).
4. The COVID Vaccine Immunisation Programme (CVIP) has asked for further information and clarification on CV TAG's recommendations in specific situations:
    a) Use of booster doses at less than 6 months after the completion of the primary vaccination course.
    b) Use of booster doses for those under the age of 18 years who are at high risk of exposure to SARS-CoV-2.
    c) Booster doses for pregnant people.
5. *Antibody waning:* Current evidence shows that antibody levels against SARS-CoV-2 wane over time following the second dose of the Pfizer COVID-19 vaccine. There is a reduction in protection against infection, particularly from 6 months after a primary vaccination course.[1-3] The reduction in protection is similar for Delta and other virus variants.[2, 4] Protection against transmission from vaccinated individuals who are infected also appears to wane over time.[5] However, evidence suggests that protection against severe disease remains high, including for the Delta variant, though follow-up times varied between studies.[1-4, 6-8]

6. *Reactogenicity of a Pfizer booster dose:* Amongst 306 participants aged 18-55 years old receiving a third dose in Pfizer's phase III trial, reactogenicity was largely in line with findings after the second dose, with the exception of lymphadenopathy which occurred at a rate of 5.2% compared to 0.4% post-second dose.[9] Other studies also suggest that the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses.[10-14]

7. *Safety of a Pfizer booster dose:* Data from Israel shows that after more than 2.8 million administered third doses, 19 serious adverse events have been reported, of which 2 have been confirmed as linked, though there is likely underreporting in this data.[15] Only one case of myocarditis has been reported and is under investigation, in a male older than 30 years, however most younger individuals have had limited follow up time.[15] Israeli data suggests that the risk of myocarditis with the booster dose is not increased when compared with the risk after second doses of vaccine.[16] However, there remain limited data on the incidence of myocarditis after second doses of the mRNA vaccines in younger people.[16-22]

8. *Immunogenicity and effectiveness of a Pfizer booster dose:* A COVID-19 vaccine booster dose administered at 6 months or more after completion of the primary vaccine course has been demonstrated to boost the immune response (e.g. neutralising antibody) and is expected to increase protection against infection and disease, particularly in older people where waning appears more marked.[9-12] Data from Israel, where Pfizer booster doses have been administered to large numbers of people, show reductions in all eligible age groups in the rate of infection, as well as severe disease in those aged ≥40 years, and deaths in those ≥60 years, after the booster dose.[16, 23, 24]

Use of booster doses at less than 6 months after the completion of the primary vaccination course

9. Potential reasons to consider early booster doses include:
    a) to provide potentially higher protection against COVID-19 caused by new variants
    b) to protect people who are close to 6 months post-primary vaccination course who are at risk of severe COVID-19 and/or SARS-CoV-2 exposure.

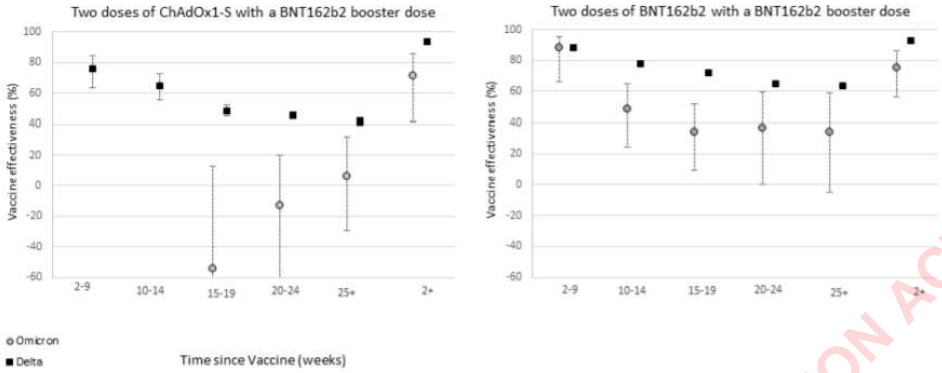
10. It is not yet clear if Omicron can evade vaccine-induced immunity. The laboratory data on Omicron from antibody neutralisation studies to date is very limited and preliminary [25-27], and cannot be used to infer an impact on vaccine protection in real world settings at this stage. Additional information about these studies is presented in Appendix 2.

11. Very early data about vaccine effectiveness (VE) against **symptomatic** disease caused by Omicron and Delta variants was released by the UK Health Security Agency (UKHSA) on 10th December 2021.[28] This analysis included data from 56,439 Delta cases including 581 Omicron cases. Results are shown in Figure 1 (Figure 7 in original document), below. Data about VE of a Pfizer primary series (weeks "2-9" to "25+") and booster dose (week "2+") against Delta and Omicron variants are shown in the right-hand panel of Figure 1. Confidence intervals for VE estimates for Omicron are extremely wide. However, they do not appear to overlap with confidence intervals for Delta at any point from 9 weeks after the primary course (including after the booster dose). This suggests a lower VE for Omicron than for Delta, but it remains unclear to what extent. The point estimate for VE against Omicron increased to ~76% at >2 weeks after a Pfizer booster dose, from ~35% at 15 to >25 weeks after the Pfizer primary course.

Figure 1: Early UKHSA data on vaccine effectiveness for Delta and Omicron (right panel show Pfizer primary course and booster, with lower effectiveness against Omicron)

Figure 7: Vaccine effectiveness against symptomatic diseases by period after dose 1 and dose 2 for Delta (black squares) and Omicron (grey circles) for (A) recipients of 2 doses of AstraZeneca vaccine as the primary course and a Pfizer as a booster[1] and (B) recipients of 2 doses of Pfizer vaccine as the primary course and a Pfizer as a booster

Supplementary data are not available for this figure.



[1] The early observations for 2 doses of AstraZeneca are particularly likely to be unreliable as they are based on relative small numbers and are likely to reflect an older population and a population with more co-morbidities than those given the Pfizer vaccine, and this may explain the negative point estimates.

12. A press release with data from South Africa during the Omicron wave states that two doses of Pfizer has a VE of **70% against hospitalisation**, and **33% against COVID-19 infection,** though the data does not mention time since vaccination.[29]
13. Other data from South Africa shows that the risk of reinfection has increased in the era of Omicron. [30] This suggests that Omicron could have increased evasion of immunity following prior infection.
14. The Australian Technical Advisory Group on Immunisation (ATAGI) advised on 3rd December 2021 in a statement about SARS-CoV-2 Omicron variant and COVID-19 booster doses, that at that time there was no evidence to suggest that earlier booster doses of current COVID-19 vaccines will augment protection against the Omicron variant. However, ATAGI also said in this statement that in certain circumstances, the routine six-month interval for booster doses may be shortened to five months for logistical reasons, for example:
    a) for patients with a greater risk of severe COVID-19 in outbreak settings;
    b) if an individual is travelling overseas and will be away when their booster dose is due; or
    c) in outreach vaccination programs where access is limited.
15. **On 12th December, ATAGI updated their statement to recommend COVID-19 booster vaccination for anyone aged 18 and older who completed their primary course of COVID-19 vaccination 5 or more months ago.**
16. The UK's Joint Committee on Vaccination and Immunisation (JCVI) have reduced the minimum interval between completion of the primary course and the booster to 3 months, stating that "it may be that higher levels of antibody induced by vaccines directed at the original 'wild type' variant will provide better protection against the Omicron variant, as has been demonstrated in laboratory studies with respect to other variants", and "additional data regarding the Omicron variant will take some time to accrue. Waiting for such data before taking some actions risks a suboptimal delayed response".

Use of booster doses in those under the age of 18 years who are at high risk of exposure to SARS-CoV-2

17. In those under 18 years of age, severe COVID-19 is uncommon, and the primary course of COVID-19 vaccines generates a strong immune response. Therefore, the benefit from additional doses of vaccine is thought to be to be small. In addition, there are currently only very limited data on the safety of repeated mRNA vaccine doses in this age group.

18. On 9th December 2021, the U.S. Food and Drug Administration (FDA) amended the emergency use authorization for the Pfizer vaccine, allowing the use of a booster in individuals 16 and 17 years of age at least six months after completion of primary vaccination with Pfizer vaccine.

19. ATAGI does not currently recommended boosters for those aged <18 years.

Booster doses for pregnant people

20. CV TAG recommendations from 10th November (Appendix 1) excluded pregnant people who received a primary course earlier in pregnancy from priority groups, but there was no specific recommendation given about booster vaccination in pregnancy outside of a prioritisation framework. Specifically, there is concern that messaging that those vaccinated in early pregnancy should not receive a booster dose while still pregnant is raising unintended concerns about the safety of vaccination with COVID-19 vaccines while pregnant (both primary and booster doses).

21. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) states that "a booster dose can be considered if you are 18 years or older and had your initial COVID-19 vaccine course (called the primary course) ≥ 6 months ago. Pfizer is the preferred brand for booster doses for all people, including in pregnancy, regardless of the brand used initially". RANZCOG argue "mRNA vaccines are safe and effective for those trying to conceive, pregnant and breastfeeding women. Booster doses have not yet been studied in those who are pregnant but have been shown to be safe and effective in non-pregnant adults. We do know that COVID-19 infection in pregnancy poses a significant risk for mothers and their babies, and RANZCOG recommends that pregnant women receive booster vaccinations in line with the recommendations for the non-pregnant adult population".[31]

Recommendations

22. CV TAG met on 14 December 2021 to consider recommendations regarding COVID-19 booster vaccinations in specific situations.

23. **CV TAG noted that:**

    a) Data are still accumulating about whether early booster doses offer any advantages in protection against the Omicron variant.

    b) There are no long term data available about the safety of early booster doses but short term side effects appear to be modest.

    c) There is insufficient data on the safety profile for booster doses in pregnant people.

    d) Medsafe has authorised boosters only from six months after completion of the primary dose.

24. **CV TAG recommends that:**

    a) A Pfizer booster dose should be offered to adults 18 years or over, 5 months after the completion of the primary vaccination course.

b) Priority should be given to those at high risk of severe disease or exposure to SARS-CoV-2, including:

   i. those aged 65 years and over

   ii. those with comorbidities that put them at higher risk of severe COVID-19

   iii. Māori and Pacific peoples

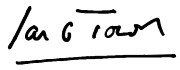
   iv. health care workers and workers in other settings at high-risk of SARS-CoV-2 exposure eg Border Workers and MIQ staff.

c) The COVID-19 Vaccine and Immunisation Programme (CVIP) of the Ministry of Health will need to work with Medsafe to manage access to boosters for the shorter 5-month interval.

d) Booster doses for 16- and 17-year-olds are not currently recommended (including for those working in settings that place them at higher risk of exposure to SARS-CoV-2), in line with the Medsafe authorisation of booster doses.

e) Boosters can be offered to pregnant people who completed their primary vaccination course more than 6 months prior. Those approaching the full-term of their pregnancy 6 months after completing their primary course can choose to receive their booster after the baby is born if preferred.

25. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.



Dr Ian Town

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Chair, CV TAG

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Appendix 1

Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Memo dated 10 November 2021

Recommendations

26. CV TAG met on 2 and 9 November 2021 to consider recommendations regarding priority groups for COVID-19 booster vaccinations.

27. **CV TAG noted that:**

    a) Data are still accumulating about waning of protective vaccination effects after primary vaccination and the benefits of a booster dose.

    b) The goal of offering booster doses in New Zealand is to prevent severe disease caused by SARS-CoV-2, to reduce burden on hospitals and other healthcare providers, and to protect those at high occupational risk of exposure.

    c) The current situation in New Zealand is different to the situation at the start of vaccine roll-out (starting in late February 2021, priority groups listed in Appendix 1). There is now greater availability of Pfizer vaccine and effective infrastructure for administering the vaccine, but there is also a higher risk of healthcare workers being exposed to SARS-CoV-2 with the virus now in the community in New Zealand, especially in Auckland.

    d) There is limited data on the safety profile for booster doses in people younger than 30 years of age from the published trials. Concern was noted around vaccine mandates requiring booster doses in this age group before further data are available

    e) There is insufficient data on the safety profile for booster doses in pregnant people.

    f) Māori and Pacific People are at an increased risk of severe disease and hospitalisation,[32] and therefore having a universal age-criteria for prioritisation is inequitable. A lower age band for Māori and Pacific People would be needed to provide equitable protection.

    g) It is now approximately 8 months since the first doses of COVID-19 vaccine were administered in New Zealand.

28. **CV TAG recommends that:**

    a) Increasing the vaccination coverage of first and second doses, particularly for Māori and Pacific People, should remain the first priority of the COVID-19 vaccination programme in New Zealand.

    b) The Pfizer vaccine is recommended as a single booster dose.

    c) COVID-19 vaccine booster doses should be offered to those 18 years of age and older, who have completed their full primary vaccination course 6 or more months prior.

    d) Those aged over 18 who are immunocompromised and have received a third primary dose of a COVID-19 vaccine as described in previous CV TAG recommendations, should

only receive a booster dose 6 months after completion of their primary course (i.e., 6 months after their third dose).

e) Any future vaccine mandates should not require booster doses in younger age groups (<30 years) until further data are available.

f) When considering prioritisation, priority groups for a booster dose (at least 6 months after completion of the primary course) are those most at risk of exposure to SARS-CoV-2, and those most at risk from serious COVID-19 disease. In particular, these are:

i. Frontline healthcare workers, particularly in regions where there is COVID-19 in the community (or regions that are at high risk of further spread of COVID-19),

ii. All those who are aged 65 years or over,

iii. Māori and Pacific People aged 50 years and over,

iv. Anyone over the age of 18 with comorbidities, as specified in Group 3 listed below, with the exception of pregnant people, who completed a full primary course of vaccination in early pregnancy.

g) AstraZeneca can also be used as a booster dose if available for specific situations including if an individual has had a significant adverse reaction after a previous Pfizer vaccine dose (e.g., anaphylaxis, myocarditis), and if AstraZeneca is not contraindicated.

29. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

Groups for initial vaccine rollout (for reference)

Group 1

Group 1 includes people working at the border or in MIQ, and the people they live with (household contacts).

Group 2

The Government is expanding the list of Alert Level 4 workers who can get early access to a COVID-19 vaccination. These people will be included in Group 2.

Group 2 will now also include frontline staff who interact with customers and transport and logistic services directly supporting the vaccination programme.

You are also in Group 2 if you:

- are a high-risk frontline healthcare worker (public or private)
- work in a long-term residential environment
- live in long-term residential care and are 12 or over
- are an older Māori or Pacific person being cared for by whānau
- live with or care for an older Māori or Pacific person
- live in the Counties Manukau DHB area and are 65 or over, have an underlying health condition or disability, are pregnant, or are in a custodial setting.

Group 3

People who are at risk of getting very sick from COVID-19. You are in this group if you:

- are aged 65 or over
- are eligible for a publicly funded influenza vaccine
- are pregnant
- are disabled, or are caring for a person with a disability
- are severely obese (defined as a BMI ≥40)
- have high blood pressure requiring 2 or more medications for control
- are an adult in a custodial setting
- have been diagnosed with a severe mental illness (which includes schizophrenia, major depressive disorder, bipolar disorder or schizoaffective disorder, and adults currently accessing secondary and tertiary mental health and addiction services).

Group 4

Everyone aged 12 and over

Appendix 2

Effectiveness of Booster doses of Pfizer Vaccine against Omicron variant

Date:	09 December 2021
To:	Ashley Bloomfield, Director General, Ministry of Health
Copy to:	Ian Town, Chief Science Advisor, Ministry of Health
From:	Fiona Callaghan, Lead Science Advisor, Ministry of Health Jeremy Tuohy, Principal Advisor, Ministry of Health
For your:	Information

Purpose of report

1. This report provides a rapid update about the effect of booster doses on the vaccine efficacy of the Pfizer BioNTech COVID-19 vaccine against the Omicron variant.

Background and context

2. The Omicron variant contains multiple mutations in coding for the spike protein which may result in decreased vaccine efficacy.

3. Rapid analysis of *in vitro* immunology studies has been undertaken by Pfizer BioNTech.

Results

4. Pfizer has reported that based on a series of in-vitro antibody neutralisation studies, the third 'booster' shot , or previous infection plus vaccination would be predicted to offer good levels of protection against Omicron.[33]

5. Similar levels of antibody neutralisation were achieved in the lab for Delta and Omicron after 3 doses (Figure 1). As has been demonstrated in several clinical and 'real-world' studies, the Pfizer vaccine offers good clinical protection against Delta (mild and severe disease). The antibody neutralisation data are a good early indication that a third dose of Pfizer may offer similar protection against Omicron. It should be noted that data is available as a media release only, and not in a peer-reviewed publication, as of 09 December 2021.

6. In addition, as with all laboratory studies, it remains to be seen how this will translate into clinical protection and vaccine effectiveness. However, strong laboratory data is promising and there is evidence that neutralising antibody data does correlate with protection from symptomatic disease [34].

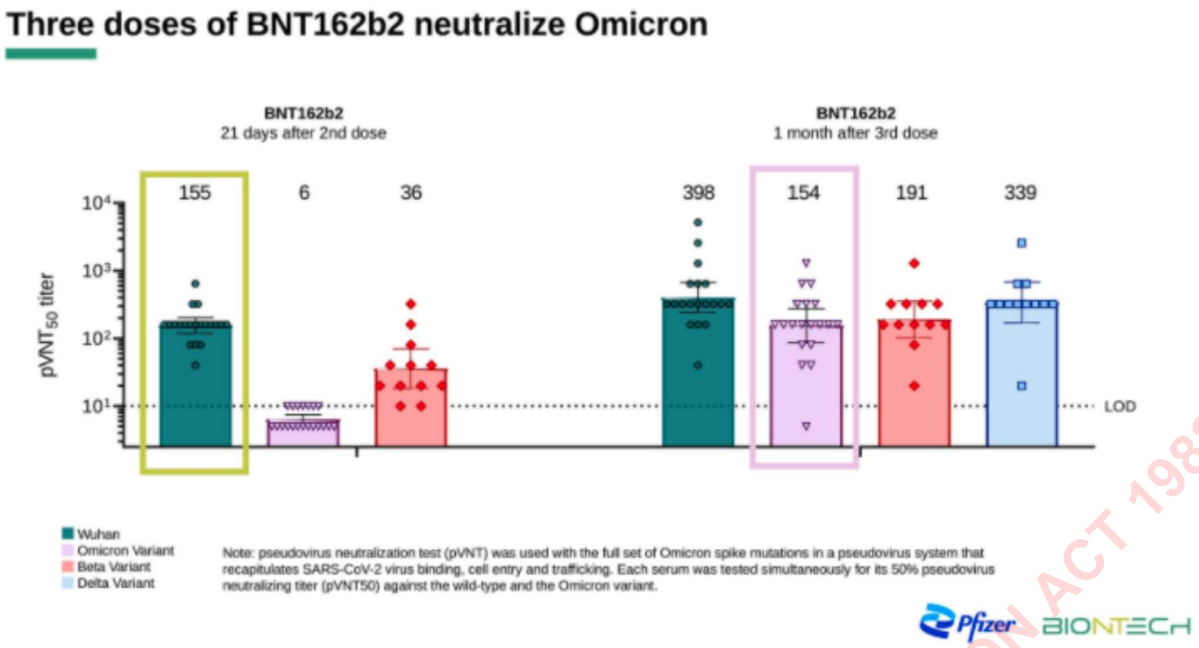


Figure 2 The neutralisation after 2 and 3 doses of Pfizer, of the early 'Wuhan' strain (green); Omicron (purple); the variant that had previously demonstrated the greatest degree of immune escape, Beta (red); and Delta (blue). Omicron shows substantial reduction in neutralisation after 2 doses compared to Beta and Wuhan; however, Omicron has similar neutralisation to other variants after 3 doses.

7. In addition to neutralising antibodies, Pfizer also considered how another arm of the immune response, the cellular response (memory T-cells), performed against Omicron. T-cell responses appeared to be largely unaffected by Omicron.

8. Pfizer also presented neutralisation data on the 'variant-specific' vaccines that they have been developing to date. The lab data for the Pfizer 'Alpha'- and 'Delta'-specific vaccines suggests that those vaccines could offer even better protection against Omicron, because they are able to neutralise Omicron more effectively than the original Pfizer vaccine.

9. In addition, there have been three other preliminary neutralisation studies that have were reported on 08 and 09 December 2021. [35-37]

10. A Swedish study of sera from healthcare workers and blood donors, all of whom had had previous infection, found that the neutralisation of the Omicron variant by Pfizer sera was similar to Delta (both in people with prior infection and as a result of vaccination).[37] Vaccination plus prior infection provided the greatest benefit.

11. Studies from South Africa and Germany found similar results: there was a substantial reduction in neutralisation by Pfizer with Omicron compared to an earlier strain and Delta, but potentially greater protection for people who were vaccinated and had prior infection.[35, 36]

Disease Severity

12. With respect to disease severity for Omicron, there is currently no evidence that the Omicron variant causes more severe disease. Evidence on disease severity takes time to emerge.

13. The media has reported on the "stealth Omicron variant", which is a variant (sub-lineage) that is missing one of the mutations usually found on Omicron, which gives a different

result with some diagnostic tests. This does not have any practical significance for the testing undertaken in New Zealand as all positive COVID-19 samples will be analysed using whole genome sequencing (see https://www.theguardian.com/world/2021/dec/07/scientists-find-stealth-version-of-omicron-not-identifiable-with-pcr-test-covid-variant)

Comment

14. This emerging data is reassuring for our COVID-19 vaccine programme, and potentially highlights the importance of the booster rollout.

15. The potential vaccine efficacy of Pfizer against Omicron will be discussed at CV TAG on 14 December 2021.

16. It should be emphasised that the data is preliminary, and all studies are based on small sample sizes. This data needs to be confirmed by larger, peer-reviewed, clinical or real-world studies in order to determine the impact on clinical outcomes.

References

(see reference list, above)

Document 4

Memo

Recommendations on the COVID-19 booster vaccination interval for those aged 18 years and over in the context of Omicron

Date:	1 February 2022
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	Astrid Koornneef, Director, National 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:	Consideration

Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the interval between COVID-19 primary course vaccinations and booster doses for those aged 18 years and over in the context of Omicron.

Background and context

2. On 8 November 2021 Medsafe updated the provisional approval for the Pfizer vaccine to state: "*a booster dose of Comirnaty may be administered intramuscularly at least 6 months after completion of the primary course in individuals aged 18 years of age and older.*"[1]

3. In November 2021, CV TAG made initial recommendations about COVID-19 booster vaccinations in the memo "*Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations*", dated 10 November 2021 (Appendix 1). At this time, it was recommended that a COVID-19 booster vaccination of Pfizer be administered at 6 months after a primary course (two doses).

4. In December 2021, the COVID Vaccine Immunisation Programme (CVIP) asked for further advice about the use of booster doses at less than 6 months after the completion of the primary vaccination course. CV TAG issued updated recommendations in the memo "*COVID-19 booster vaccinations in specific situations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations*", dated 17 December 2021 (Appendix 2). This memo advised a Pfizer booster dose should be offered to adults 18 years or over 5 months after the completion of the primary vaccination course. Further advice from the Director-General and the Ministry of Health's Policy team saw the interval reduced to 4 months from 5 January 2022 onwards.

5. The Director-General has requested CV TAG's advice about shortening the interval between the primary course and booster dose to 3 months.

Evidence and international guidance

Evidence on waning of immunity and need for boosters

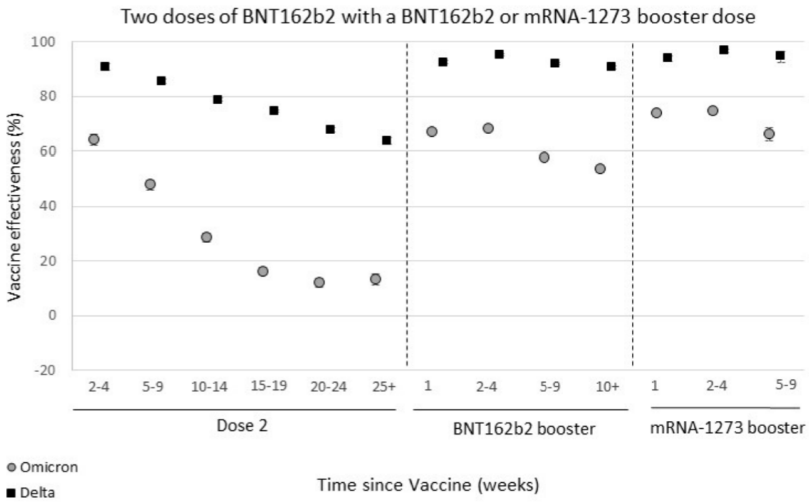
6. Even prior to Omicron, evidence showed that antibody levels against SARS-CoV-2 waned over time following the second Pfizer COVID-19 vaccine dose. Waning of vaccine effectiveness, particularly protection against infection, was observed after the second dose, with a large decline in protection observed 6 months after the primary vaccination course.[2-4] The rate of waning may be influenced by co-morbidities, prior infection, and other factors (for example, immunity may wane faster in older populations) but there are currently limited data on this and it is not known to what extent these factors influence protection.

7. With regards to transmission from vaccinated individuals who are infected, protection against onwards transmission also appears to wane over time.[5] Evidence suggests that protection against severe disease also wanes slightly over time, including for the Delta and Omicron variants, though follow-up times varied between studies.[2-4, 6-9] Although waning is less of an issue for protection against severe disease regardless of variant, vaccine effectiveness (VE) against hospitalisation following a primary course is substantially reduced for Omicron compared to Delta, as outlined below.

8. Omicron is becoming the dominant variant globally, including in Aotearoa New Zealand. Omicron has substantial immune evasion properties, and vaccine effectiveness is generally much lower against Omicron compared to previous variants. Evidence on VE against the Omicron variant and the need for booster doses is emerging:

    a. Data on VE against infection after a primary course suggest that protection wanes more rapidly with Omicron compared to Delta. A Danish cohort study reported that one month after a Pfizer primary course, VE against infection had dropped to 55.2% (95% CI: 23.5-73.7) and continued to wane over time, with no protection observed after 3 months.[10] A booster dose restored VE against infection to 54.6% (95% CI: 30.4-70.4).

    b. VE against symptomatic disease wanes after the a primary course according to data from South Africa[11, 12] and the UK.[13-17] For example, current evidence from England[17] shows marked waning of the VE against symptomatic disease after 2 doses of Pfizer against Omicron, from >60% after 2 weeks to <20% from 15 weeks after dose 2. Protection against symptomatic disease is restored to >50% even after 10 weeks post-dose 3 (see Figure below):



c. A booster dose of mRNA vaccine restored the protection against symptomatic COVID-19 to levels similar to that observed immediately after the primary course in the UK. [14, 17, 18] However, these studies did not specify the interval between the second dose and the booster dose.

d. In South Africa, VE against hospitalisation after a primary course of Pfizer vaccine was 70% (95%CI 62-76) during Omicron dominance, compared with 93% [95%CI 90-94] during the period of Delta dominance.[19]

e. In the UK, VE (all vaccines combined) against hospitalisation with the Omicron variant was 64% (95% CI: 54-71) 2 to 24 weeks after dose 2, declining to 44% (95%CI: 30-54) at 25+ weeks.[17] VE (all vaccines combined) against hospitalisation after a booster dose increased to approximately 90% 2+ weeks after a booster dose, including in those over 65 years of age.[17, 20]

f. In the US, VE against Omicron-related hospitalisation for two doses of Pfizer was 68% (95% CI: 58−75), and VE for three doses of Pfizer was 89% (95% CI: 84−92).[21]

9. Currently, data are limited regarding the immune response provided by prior COVID-19 infection and the duration of protection from infection. Current evidence suggests that the risk of SARS-CoV-2 reinfection is low after a previous infection but may increase with time due to waning immunity.[22] Data from multiple studies indicate that COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection.[22]

10. Potential reasons to consider a shorter booster interval include:

a. to provide protection against symptomatic COVID-19 caused by new variants, such as Omicron, sooner.

b. to provide increased protection against hospitalisation due to COVID-19 caused by Omicron infection, particularly for older adults who comprise the majority of hospitalisations.

c. to protect people who are close to 4 months post-primary vaccination course who are at high risk of severe COVID-19 and/or SARS-CoV-2 exposure, and subsequent waning of immunity.

Safety data for boosters

11. Booster doses have been shown to have a very good safety profile.[23-25] However, there are limited safety data on differing intervals for a booster dose of the Pfizer vaccine.

12. *Pfizer trial data:* Amongst 306 participants aged 18-55 receiving a third dose 5–8 months after completion of a 2-dose primary series, reactogenicity was largely in line with that reported after the second dose, with the exception of lymphadenopathy which occurred at a rate of 5.2% compared to 0.4% after the second dose.[23] No cases of myocarditis/pericarditis were reported.

13. An analysis of V-Safe data from 12,591 registrants in the US found that 79.4% and 74.1% reported local or systemic reactions, respectively, after the third dose, and 77.6% and 76.5% reported local or systemic reactions after the second dose.[24] However, the majority of recipients were likely immunocompromised given third dose recommendations at the time. The median interval from completion of the primary COVID-19 vaccination series to receipt of an additional dose was 182 days.

14. The AusVaxSafety active surveillance system has collated data from more than 491,000 respondents who received booster doses (interval from second dose not clear but is likely to be 3-6 months).[26] The proportion reporting common systemic and local reactions are similar after the booster dose compared with after the second primary dose.

15. Data on adverse events when boosters are administered earlier than 5-6 months is limited. Data from the UK COV-BOOST study with 2,878 participants indicate that a booster dose of Pfizer or AstraZeneca given around 3 months after a primary course of either vaccine were both generally well tolerated.[27] The most common systemic reactions for booster vaccines were fatigue and headache, and the most common local reaction was injection site pain. Adverse events were more common in those who had a different brand of booster vaccine than what was used for the primary course (compared with those who had the same vaccine brand for all doses), and in younger (compared with older) participants.

16. *Myocarditis:* Israel has reported 37 cases of myocarditis after the administration of approximately 4.1 million third doses.[28] Young males still remain the most affected group, however rates appear to be lower than that after the second dose. US Vaccine Adverse Event Reporting System (VAERS) data indicate that after approximately 930,000 booster doses administered to those aged 18-24 years, there were 2 reports of myocarditis that met the case definition.[29] A non-peer-reviewed UK analysis in those aged 13 years or more (interval between second and third dose not specified) found that myocarditis risk was slightly increased during 1-28 days following a third dose of the Pfizer vaccine (IRR 2.02, 95% CI: 1.40-2.91) compared to the second dose (IRR 1.60, 95% CI 1.31-1.97).[30] Associations were strongest in males younger than 40 years, with an estimated additional 12 (95% CI: 1-7) events per million following a second dose and 13 (95% CI: 7-15) events per million following a third dose. There remain limited data on the incidence of myocarditis after third doses of mRNA vaccines.

International guidance on booster interval post-primary course

17. Booster programmes are now well underway in many countries, including but not limited to the United Kingdom, the United States, Australia, and Canada.

18. On 24 December 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) updated their recommendations on COVID-19 booster vaccinations[31]: "*ATAGI recommends bringing forward the minimum interval between the primary course and the booster dose from 5 months to 4 months as soon as practical, noting the holiday period. It is understood that this is achievable from 4 January, although some providers may have flexibility to administer before that time. As soon as practical, ATAGI recommends providing boosters to all eligible adults from a minimum of 3 months following the second dose of the primary course.*" Five of Australia's six states have made the decision to shorten the interval to 3 months amid unprecedented strain on hospitals (NSW, Victoria, South Australia, ACT, and Tasmania).[32, 33]

19. The UK's Joint Committee on Vaccination and Immunisation (JCVI) have reduced the minimum interval between completion of the primary course and the booster to 3 months, stating that "*it may be that higher levels of antibody induced by vaccines directed at the original 'wild type' variant will provide better protection against the Omicron variant, as has been demonstrated in laboratory studies with respect to other variants*", and "*additional data regarding the Omicron variant will take some time to accrue. Waiting for such data before taking some actions risks a suboptimal delayed response*".[34]

20. On 4 January 2022, the CDC updated their recommendations for when people can receive a booster dose, shortening the interval from 6 months to 5 months after their primary course.[35]

21. The National Advisory Committee on Immunization (NACI) in Canada continue to recommend an interval of 6 months between primary course vaccination and booster doses.[36] However, Ontario has reduced the interval to 3 months in response to Omicron.

International guidance on booster interval post-infection

22. On 24 January 2022, ATAGI decreased the time allowable for deferral of vaccination after prior SARS-CoV-2 infection to 4 months. This was due to the increased risk of re-infection with the Omicron variant, particularly for those who had a Delta variant infection in 2021. ATAGI continues to advise that previous infection is not a contraindication to vaccination and that vaccination can occur following recovery of acute illness from COVID-19. Currently advice states that vaccination can occur following resolution of acute illness. A precaution for any vaccination is acute illness to avoid adverse events (including common side effects of vaccination) in an already ill person or to avoid attributing illness symptoms to vaccination, however, no time interval is given. Those with prolonged symptoms of COVID-19 should be vaccinated on a case-by-case basis.[37]

23. In the UK, it is advised that vaccinations should be deferred until people with a current or previous history of COVID-19 have recovered to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive test in those who are asymptomatic. This is applicable to primary courses and the booster programme. In younger people, it is advised that protection from natural infection is likely to be high for a period of months and vaccination in those recently infected may increase the chance of side effects, and therefore those aged under 18 are advised to have a 12-week deferral for primary course first or second doses, though this is not relevant to the booster programme.[38]

24. The CDC states that *"People with known current SARS-CoV-2 infection should defer vaccination at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. Current evidence about the optimal timing between SARS-CoV-2 infection and vaccination is insufficient to inform guidance. This recommendation for vaccination applies to people who experience SARS-CoV-2 infection before receiving any vaccine dose and those who experience SARS-CoV-2 infection after the first dose of a COVID-19 vaccine, but before receipt of subsequent doses."*[39]

25. In Canada, NACI advises that vaccination should be offered to individuals with previous laboratory-confirmed SARS-CoV-2 infection who are in the authorised age group without contraindications. The booster dose recommendations also apply to individuals with previous laboratory-confirmed SARS-CoV-2 infection. It is recommended that before vaccination, the individual should no longer be considered infectious, and symptoms of an acute illness should be completely resolved. These waiting times are intended to, respectively, minimise the risk of transmission of COVID-19 at an immunisation venue and to enable monitoring for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses.[40]

Recommendations

26. CV TAG met on Tuesday 1 February 2022 to consider guidance on shortening the interval between the primary course and COVID-19 booster vaccinations for those aged 18 years and over.

27. **CV TAG noted that:**

    a. The goal of offering booster doses in New Zealand is to prevent severe disease caused by SARS-CoV-2, to reduce burden on hospitals and other healthcare providers, and to protect those at high occupational risk of exposure. This has grown to become more important in the context of Omicron infection, which is associated with substantially less protection after 2 doses, and where early waning reduces levels of protection sooner.

    b. Baseline levels of protection shortly after vaccination and the rate of waning of immunity can vary by several demographic and clinical factors.

    c. Māori and Pacific peoples are at an increased risk of severe disease and hospitalisation[41] and age-specific rates are higher. This therefore means that having a universal age-criteria for prioritisation is inequitable. A lower age band for Māori and Pacific peoples would be needed to provide equitable protection.

    d. There is strong evidence that boosters have a good safety profile.[23-25] Data around the safety profile associated with different booster intervals is limited. Data from studies where individuals received boosters around 6 months after the second dose show that local and systemic reactions are mostly mild to moderate and the frequency is similar to that observed after the second dose.

    e. There is no evidence to date that receiving a booster dose at 3 months produces a lower immune response than a booster dose at 4 months or 6 months. Further follow up studies will be required to determine if there are any negative impacts on the secondary immune response that boosters generate. It is still unclear if the primary vaccination course for COVID requires three primary doses rather than the current two.

    f. Medsafe has approved booster doses at least six months after completion of the primary course in those aged 18 years and over.

    g. The Vaccine Programme Team have advised that there are no immediate supply constraints.

28. **CV TAG recommends that:**

    a. A booster dose of the COVID-19 vaccine should be given from 3 months after the primary course to all eligible people aged 18 years and over, including immunocompromised individuals and pregnant persons.

    b. The following groups should be prioritised:

        i. Māori and Pacific people aged 18 years and over

        ii. Those aged 65 years or over

        iii. Residents of aged care and disability facilities

iv. Frontline healthcare workers, border workers, or essential workers whose ability to work is critical for infrastructure and supply chains

v. Anyone aged 18 years and over with comorbidities (as previously specified for Group 3 - Appendix 3).

29. For those with PCR-confirmed COVID-19 infection after their primary course, a COVID-19 vaccine booster dose should be offered 3 months after recovery from acute illness.

30. Guidance on the use of COVID-19 booster vaccinations in younger age groups (e.g., 12-17-year-olds) will be considered separately.

31. Vaccine mandates should not require booster doses for those under 18 years of age.

32. CV TAG will continue to monitor all relevant information (including vaccine effectiveness data against variants of concern and emerging evidence on the duration of immunity) 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

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Appendix 1: Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Memo

Date:	10 November 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
Copy:	Dr Ashley Bloomfield, Director-General of Health Allison Bennett, Manager, System Enablers, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
Subject:	Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations
For your:	Consideration

Purpose

33. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations about COVID-19 booster vaccinations.

Context

34. Current evidence shows that antibody levels against SARS-CoV-2 wane over time following the second Pfizer COVID-19 vaccine dose, and that there is a reduction in protection against infection, particularly from 6 months after a primary vaccination course.[2-4] The reduction in protection is similar for Delta and other virus variants.[3, 6] Protection against transmission from vaccinated individuals who are infected also appears to wane over time.[5] However, evidence suggests that protection against severe disease remains high, including for the Delta variant, though follow-up times varied between studies.[2-4, 6-9]

35. Booster doses are now being given in several countries, including but not limited to the United Kingdom, the United States, Germany, Israel, Singapore, and Malaysia.

36. Medsafe has assessed an application submitted by Pfizer for the use of booster vaccines within New Zealand. On 8 November 2021 Medsafe updated the provisional approval for the Pfizer vaccine to state "a booster dose of Comirnaty may be administered intramuscularly at least 6 months after completion of the primary course in individuals aged 18 years of age and older".

37. *Reactogenicity of a Pfizer booster dose:* Amongst 306 participants aged 18-55 years old receiving a third dose in Pfizer's phase III trial, reactogenicity was largely in line with findings after the second dose, with the exception of lymphadenopathy which occurred at a rate of 5.2% compared to 0.4% post-second dose.[42] Other studies also suggest that

the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses.[43-47]

38. *Safety of a Pfizer booster dose:* Data from Israel shows that after more than 2.8 million administered third doses, 19 serious adverse events have been reported, of which 2 have been confirmed as linked, though there is likely underreporting in this data.[48] Only one case of myocarditis has been reported and is under investigation, in a male older than 30 years, however most younger individuals have had limited follow up time.[48] Israeli data suggests that the risk of myocarditis with the booster dose is not increased when compared with the risk after second doses of vaccine.[49] However, there remain limited data on the incidence of myocarditis after second doses of the mRNA vaccines in younger people.[49-55]

39. *Immunogenicity and effectiveness of a Pfizer booster dose:* A COVID-19 vaccine booster dose administered at 6 months or more after completion of the primary vaccine course has been demonstrated to boost the immune response and is expected to increase protection against infection and disease, particularly in older people where waning appears more marked.[42-45] Data from Israel, where booster doses have been administered to large numbers of people, show reductions in all eligible age groups in the rate of infection, as well as severe disease in those aged ≥40 years, and deaths in those ≥60 years, after the booster dose.[49, 56, 57]

40. *AstraZeneca booster dose:* A small study suggests that AstraZeneca, when used as a booster following a full primary course of Pfizer or Moderna, augments humoral and T cell immune responses, and is well tolerated.[8]

41. *Prioritisation:* The UK's Joint Committee on Immunisation (JCVI) advised on 14 September 2021 that booster vaccines be offered to those more at risk from serious disease, and who were vaccinated during Phase 1 of the vaccine programme (priority groups 1 to 9). This was seen as needed in order to maintain a high level of protection against hospitalisation or death from the virus through winter 2021/2 (while acknowledging that insufficient time has passed to know what levels of protection might be expected 6 to 12 months after the primary course). Those to be offered boosters in the UK include:

    a. those living in residential care homes for older adults
    b. all adults aged 50 years or over
    c. frontline health and social care workers
    d. all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19, and adult carers
    e. adult household contacts of immunosuppressed individuals

    The JCVI advised that the booster vaccine dose is offered no earlier than 6 months after completion of the primary vaccine course, in the same order as during Phase 1. They also indicated a preference for the Pfizer vaccine for the booster programme, regardless of which vaccine brand someone received for their primary doses.

42. The Australian Technical Advisory Group on Immunisation (ATAGI) advised on 27 October 2021 that the highest priority groups to receive booster doses should be those with risk factors for severe COVID-19 and/or those at increased occupational risk of COVID-19, notably:

a. People at greater risk of severe COVID-19: individuals aged 50 years and older, those with underlying medical conditions, residents of aged care and disability facilities, and Aboriginal and Torres Strait Islander adults. In these groups the benefit of a booster dose is primarily to reduce the risk of severe COVID-19.

b. People at increased occupational risk of COVID-19: a booster dose for individuals in this group is expected to reduce their likelihood of SARS-CoV-2 infection and associated occupation-related impacts, acknowledging that infection will be mostly mild in these individuals due to prior vaccination and younger age. Booster doses may also reduce the potential for infected individuals to transmit SARS-CoV-2, although evidence for this is currently limited.

43. ATAGI supports the use of a single booster dose for those who completed their primary COVID-19 vaccine course ≥6 months ago. This will initially include, but not be limited to, the groups who were prioritised in the rollout of the vaccine programme from early 2021. This recommendation will be reviewed by ATAGI in January 2022, as groups other than the high-risk groups listed above will become eligible in larger numbers. Pfizer is recommended as a single booster dose, irrespective of the primary COVID-19 vaccine used. Although not preferred, ATAGI recommended that AstraZeneca can also be used as a booster dose in the following situations:

a. For individuals who have received AstraZeneca for their first two doses if there are no contraindications or precautions for use.

b. If a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g., anaphylaxis, myocarditis).

44. ATAGI does not currently recommended boosters for those aged <18 years. In this age group, severe COVID-19 is uncommon, and the primary course of COVID-19 vaccines generates a strong immune response, and therefore the benefit from additional doses of vaccine is thought to be to be small. In addition, there are currently only very limited data on the safety of repeated mRNA vaccine doses in this age group.

45. The Ministry of Health's Policy team requested CV TAG's clinical guidance on which groups should be prioritised for booster vaccines, and when these vaccinations should start.

Recommendations

46. CV TAG met on 2 and 9 November 2021 to consider recommendations regarding priority groups for COVID-19 booster vaccinations.

47. **CV TAG noted that:**

a. Data are still accumulating about waning of protective vaccination effects after primary vaccination and the benefits of a booster dose.

b. The goal of offering booster doses in New Zealand is to prevent severe disease caused by SARS-CoV-2, to reduce burden on hospitals and other healthcare providers, and to protect those at high occupational risk of exposure.

c. The current situation in New Zealand is different to the situation at the start of vaccine roll-out (starting in late February 2021, priority groups listed in Appendix 1). There is now greater availability of Pfizer vaccine and effective infrastructure for administering the vaccine, but there is also a higher risk of healthcare workers being exposed to

SARS-CoV-2 with the virus now in the community in New Zealand, especially in Auckland.

d. There is limited data on the safety profile for booster doses in people younger than 30 years of age from the published trials. Concern was noted around vaccine mandates requiring booster doses in this age group before further data are available

e. There is insufficient data on the safety profile for booster doses in pregnant people.

f. Māori and Pacific People are at an increased risk of severe disease and hospitalisation,[41] and therefore having a universal age-criteria for prioritisation is inequitable. A lower age band for Māori and Pacific People would be needed to provide equitable protection.

g. It is now approximately 8 months since the first doses of COVID-19 vaccine were administered in New Zealand.

48. **CV TAG recommends that:**

a. Increasing the vaccination coverage of first and second doses, particularly for Māori and Pacific People, should remain the first priority of the COVID-19 vaccination programme in New Zealand.

b. The Pfizer vaccine is recommended as a single booster dose.

c. COVID-19 vaccine booster doses should be offered to those 18 years of age and older, who have completed their full primary vaccination course 6 or more months prior.

d. Those aged over 18 who are immunocompromised and have received a third primary dose of a COVID-19 vaccine as described in previous CV TAG recommendations, should only receive a booster dose 6 months after completion of their primary course (i.e., 6 months after their third dose).

e. Any future vaccine mandates should not require booster doses in younger age groups (<30 years) until further data are available.

f. When considering prioritisation, priority groups for a booster dose (at least 6 months after completion of the primary course) are those most at risk of exposure to SARS-CoV-2, and those most at risk from serious COVID-19 disease. In particular, these are:

i. Frontline healthcare workers, particularly in regions where there is COVID-19 in the community (or regions that are at high risk of further spread of COVID-19),

ii. All those who are aged 65 years or over,

iii. Māori and Pacific People aged 50 years and over,

iv. Anyone over the age of 18 with comorbidities, as specified in Group 3 in Appendix 1, with the exception of pregnant people, who completed a full primary course of vaccination in early pregnancy.

g. AstraZeneca can also be used as a booster dose if available for specific situations including if an individual has had a significant adverse reaction after a previous Pfizer vaccine dose (e.g., anaphylaxis, myocarditis), and if AstraZeneca is not contraindicated.

49. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

Dr Ian Town

Chief Science Advisor

Chair, CV TAG

Appendix 2: COVID-19 booster vaccinations in specific situations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Memo

Date:	17 December 2021
To:	Dr Ashley Bloomfield, Director-General of Health
Copy:	Astrid Koornneef, Director of National 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
Subject:	COVID-19 booster vaccinations in specific situations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations
For your:	Consideration

Purpose

50. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations about booster doses of the Pfizer vaccine.

Context

51. On 8 November 2021 Medsafe updated the provisional approval for the Pfizer vaccine to state: ***"a booster dose of Comirnaty may be administered intramuscularly at least 6 months after completion of the primary course in individuals aged 18 years of age and older".***

52. CV TAG has previously made recommendation about booster vaccinations in the memo "Priority groups for COVID-19 booster vaccinations: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations", dated 10 November 2021 (Appendix 1).

53. The COVID Vaccine Immunisation Programme (CVIP) has asked for further information and clarification on CV TAG's recommendations in specific situations:

    a. Use of booster doses at less than 6 months after the completion of the primary vaccination course.

    b. Use of booster doses for those under the age of 18 years who are at high risk of exposure to SARS-CoV-2.

    c. Booster doses for pregnant people.

54. *Antibody waning:* Current evidence shows that antibody levels against SARS-CoV-2 wane over time following the second dose of the Pfizer COVID-19 vaccine. There is a reduction in protection against infection, particularly from 6 months after a primary vaccination course.[2-4] The reduction in protection is similar for Delta and other virus variants.[3, 6] Protection against transmission from vaccinated individuals who are infected also appears

to wane over time.[5] However, evidence suggests that protection against severe disease remains high, including for the Delta variant, though follow-up times varied between studies.[2-4, 6-9]

55. *Reactogenicity of a Pfizer booster dose:* Amongst 306 participants aged 18-55 years old receiving a third dose in Pfizer's phase III trial, reactogenicity was largely in line with findings after the second dose, with the exception of lymphadenopathy which occurred at a rate of 5.2% compared to 0.4% post-second dose.[42] Other studies also suggest that the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses.[43-47]

56. *Safety of a Pfizer booster dose:* Data from Israel shows that after more than 2.8 million administered third doses, 19 serious adverse events have been reported, of which 2 have been confirmed as linked, though there is likely underreporting in this data.[48] Only one case of myocarditis has been reported and is under investigation, in a male older than 30 years, however most younger individuals have had limited follow up time.[48] Israeli data suggests that the risk of myocarditis with the booster dose is not increased when compared with the risk after second doses of vaccine.[49] However, there remain limited data on the incidence of myocarditis after second doses of the mRNA vaccines in younger people.[49-55]

57. *Immunogenicity and effectiveness of a Pfizer booster dose:* A COVID-19 vaccine booster dose administered at 6 months or more after completion of the primary vaccine course has been demonstrated to boost the immune response (e.g. neutralising antibody) and is expected to increase protection against infection and disease, particularly in older people where waning appears more marked.[42-45] Data from Israel, where Pfizer booster doses have been administered to large numbers of people, show reductions in all eligible age groups in the rate of infection, as well as severe disease in those aged ≥40 years, and deaths in those ≥60 years, after the booster dose.[49, 56, 57]

Use of booster doses at less than 6 months after the completion of the primary vaccination course

58. Potential reasons to consider early booster doses include:

    a. to provide potentially higher protection against COVID-19 caused by new variants

    b. to protect people who are close to 6 months post-primary vaccination course who are at risk of severe COVID-19 and/or SARS-CoV-2 exposure.

59. It is not yet clear if Omicron can evade vaccine-induced immunity. The laboratory data on Omicron from antibody neutralisation studies to date is very limited and preliminary [58-60], and cannot be used to infer an impact on vaccine protection in real world settings at this stage. Additional information about these studies is presented in Appendix 2.

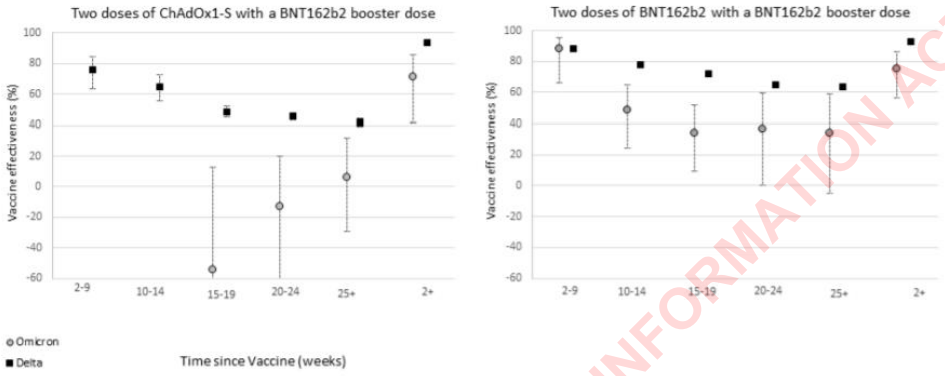
60. Very early data about vaccine effectiveness (VE) against **symptomatic** disease caused by Omicron and Delta variants was released by the UK Health Security Agency (UKHSA) on 10th December 2021.[18] This analysis included data from 56,439 Delta cases including 581 Omicron cases. Results are shown in Figure 1 (Figure 7 in original document), below. Data about VE of a Pfizer primary series (weeks "2-9" to "25+") and booster dose (week "2+") against Delta and Omicron variants are shown in the right-hand panel of Figure 1. Confidence intervals for VE estimates for Omicron are extremely wide. However, they do not appear to overlap with confidence intervals for Delta at any point from 9 weeks after the primary course (including after the booster dose). This suggests a lower VE for

Omicron than for Delta, but it remains unclear to what extent. The point estimate for VE against Omicron increased to ~76% at >2 weeks after a Pfizer booster dose, from ~35% at 15 to >25 weeks after the Pfizer primary course.

Figure 1: Early UKHSA data on vaccine effectiveness for Delta and Omicron (right panel show Pfizer primary course and booster, with lower effectiveness against Omicron)

Figure 7: Vaccine effectiveness against symptomatic diseases by period after dose 1 and dose 2 for Delta (black squares) and Omicron (grey circles) for (A) recipients of 2 doses of AstraZeneca vaccine as the primary course and a Pfizer as a booster[1] and (B) recipients of 2 doses of Pfizer vaccine as the primary course and a Pfizer as a booster

Supplementary data are not available for this figure.



[1] The early observations for 2 doses of AstraZeneca are particularly likely to be unreliable as they are based on relative small numbers and are likely to reflect an older population and a population with more co-morbidities than those given the Pfizer vaccine, and this may explain the negative point estimates.

61. A press release with data from South Africa during the Omicron wave states that two doses of Pfizer has a VE of **70% against hospitalisation**, and **33% against COVID-19 infection,** though the data does not mention time since vaccination.[11]

62. Other data from South Africa shows that the risk of reinfection has increased in the era of Omicron. [61] This suggests that Omicron could have increased evasion of immunity following prior infection.

63. The Australian Technical Advisory Group on Immunisation (ATAGI) advised on 3rd December 2021 in a statement about SARS-CoV-2 Omicron variant and COVID-19 booster doses, that at that time there was no evidence to suggest that earlier booster doses of current COVID-19 vaccines will augment protection against the Omicron variant. However, ATAGI also said in this statement that in certain circumstances, the routine six-month interval for booster doses may be shortened to five months for logistical reasons, for example:

    a. for patients with a greater risk of severe COVID-19 in outbreak settings;

    b. if an individual is travelling overseas and will be away when their booster dose is due; or

    c. in outreach vaccination programs where access is limited.

64. **On 12th December, ATAGI updated their statement to recommend COVID-19 booster vaccination for anyone aged 18 and older who completed their primary course of COVID-19 vaccination 5 or more months ago.**

65. The UK's Joint Committee on Vaccination and Immunisation (JCVI) have reduced the minimum interval between completion of the primary course and the booster to 3 months, stating that "it may be that higher levels of antibody induced by vaccines directed at the original 'wild type' variant will provide better protection against the Omicron variant, as has been demonstrated in laboratory studies with respect to other variants", and "additional data regarding the Omicron variant will take some time to accrue. Waiting for such data before taking some actions risks a suboptimal delayed response".

Use of booster doses in those under the age of 18 years who are at high risk of exposure to SARS-CoV-2

66. In those under 18 years of age, severe COVID-19 is uncommon, and the primary course of COVID-19 vaccines generates a strong immune response. Therefore, the benefit from additional doses of vaccine is thought to be to be small. In addition, there are currently only very limited data on the safety of repeated mRNA vaccine doses in this age group.

67. On 9th December 2021, the U.S. Food and Drug Administration (FDA) amended the emergency use authorization for the Pfizer vaccine, allowing the use of a booster in individuals 16 and 17 years of age at least six months after completion of primary vaccination with Pfizer vaccine.

68. ATAGI does not currently recommended boosters for those aged <18 years.

Booster doses for pregnant people

69. CV TAG recommendations from 10th November (Appendix 1) excluded pregnant people who received a primary course earlier in pregnancy from priority groups, but there was no specific recommendation given about booster vaccination in pregnancy outside of a prioritisation framework. Specifically, there is concern that messaging that those vaccinated in early pregnancy should not receive a booster dose while still pregnant is raising unintended concerns about the safety of vaccination with COVID-19 vaccines while pregnant (both primary and booster doses).

70. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) states that "a booster dose can be considered if you are 18 years or older and had your initial COVID-19 vaccine course (called the primary course) ≥ 6 months ago. Pfizer is the preferred brand for booster doses for all people, including in pregnancy, regardless of the brand used initially". RANZCOG argue "mRNA vaccines are safe and effective for those trying to conceive, pregnant and breastfeeding women. Booster doses have not yet been studied in those who are pregnant but have been shown to be safe and effective in non-pregnant adults. We do know that COVID-19 infection in pregnancy poses a significant risk for mothers and their babies, and RANZCOG recommends that pregnant women receive booster vaccinations in line with the recommendations for the non-pregnant adult population".[62]

Recommendations

71. CV TAG met on 14 December 2021 to consider recommendations regarding COVID-19 booster vaccinations in specific situations.

72. **CV TAG noted that:**

    a. Data are still accumulating about whether early booster doses offer any advantages in protection against the Omicron variant.

b. There are no long term data available about the safety of early booster doses but short term side effects appear to be modest.

c. There is insufficient data on the safety profile for booster doses in pregnant people.

d. Medsafe has authorised boosters only from six months after completion of the primary dose.

73. **CV TAG recommends that:**

a) A Pfizer booster dose should be offered to adults 18 years or over, 5 months after the completion of the primary vaccination course.

b) Priority should be given to those at high risk of severe disease or exposure to SARS-CoV-2, including:

i. those aged 65 years and over

ii. those with comorbidities that put them at higher risk of severe COVID-19

iii. Māori and Pacific peoples

iv. health care workers and workers in other settings at high-risk of SARS-CoV-2 exposure eg Border Workers and MIQ staff.

c) The COVID-19 Vaccine and Immunisation Programme (CVIP) of the Ministry of Health will need to work with Medsafe to manage access to boosters for the shorter 5-month interval.

d) Booster doses for 16- and 17-year-olds are not currently recommended (including for those working in settings that place them at higher risk of exposure to SARS-CoV-2), in line with the Medsafe authorisation of booster doses.

e) Boosters can be offered to pregnant people who completed their primary vaccination course more than 6 months prior. Those approaching the full-term of their pregnancy 6 months after completing their primary course can choose to receive their booster after the baby is born if preferred.

74. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

Dr Ian Town

Chief Science Advisor

Chair, CV TAG

Appendix 3: Groups 1- 4 in New Zealand's Pfizer primary vaccination roll-out (as at 30th October 2021)

Group 1

Group 1 includes people working at the border or in MIQ, and the people they live with (household contacts).

Group 2

The Government is expanding the list of Alert Level 4 workers who can get early access to a COVID-19 vaccination. These people will be included in Group 2.

Group 2 will now also include frontline staff who interact with customers and transport and logistic services directly supporting the vaccination programme.

You are also in Group 2 if you:

- are a high-risk frontline healthcare worker (public or private)
- work in a long-term residential environment
- live in long-term residential care and are 12 or over
- are an older Māori or Pacific person being cared for by whānau
- live with or care for an older Māori or Pacific person
- live in the Counties Manukau DHB area and are 65 or over, have an underlying health condition or disability, are pregnant, or are in a custodial setting.

Group 3

People who are at risk of getting very sick from COVID-19. You are in this group if you:

- are aged 65 or over
- are eligible for a publicly funded influenza vaccine
- are pregnant
- are disabled, or are caring for a person with a disability
- are severely obese (defined as a BMI ≥40)
- have high blood pressure requiring 2 or more medications for control
- are an adult in a custodial setting
- have been diagnosed with a severe mental illness (which includes schizophrenia, major depressive disorder, bipolar disorder or schizoaffective disorder, and adults currently accessing secondary and tertiary mental health and addiction services).

Group 4

Everyone aged 12 and over

Document 5

Memo

Decision to use the AstraZeneca COVID-19 vaccine as a booster for those aged 18 years and over 3 months after a primary vaccine course

Date:	10 February 2022
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	Astrid Koornneef, Director, National 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:	Consideration

Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendation on the decision to use the AstraZeneca COVID-19 vaccine ('the AstraZeneca vaccine') as a booster 3 months after a primary vaccination course for those aged 18 years and over.

Background and context

2. As at 7 February 2022, 94 per cent (3,935,736) of eligible New Zealanders have received two COVID-19 vaccine doses (fully vaccinated), a further 2 per cent have received at least one dose, and 5 per cent of the eligible population remain unvaccinated. The booster programme is underway, and there are currently high levels of uptake. As at 7 February 2022 1,604,760 boosters had been administered to those aged 18 years and over.
3. The current objective of the COVID-19 vaccine immunisation programme is to protect individuals from severe disease outcomes and to reduce the impact of the virus on the healthcare system.
4. To date, New Zealand has implemented a predominantly Pfizer-based COVID-19 immunisation programme. Pfizer is currently the only product with regulatory approval from Medsafe for use as a booster for those 18 years and over.
5. In December 2021 CV TAG advised that based on emerging evidence of waning immunity provided by COVID-19 vaccines, and the threat posed by the Omicron variant, the booster dose interval should be reduced from 6 months after the second primary vaccination to 5 months. After further consideration and advice from the Director-General of Health, Cabinet decided to reduce the dose interval to a 4 month (minimum) from second primary dose. In February 2022 CV TAG recommended that a booster dose of the COVID-19 vaccine should be given from 3 months after the primary course.

6. In New Zealand the AstraZeneca COVID-19 vaccine is available for those aged 18 and older who cannot receive the Pfizer vaccine, and for people who would like a different option.

7. The AstraZeneca COVID-19 vaccine is a two-dose non-replicating viral vector vaccine, and the second dose is administered between 4 and 12 weeks after the first dose. It can be stored at 2-8°C for up to 6 months. Multiple doses may be pre-drawn from one vial and used within one hour if stored at room temperature, or within six hours if stored at 2-8°C.[1] AstraZeneca boosters are currently available on prescription 4 months after completion of a primary course.

AstraZeneca as a booster dose

8. A booster dose of the AstraZeneca vaccine restored the protection against symptomatic COVID-19 to levels similar to that observed immediately after the primary course in the UK.[2,3] However, studies did not specify the interval between the second dose and the booster dose.

9. A small study suggested that AstraZeneca, when used as a booster following a full primary course of Pfizer or Moderna, augments humoral and T cell immune responses, and is well tolerated.[4]

10. The UK COV-BOOST study evaluated the reactogenicity profiles of different boosters in people inoculated with either two doses of AstraZeneca or Pfizer as their primary vaccination.[5] Participants primed with Pfizer reported more frequent local and systemic reactions after receiving a booster of AstraZeneca, Janssen, Moderna and Coronavac, compared with other vaccines. From these, malaise was reported in 5.6% of the AstraZeneca recipients, in 5.5% of the Moderna's, and in 5.8% of the Coronavac's, while 5.8% boosted with Janssen reported chills and 7.8% fatigue. All other severe reactions were reported in less than 5% of the participants.

11. The AstraZeneca vaccine has been available in New Zealand since 26 November 2021, and the adverse events following immunisation (AEFI) data collated by the Centre for Adverse Reactions Monitoring (CARM) will be reported for AstraZeneca in the next safety report #40, for the period ending 31 January 2022 which will be published soon. It is anticipated that this report will also capture any reports of adverse events associated with the administration of the AstraZeneca as a booster. The AstraZeneca vaccine has been thoroughly assessed for safety by Medsafe, as with all medicines approved for use in Aotearoa New Zealand, and this is publicly available.

Recommendation

12. CV TAG met on Tuesday 8 February 2022 to consider guidance on the use of the AstraZeneca vaccine as a booster vaccine three months after completion of a primary vaccination course for those aged 18 or over.

13. **CV TAG recommends that:**

    13.1 The AstraZeneca COVID-19 vaccine can be given as a booster to those 18 years and over, 3 months after a primary vaccine course

14. CV TAG will continue to monitor all relevant information and will update their recommendation where appropriate in the coming weeks.

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group

References

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