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.

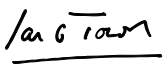
e. Although not required to meet the definition of fully vaccinated, CV TAG recommends offering another dose of a vaccine approved by Medsafe to those who have had a single dose of the Janssen vaccine, particularly those at high risk of serious disease or occupational exposure.

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

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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.

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