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

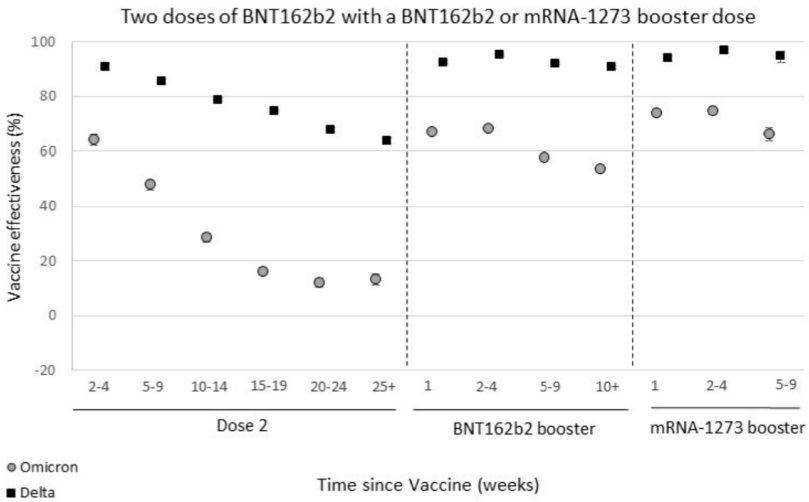
6. Even prior to Omicron, evidence showed that antibody levels against SARS-CoV-2 waned over time following the second Pfizer COVID-19 vaccine dose. Waning of vaccine effectiveness, particularly protection against infection, was observed after the second dose, with a large decline in protection observed 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

MINISTRY OF HEALTH
MANATŪ HAUORA

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),

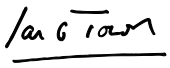
ii. All those who are aged 65 years or over,

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

MINISTRY OF HEALTH
MANATŪ HAUORA

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.

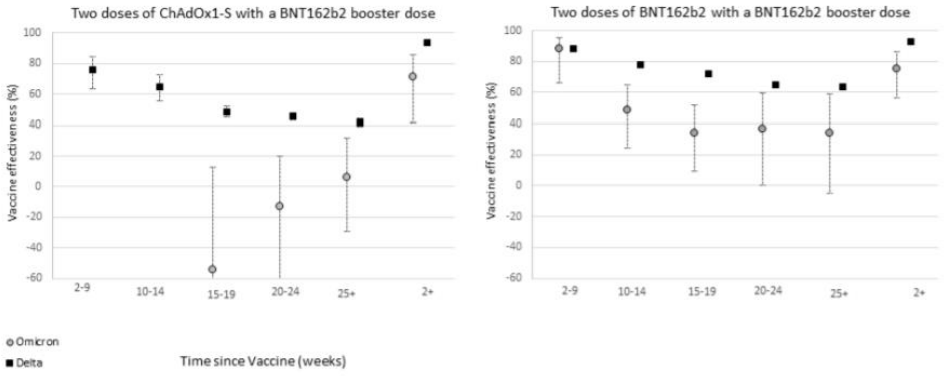
60. Very early data about vaccine effectiveness (VE) against **symptomatic** disease caused by Omicron and Delta variants was released by the UK Health Security Agency (UKHSA) on 10th December 2021.[18] This analysis included data from 56,439 Delta cases including 581 Omicron cases. Results are shown 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

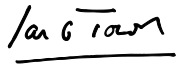
   iv. health care workers and workers in other settings at high-risk of SARS-CoV-2 exposure eg Border Workers and MIQ staff.

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