

# Memo

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

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## 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  $\geq 40$  years, and deaths in those  $\geq 60$  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  $\geq 6$  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 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,<sup>[25]</sup> 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.

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Chair, CV TAG

## **Appendix 1: Groups 1- 4 in New Zealand's Pfizer primary vaccination roll-out (as at 30<sup>th</sup> 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  $\geq 40$ )
- 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

## References

1. Chemaitelly, H., et al., *Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar*. New England Journal of Medicine, 2021.
2. Tartof, S.Y., et al., *Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study*. The Lancet.
3. Goldberg, Y., et al., *Waning Immunity after the BNT162b2 Vaccine in Israel*. N Engl J Med, 2021.
4. Andrews, N., et al., *Vaccine effectiveness and duration of protection of Comirnaty, Vaxzevria and Spikevax against mild and severe COVID-19 in the UK*. medRxiv, 2021: p. 2021.09.15.21263583.
5. Eyre, D.W., et al., *The impact of SARS-CoV-2 vaccination on Alpha and Delta variant transmission*. medRxiv, 2021: p. 2021.09.28.21264260.
6. De Gier, B., et al., *COVID-19 vaccine effectiveness against hospitalizations and ICU admissions in the Netherlands, April- August 2021*. medRxiv, 2021: p. 2021.09.15.21263613.
7. Self, W.H., et al., *Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions - United States, March-August 2021*. MMWR Morb Mortal Wkly Rep, 2021. **70**(38): p. 1337-1343.
8. Nunes, B., et al. *mRNA vaccines effectiveness against COVID-19 hospitalizations and deaths in older adults: a cohort study based on data-linkage of national health registries in Portugal*. 2021; Available from: <https://www.medrxiv.org/content/10.1101/2021.08.27.21262731v1.full.pdf>.
9. Pfizer. *BNT162b2, COMIRNATY (COVID-19 Vaccine, mRNA), Evaluation of a Booster Dose (Third Dose), VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE BRIEFING DOCUMENT, MEETING DATE: 17 September 2021*. 2021; Available from: <https://www.fda.gov/media/152161/download>.
10. Falsey, A.R., et al., *SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3*. N Engl J Med, 2021. **385**(17): p. 1627-1629.
11. Choi, A., et al., *Safety and immunogenicity of SARS-CoV-2 variant mRNA vaccine boosters in healthy adults: an interim analysis*. Nat Med, 2021.
12. Flaxman, A., et al., *Reactogenicity and immunogenicity after a late second dose or a third dose of ChAdOx1 nCoV-19 in the UK: a substudy of two randomised controlled trials (COV001 and COV002)*. Lancet, 2021. **398**(10304): p. 981-990.
13. Hause, A.M., et al., *Safety Monitoring of an Additional Dose of COVID-19 Vaccine - United States, August 12-September 19, 2021*. MMWR Morb Mortal Wkly Rep, 2021. **70**(39): p. 1379-1384.
14. Mofaz, M., et al. *Self-reported and physiological reactions to the third BNT162b2 mRNA COVID-19 (booster) vaccine dose*. 2021 [cited 30 Oct 2021; Available from: <https://www.medrxiv.org/content/10.1101/2021.09.15.21263633v3.full.pdf>].
15. Alroy-Preis, S. and R. Milo. *Booster protection against confirmed infections and severe disease - data from Israel*. 17th September 2021; Available from: <https://www.fda.gov/media/152205/download>.
16. Israeli Ministry Of Health, et al. *Vaccines and Related Biological Products Advisory Committee October 14-15, 2021: Booster protection across ages - data from Israel*. 2021; Available from: <https://www.fda.gov/media/153086/download>.
17. Simone, A., et al., *Acute Myocarditis Following COVID-19 mRNA Vaccination in Adults Aged 18 Years or Older*. JAMA Internal Medicine, 2021.
18. Larson, K.F., et al., *Myocarditis after BNT162b2 and mRNA-1273 Vaccination*. Circulation, 2021. **0**(0).

19. Mevorach, D., et al., *Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel*. New England Journal of Medicine, 2021.
20. Witberg, G., et al., *Myocarditis after Covid-19 Vaccination in a Large Health Care Organization*. New England Journal of Medicine, 2021.
21. Centers for Disease Control and Prevention (CDC). *Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination*. 2021; Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>.
22. Public Health Ontario. *Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to August 7, 2021*. Available from: [https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc\\_lang=en](https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en).
23. Patalon, T., et al. *Short Term Reduction in the Odds of Testing Positive for SARS-CoV-2; a Comparison Between Two Doses and Three doses of the BNT162b2 Vaccine*. 2021; Available from: <https://www.medrxiv.org/content/10.1101/2021.08.29.21262792v1.full.pdf>.
24. Bar-On, Y.M., et al. *Protection Across Age Groups of BNT162b2 Vaccine Booster against Covid-19*. medRxiv 2021:2021.10.07.21264626. 2021; Available from: <https://www.medrxiv.org/content/10.1101/2021.10.07.21264626v1.full.pdf>.
25. Steyn, N., Binny, R. N., Hannah, K., Hendy, S. C., James, A., Lustig, A., Ridings, K., Plank, M. J., Sporle, A., *Māori and Pacific people in New Zealand have a higher risk of hospitalisation for COVID-19*. New Zealand Medical Journal, 2021. **134**(1538).