

# Memo

## Fourth dose (second booster): COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

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<b>Date:</b>	1 April 2022
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<b>From:</b>	Dr Ian Town, Chief Science Advisor
<b>For your:</b>	Consideration

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### Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) advice about the waning of immunity after first boosters (third doses) and the need for a second booster (fourth) dose in groups at greater risk of experiencing impacts from COVID-19.

### 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.*
3. In November 2021, CV TAG made initial recommendations on 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. In this memo, CV TAG also noted that (emphasis added) *"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)." A six-month interval was also recommended for the general population at this time. At this time CV TAG noted "there is insufficient data on the safety profile for booster doses in pregnant people" and therefore the recommendations did not include pregnant people who received a primary course earlier in pregnancy.*
4. 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. In this memo, CV TAG noted that data was still accumulating about whether early booster doses offer any advantages in protection against the Omicron variant, that there continued to be insufficient data on the safety profile for booster doses in pregnant people, and that Medsafe had authorised boosters only from six months after completion of the primary course. CV TAG recommended that a booster 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. No further recommendation was given on boosters in severely immunocompromised people.

5. The Ministry of Health was requested to provide interim advice over the 2021/22 Christmas and New Year period on these two issues. The Science and Technical Advisory noted the updated (24 December 2021) Australian Technical Advisory Group on Immunisation (ATAGI) advice and that of jurisdictions such as the UK and Canada, and recommended that pregnant people and those who are severely immunocompromised be able to access the booster dose at the same dosing interval as the rest of the adult population.
6. In light of emerging evidence on the importance of boosters for protection against infection for Omicron, and updates to guidance in other countries, CV TAG recommended in January 2022 that pregnant people aged 18 and older can receive the Pfizer booster vaccine at any stage of pregnancy, at least 4 months after the second dose, and are encouraged to discuss the timing of their booster with their midwife, obstetrician or general practitioner. They also recommended that immunocompromised people who have received three primary doses should have a booster dose in line with the timing for the general population i.e., a 4-month interval from their primary course (three doses).
7. **In early February 2022, the current recommendation was made by CV TAG, that a booster dose of the COVID-19 vaccine should be given sooner after the primary course to all eligible people aged 18 years and over, including immunocompromised individuals and pregnant persons. Cabinet agreed to give boosters from 3 months.**
8. As cases of COVID-19 climb globally due to outbreaks of the Omicron variant, and evidence has emerged on the waning of protection, some jurisdictions have rolled out second boosters (fourth doses) to their most vulnerable (people with comorbidities, the elderly, and healthcare workers).
9. The Director-General of Health has requested further information on the waning of immunity after a first booster dose and groups in which waning may occur more rapidly. The Director-General of Health has also asked for advice on whether a second booster dose is needed, and if so, the interval at which this should be given and the priority groups for this second booster dose.

## Evidence informing advice

### *Waning of immunity after a first booster dose*

10. Data from the United Kingdom and United States show that vaccine effectiveness (VE) against symptomatic infection and severe disease caused by Omicron wanes over time.
  - a. A CDC study found the VE for Pfizer against Omicron *hospitalisation* after three doses wanes from 91% (95% CI: 88–93) at  $\leq 2$  months to 78% (95% CI: 67–85) at  $\geq 4$  months.[1] This trend is broadly in line with the UK Health Security Agency (UKHSA), who found VE after three doses of Pfizer against *hospitalisation* wanes from 85–90% at 2–4 weeks to approximately 75% at 10–14 weeks (~2–3 months).[2]
  - b. Data from the UKHSA also shows that 2–4 weeks after a booster dose of the Pfizer vaccine, VE against *symptomatic* COVID-19 caused by Omicron is approximately 65% and declines to around 45% from 10–14 weeks after the booster.[2]
11. *Pace of waning and at-risk groups*: Evidence also shows that protection does not wane at the same pace for everyone, and appears to wane faster for the elderly, and for some people with other health conditions their immune response to the vaccine is lower.
  - a. A study of people aged over 80 years found participants to have significantly lower neutralising titres against the wild type and some variants of concern than people aged under 80 years, particularly before receiving a second dose.[3]

- b. Similarly, a study of Greek healthcare workers found that although titres did not significantly differ among participants aged 20–49 years, there was a significant decline in the 50-59 years age group and a further decline among those over 60.[4]
- c. Another study with a cohort of 83 individuals aged 81-91 years showed that after 1 month, individuals vaccinated with one dose of Pfizer had high enough antibody titres to protect against infection (>141 BAU/ml) while seven months later, this was reduced.[5]
- d. A study conducted in Germany found that neutralising antibody titres had waned to a significantly greater extent among the elderly, compared with young healthcare workers, at six months after the first vaccination.[6]
- e. Immunogenicity data suggests that cancer, transplant, dialysis patients, and those on immunosuppressant therapy have a reduced response to a first dose of vaccine which can improve with a second dose,[8-15] although it still may not be optimal, with both reduced antibody and T cell responses.[16-24]
- f. A (non-peer reviewed) study of antibody responses following the second dose of Pfizer has been conducted using data from the UK's national COVID-19 Infection Survey. This study found that antibody responses can last for over a year, though they declined more rapidly in older people, males, and those with underlying health conditions. The greatest antibody half-life was observed among those previously infected by SARS-CoV-2.[25]

#### *Safety, reactogenicity and efficacy of a second booster dose*

12. Data on the reactogenicity, safety, immunogenicity, and efficacy of a second booster dose are currently limited to three studies from Israel.
  - a. One study of Israelis aged 60 years and over extracted data for the Omicron-dominated period (15 January through 27 January 2022) from the Israeli Ministry of Health database. It included 1,138,681 persons aged over 60 years, who were eligible for a fourth dose in Israel at the time.[26] The rate of confirmed COVID-19 infections and severe illness was analysed and compared between those who had received a fourth dose at least 12 days prior, those who had received a fourth dose 3-7 days prior, and those who had received only three doses.
  - b. Another study of Israeli healthcare workers aged 18 years and over evaluated a fourth dose of Pfizer or Moderna administered after three Pfizer doses. The study population were 1,050 eligible healthcare workers with no known history of SARS-CoV-2 infection, who received the third dose of Pfizer at least 4 months earlier.[27] Of 1050 eligible, 154 and 120 (274 total) were enrolled to receive Pfizer and Moderna, respectively, and compared to 426 age-matched controls. Primary endpoints were safety and immunogenicity. and secondary endpoints were vaccine efficacy in preventing SARS-CoV-2 infections and COVID-19 symptomatic disease.
  - c. A preprint retrospective cohort study was also conducted with all members of Clalit Health Services, aged 60 to 100, eligible for the second booster in Israel. Mortality due to COVID-19 among participants who received the second booster was compared with participants who received one booster dose. A Cox proportional-hazards regression model with time-dependent covariates was used to estimate the association between the second booster and death due to COVID-19 while adjusting for demographic factors and coexisting illnesses. A total of 563,465 participants met the eligibility criteria. Of those, 328,597 (58%) received a second-booster dose during the 40-day study period.[28]
13. *Safety and Reactogenicity:* In the trial of healthcare workers, most adverse events (AEs) were reported as mild and resolved within 1.7 days post booster dose. No serious AEs or hospital admissions were reported. Solicited local AEs were common, and for Pfizer 78.6% (95% CI: 71.2-84.8) of second booster dose recipients reported an adverse event. Among Pfizer second booster dose recipients, more were reported by younger participants: 88% (95%CI: 80.6-95.3) compared with

69.6% (95% CI: 59.4-79.7) in those >60 years of age. Solicited systemic AEs were reported by 42.9% (95% CI: 35-50.7) of Pfizer second booster dose recipients. Younger participants reported systemic AEs more commonly than older participants for each of the AEs and in both vaccines, but this effect was small and did not reach statistical significance. Systemic adverse events resolved within 1.3 days. The most common systemic AE reported was fatigue (27.3%, 95% CI: 20.4-35.0% for Pfizer second booster dose), followed by myalgia and headache. Fever was relatively uncommon, with only 7.1% (95% CI 3.1-11.2). Fever resolved within 24-36 hours in either group.[27] The study of Israelis 60 years and over did not report any safety or reactogenicity data.[26]

14. **Breakthrough infection:** In the trial of Israeli healthcare workers, 18.3% of participants that received a Pfizer second booster had breakthrough infection compared with 25.0% of the control group who had only had three doses. In the majority of cases (65-72%) symptoms were mild (without fever of  $\geq 38^{\circ}\text{C}$ ).[27]
15. **Effectiveness:** The study of healthcare workers was not originally designed to assess vaccine effectiveness, which was only a secondary outcome. However, after adjustment for period of exposure and age-group, the second booster dose relative vaccine effectiveness (compared to first booster only) against infection was 30% (95% CI: -9-55) for Pfizer. For symptomatic disease, the relative vaccine effectiveness (compared to first booster only) was 43% (95% CI: 7-65).[27]
16. In the study of Israelis aged over 60 years, the rate of confirmed infection for those who received the fourth dose at least 12 days prior was lower by a factor of 2.0 (95% CI: 2.0-2.1) compared to those who had not received the fourth dose and was lower by a factor of 1.9 (95% CI: 1.8-1.9) compared to those who had received the fourth dose 3-7 days prior (Figure 1). The rate of severe illness for those who received the fourth dose at least 12 days prior was lower by a factor of 4.3 (95% CI: 2.4-7.6) compared to those who had received only three doses, and was lower by a factor of 4.0 (95% CI: 2.2-7.5) compared to those who had received the fourth dose 3-7 days prior (Figure 1).[26]

	Cases (person-days at risk)			Rate Ratio (95% CI)		Adjusted rate difference per 100,000 person-days at risk (95% CI)	
	3rd dose only	3-7 days after 4th dose	12+ days after 4th dose	3rd dose only vs. 12+ days after 4th dose	3-7 vs. 12+ days after 4th dose	3rd dose only vs. 12+ after 4th dose	3-7 vs. 12+ days after 4th dose
Confirmed Infections	42,693 (7,603,132)	5,945 (1,264,767)	9,071 (3,421,826)	2.0 [2.0, 2.1]	1.9 [1.8, 2.0]	279 [271, 287]	234 [219, 247]
Severe illness	195 (4,277,639)	55 (1,023,355)	13 (980,984)	4.3 [2.4, 7.6]	4.0 [2.2, 7.5]	3.8 [2.8, 4.8]	3.5 [2.1, 5.1]

Figure 1: Results of the Poisson regression analysis for confirmed infection and severe illness between the different study groups. [26]

17. Israelis aged 60-100 who received a second booster of Pfizer had a 78% lower mortality rate from the disease than those who only received one booster, a preprint study from Israel has shown from the country's largest healthcare provider, Clalit Health Services. 58% of participants had received a second booster and the remainder had received only one booster (at least 4 months prior). Researchers recorded 92 deaths among the first group and 232 deaths among the second, smaller group, with 40 days follow-up after the second booster. The research excluded people who received Moderna's vaccine and those who had taken oral anti-COVID therapy.[28]
18. **Limitations:** More data is required to understand the relative effectiveness of a second booster against infection and severe disease, as the sample sizes for these studies were small. Participants in both studies were selected based on having low antibody titres, which may overestimate the benefit for general population. If borne out by more data, effectiveness estimates are significantly lower than efficacy against infection post-third (first booster) dose and suggest that current mRNA vaccines may produce a "peak" response after the third dose, but further doses may only recover the immunity lost over time owing to waning. Despite this, the authors note that the second booster dose could be

beneficial for people at higher risk of severe illness, particularly during periods of surge and rising infections, while emphasising the urgency of next generation development.[29]

## International recommendations from peak bodies and rollout of second booster doses

19. Given the potential for waning immunity following a first booster, particularly against severe disease (as measured by hospitalisation), some countries have begun recommending the administration of a second booster dose to elderly populations or individuals at increased risk of severe disease or exposure.
- a. *Australia:* The Australian Technical Advisory Group on Immunisation (ATAGI) issued recommendations about fourth doses on 25 March 2022. ATAGI recommended an additional booster dose of COVID-19 vaccine to increase vaccine protection before winter for selected population groups who are at greatest risk of severe illness from COVID-19 and who have received their primary vaccination and first booster dose ([link](#)). These groups are:
    - i. Adults aged 65 years and older
    - ii. Residents of aged care or disability care facilities
    - iii. People aged 16 years and older with severe immunocompromise (as defined in the ATAGI statement on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised)
    - iv. Aboriginal and Torres Strait Islander people aged 50 years and older.
  - b. ATAGI have recommended that the additional winter booster dose can be given from 4 months or longer after the person has received their first booster dose, or from 4 months after a confirmed SARS-CoV-2 infection, if infection occurred since the person's first COVID-19 booster dose. ATAGI recommended that the rollout of the additional booster dose for these groups starts from April 2022, coinciding with the rollout of the 2022 influenza vaccination programme. ATAGI state that there is currently insufficient evidence to recommend additional booster doses for other population groups, including people with medical risk factors; individuals with disability and National Disability Insurance Scheme (NDIS) recipients who are not in residential disability care; aged care, disability care and healthcare workers; healthy individuals aged 16 to 64 years, and; Aboriginal and Torres Strait Islander people aged under 50 years.
  - c. *Israel:* In January 2022, Israel began administering a fourth dose of the Pfizer vaccine to people aged over 60 years and at-risk populations who had received a third dose at least 4 months earlier. An Israeli hospital is also conducting a trial of the second booster dose in healthcare workers. ([link](#)) Early data from Israel's rollout of a second booster dose is presented below. On 22 January 2022, Israel's vaccine advisory committee recommended that those aged 18 and over be offered a fourth vaccine dose at least five months after their third dose or after recovering from the disease. ([link](#))
  - d. *UK:* The Joint Committee on Vaccination and Immunisation (JCVI) has advised an additional spring booster dose be given for the most vulnerable individuals in the population. ([link](#)) As a precaution, a further booster dose is advised 6 months after the last vaccine dose for adults aged 75 years and over, older residents in a care home, and individuals aged 12 years and over who are immunosuppressed.
  - e. *US:* Pfizer applied for authorisation to the US FDA on 15 March 2022 for adults 65 years and over, ([link](#)) and the US FDA has been reviewing data to authorise a second booster dose of vaccines from Pfizer and Moderna. ([link](#)) On 29 March 2022, the FDA authorised second boosters for people aged 50 and over, and immunocompromised people. ([link](#))

- f. *Europe*: The European Medical Authority are yet to receive any application for a second booster dose, though the Head of Vaccine Strategy has been reported in the media to say there is not yet enough evidence on its need ([link](#)).
- g. *Chile*: Media reports have stated that from 7 February 2022, eligibility for a fourth dose will be extended to people aged over 55 years who had a third vaccine dose at least 6 months prior. ([link](#)) The fourth vaccine regimen has not been specified.
- h. *Hungary*: In January 2022, Hungary made a fourth COVID-19 vaccine shot available to people who ask for it, after a consultation with a doctor, in order to combat growing Omicron infections. ([link](#))
- i. *South Korea*: In February 2022, populations that are at increased risk of severe disease (the elderly and immunocompromised) or at increased risk of exposure (healthcare workers) became eligible for a fourth dose, however authorities are not currently considering expanding it more widely. ([link](#))

## Recommendations

- 20. CV TAG met on 1 March and 22 March 2022 to discuss the waning of protection after first booster doses, and the need for second booster doses.
- 21. CV TAG noted that:
  - a. There is evidence of waning of protection following the first booster dose. Protection also appears to wane faster in some populations, e.g., the elderly. People with other health conditions or comorbidities are at an increased risk of poor outcomes also, and may have a lower immune response to vaccines, though evidence is still emerging on the need for a further dose.
  - b. Booster doses began to be administered from 29 November 2021, and therefore some groups are now four months from receiving their first booster dose as we approach winter.
  - c. The influenza immunisation programme is starting in April, and there is a risk of increased burden on the healthcare system from having both SARS-CoV-2 and influenza circulating. Research from 305,000 people in hospital in the UK with COVID-19 between February 2020 and December 2021 found 6,965 people were also recorded as having another respiratory infection alongside COVID - 227 of which were influenza. The researchers estimated that people with COVID-19 and influenza combined were 2.4 times more likely to die and four times more likely to end up on a ventilator than if they only had COVID.[30]
  - d. Data on the reactogenicity, safety, immunogenicity, and efficacy of a second Pfizer booster dose is currently limited to three studies from Israel, which studied the immunogenicity and safety among healthcare workers and the elderly. However, a second booster of the Pfizer vaccine appears to be safe and effective at restoring protection against COVID-19, including Omicron. The vaccine is a reactogenic vaccine, with 78.6% (95%CI: 71.2-84.8) of people who received a second booster dose reporting a local adverse event, and 42.9% (95%CI: 35-50.7) reporting systemic adverse events. Most of these were mild and resolved quickly.
  - e. Some countries have begun rolling out second booster doses, and these have been from four to six months after the first booster dose.
  - f. The goal of the COVID-19 vaccination programme and offering a second booster dose in New Zealand is to prevent severe disease caused by SARS-CoV-2.
  - g. There are a number of equity considerations which are important to consider:
    - i. Māori and Pacific peoples have been disproportionately affected in the current outbreak.

- ii. Māori and Pacific peoples are at greater risk of COVID-19 hospitalisation and severe disease, having respectively a 2.5-fold and 3-fold higher odds of being hospitalised compared to non-Māori, and Māori are likely to spend 4.9 days longer in hospital [31, 32].
  - iii. Māori and Pacific peoples are more likely to live in multigenerational families housing in overcrowded conditions, increasing the risk of transmission [33, 34].
  - h. Medsafe are yet to approve the use of Pfizer as a second booster dose, and therefore these recommendations are requiring Medsafe approval.
  - i. Data is limited on the safety and efficacy of a second booster dose in populations younger than 65 years of age, in healthy individuals, in people with medical or social risk factors, and in pregnant people. Young people (aged under 30) appear to produce a strong immune response to three doses and are considered well protected.
22. CV TAG recommended that:
- a. a second booster dose be offered to:
    - i. people aged 65 years and over
    - ii. Māori and Pacific peoples aged 50 years and over
    - iii. residents of aged care and disability care facilities
    - iv. severely immunocompromised people who received a three-dose primary course and a fourth dose as a first booster (noting this is a fifth dose for these people).
  - b. The second booster dose should be offered from six months after a first booster dose, however consideration should be given to aligning the rollout of second boosters with the influenza immunisation programme. This would require a shorter interval between the first and second booster dose (for example, from 4 months after the first booster dose) to allow it to be given at the same time as influenza vaccine. CV TAG would support an interval of greater than or equal to 4 months for this purpose. Consideration should also be given to bringing the age range eligibility for the funded influenza vaccine down to align with the age ranges recommended for the COVID-19 second booster vaccines.
  - c. A second booster dose, if due, should be postponed for three months after SARS-CoV-2 infection. Clinical discretion can be applied when considering vaccination prior to 3 months after infection. This may be appropriate for those individuals considered to be at high risk of severe disease from COVID-19 re-infection.
  - d. The influenza, MMR, HPV, diphtheria/tetanus/pertussis combination vaccine (Boostrix), and other vaccines may be administered before, after, or at the same time as the Pfizer COVID-19 vaccine, without concern for the spacing of the vaccinations. The only exception to this advice is for the live-attenuated shingles vaccine (Zostavax) where a 7-day interval, before or after administering Pfizer COVID-19 vaccine, is advised.
23. CV TAG will continue to monitor all relevant information and will update their recommendations as further evidence becomes available.

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