



Australian Technical Advisory Group on Immunisation (ATAGI) recommendations on the use of a booster dose of COVID-19 vaccine

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What's changed:

- *Nuvaxovid (Novavax) can be used as a booster in an individual aged 18 years and above if no other COVID-19 vaccine is considered suitable for that individual.*
- *Recommendations concerning the use of AstraZeneca COVID-19 vaccine as a booster dose have been updated. AstraZeneca is no longer recommended for use as the booster dose for people who received a primary vaccination course of the AstraZeneca COVID-19 vaccine, although it can still be used for this purpose if these individuals decline receiving an mRNA vaccine as a booster dose. AstraZeneca is now only recommended when there are medical contraindications to the mRNA vaccines.*
- *Comirnaty (Pfizer) can be used as a booster in individuals aged 16 years and above.*
- *Updated evidence of vaccine effectiveness of booster doses against the Omicron variant has been included.*

Introduction

The overarching goal of Australia's COVID-19 vaccination program is to protect all people in Australia from the harm caused by SARS-CoV-2, primarily through preventing serious illness and death. As the virus that causes COVID-19, SARS-CoV-2, is likely to become endemic in Australia, ATAGI strongly advises that the highest priority for providing optimal community-wide protection against COVID-19 is achieving very high vaccination coverage of primary vaccination doses for all eligible Australians.

ATAGI recommends booster doses of COVID-19 vaccine for all Australians aged 16 years and above, to mitigate against waning immunity to SARS-CoV-2 and emergence of SARS-CoV-2 variants.

The Delta variant of SARS-CoV-2 was the predominant circulating strain in Australia throughout most of 2021. On 24 November 2021, the Omicron variant was first reported in South Africa.

The [World Health Organization \(WHO\)](#) declared Omicron to be a SARS-CoV-2 Variant Of Concern on 26 November 2021 and it is now the dominant strain globally.

ATAGI is closely examining all data on the epidemiology of COVID-19 and COVID-19 vaccine impact, particularly emerging data on the new Omicron SARS-CoV-2 variant, and has [updated its recommendations](#) on the use of booster doses of COVID-19 vaccine in response.

Recommendations

In the current context of ongoing transmission of the Omicron variant:

- For all individuals aged 16 years and above, a single booster dose of COVID-19 vaccine is recommended for those who completed their primary course, 3 or more months ago.
- Either of the available mRNA COVID-19 vaccines (Pfizer or Moderna) is preferred for this booster dose in those aged 18 years and above. For those aged 16 – 17 years, only Pfizer vaccine should be used. These brands can be used for the booster dose regardless of which vaccine brand was used for the primary course.
- For people who have received a primary course of the AstraZeneca vaccine, including those who are severely immunocompromised, AstraZeneca vaccine is no longer a recommended vaccine for use as a booster, even when there are no contraindications or precautions for its further use. However, it can still be used for this purpose in individuals who decline receiving an mRNA vaccine as a booster dose. There is no requirement for people who have already received a booster dose of AstraZeneca COVID-19 vaccine to receive an additional dose of mRNA vaccine.
- The only scenario in which a booster dose using AstraZeneca vaccine is actively recommended is for people with medical contraindications to the Pfizer and/or Moderna vaccines (e.g. anaphylaxis, myocarditis).
- Nuvaxovid (Novavax) has been provisionally approved by the Therapeutic Goods Administration (TGA) for use in a primary course of COVID-19 vaccination. There are limited data on the safety and immunogenicity of Novavax as a booster dose and it is not TGA-registered for this indication. ATAGI advises that Novavax can be used as a booster dose in an individual aged 18 or older if no other COVID-19 vaccine brand is suitable for that individual.
- Severely immunocompromised individuals aged 16 years and above who have received a third dose of a primary COVID-19 vaccine, are also recommended to receive a booster dose 3 months after the third primary dose, in line with the timing for the general population (Refer to ATAGI advice).
- Pregnant women and adolescents aged 16 and above who received their primary COVID-19 vaccination course 3 or more months ago are recommended to receive a booster dose.
- ATAGI recommends that it is acceptable to co-administer a COVID-19 booster vaccine dose with other vaccines. More information is available at: ATAGI Clinical Guidance on Use of COVID-19 Vaccine in Australia.
- Further booster doses (i.e. 4th doses for immunocompetent or 5th doses for immunocompromised) are not recommended at this time.

The anticipated benefits of ATAGI bringing forward the booster dose from 6 to 3 months include a reduction in the risk of symptomatic infection, severe illness and death from COVID-19 caused by the Omicron variant. In combination with enhanced public health and social measures, it is also expected to mitigate the impacts of COVID-19 on the health system and its broader impacts on the community.

These recommendations will continue to be reviewed regularly as further evidence regarding the Omicron variant become available.

Background:

Definition of booster doses and eligibility

A booster dose refers to an additional vaccine dose after the primary vaccine course. A primary COVID-19 vaccine course consists of two doses of the following COVID-19 vaccines available in Australia: Comirnaty (Pfizer), Spikevax (Moderna), Vaxzevria (AstraZeneca) or Nuvaxovid (Novavax) COVID-19 vaccines; or one dose of the Johnson & Johnson/Janssen COVID-19 vaccine (which is registered but not available in Australia). For people with severe immunocompromise, a primary course is defined as 3 doses of a COVID-19 vaccine, as recommended by ATAGI.¹ Mixed schedules of these vaccines are also included in the definition of an acceptable primary course, as are additional TGA-recognised vaccines.²

Summary of evidence:

Benefits of booster doses

During the period of Delta variant predominance, evidence suggested that humoral immunity to the SARS-CoV-2 virus (measured by virus-specific antibody) waned over time against infection. Protection against severe disease also waned, though at a slower rate.¹⁻⁷ Protection against transmission from vaccinated individuals who were infected also appeared to wane over time.⁸ A booster dose augmented protection against infection in people aged 16 years and above, and for severe disease and death across older age groups.⁹⁻¹¹ Limited evidence suggested a booster dose also reduced the potential of infected individuals to transmit the virus to others.⁸

Since the emergence of the Omicron variant in December 2021, it has become apparent that waning of protection after two doses of COVID-19 vaccine is more rapid and pronounced. This is due to the ability of the Omicron variant to evade natural and vaccine-induced immunity.^{12,13} Strong evidence suggests that booster doses of COVID-19 vaccines may enhance protection against symptomatic disease due to the Omicron variant. Multiple studies have shown up to a 20-fold decrease in neutralising antibody titre against Omicron compared with wild type and/or Delta variant in sera after the primary vaccination course, which can be overcome by substantially increased antibody concentrations following a booster dose of an mRNA vaccine.¹⁴⁻¹⁸

This waning in antibody levels is matched by recent preliminary data from several countries suggesting that clinical protective effectiveness against symptomatic COVID-19 due to the Omicron variant wanes rapidly to quite modest effectiveness by about 4 months after 2 doses of the AstraZeneca or Pfizer vaccine.¹⁹⁻²¹ However, a substantial increase in the protective effectiveness against symptomatic disease and infection by the Omicron variant was observed after a booster dose of an mRNA vaccine (Pfizer or Moderna) among those who received either the AstraZeneca or mRNA vaccination for their primary course.²¹ Recent data from England showed that following a booster dose of mRNA vaccine, the effectiveness against symptomatic disease was restored to 50-75% for the first three months then 40-50% between 4-6 months after the booster dose. This was similar across those who had received AstraZeneca, Pfizer or Moderna in the primary course.²¹ The

booster dose of an mRNA vaccine was between 80-95% effective against hospitalisation due to infection with Omicron variant for the first 3 months after boosting and 70-85% effective 4-6 months after boosting. Furthermore, strong protection against death due to the Omicron variant for the first 3 months after boosting was seen, with vaccine effectiveness at 85-99%.²¹

The recent identification of the Omicron sub-lineage BA.2 has raised concerns due to some differences in diagnosis characteristics and potentially greater transmission over the original Omicron sub-lineage BA.1. However, vaccine effectiveness against symptomatic disease 2 weeks after a booster dose was 63% for BA.1 and 70% for BA.2.²¹

The groups most likely to benefit from a single booster dose are those with risk factors for severe COVID-19 (the elderly, those with underlying medical conditions, residents of aged care and disability facilities, pregnant individuals and Aboriginal and Torres Strait Islander adults) and/or those at increased risk of COVID-19 due to occupational risk or living in areas of active community transmission (refer to “Risk factors for severe disease” in the [ATAGI Advice for COVID-19 vaccine providers and administrators](#)).

Safety of booster doses

Studies suggest that the common mild and transient side effects after booster doses are comparable to those following primary vaccine doses.²²⁻²⁷ However, there are limited data on the incidence of rare but potentially serious adverse events following booster doses, such as myocarditis and pericarditis. Myocarditis and pericarditis have been particularly associated with second doses of the mRNA vaccines (Pfizer or Moderna) in younger people.²⁸⁻³³ Preliminary data from Israel on the use of the Pfizer vaccine as a booster dose suggests the risk of myocarditis with the booster dose is not increased, as compared with the risk after second doses of vaccine.^{28,34} Vaccine-related myocarditis and pericarditis adverse event reporting rates after COVID-19 vaccine in the United Kingdom also appear lower after 3rd or booster doses of mRNA vaccines compared to 2nd doses. These rare adverse events are mostly mild after booster doses and do not appear more severe than first or second doses.³⁵ Early US booster safety data suggest similar patterns.³⁶ Any risk of myocarditis or pericarditis following Novavax is not yet known.

If an individual does have chest pain, particularly in the 1-7 days following their booster dose, ATAGI has provided clinical guidance regarding the investigation and management of myocarditis. Refer to [Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines](#).

Choice of vaccine for boosters

The Pfizer or Moderna vaccine as booster dose

Both the Pfizer and Moderna COVID-19 vaccines are recommended as a single booster dose in adults aged 18 years and above. Only Pfizer vaccine is currently recommended for those aged 16 – 17 years. These vaccines can be used irrespective of the primary COVID-19 vaccine received.

Both the Pfizer and Moderna (50µg) COVID-19 booster vaccines have already been approved for use as a booster by the Therapeutics Goods Administration and international regulatory agencies such as the United States Food and Drug Administration, Health Canada and the United Kingdom

Medicines and Healthcare Products Regulatory Agency, and are recommended under their respective COVID-19 vaccination programs.

The AstraZeneca vaccine as booster dose

AstraZeneca was initially included as an alternative booster option for people who had received a primary course of AstraZeneca vaccine, as long as there were no contraindications or precautions for its use. While the AstraZeneca COVID-19 vaccine provides a booster effect after a 3rd dose²³ and is well tolerated, more recent immunogenicity studies show that mRNA vaccines as a booster produce significantly higher antibody levels, which suggest that they could provide better protection.^{13,37} This is particularly important with Omicron becoming the dominant circulating SARS-CoV-2 variant, where higher antibody levels after the booster dose appear important for providing protection against Omicron.

In the UK, one study observed a 25- to 35-fold increase in the geometric mean concentration (GMC) of anti-spike IgG antibody against the Delta and earlier variants of SARS-CoV-2 when AstraZeneca primed subjects were given a single booster dose of an mRNA COVID-19 vaccine, compared to a 3-fold increase when an AstraZeneca booster was used.³⁷ Another study reported a 34-fold increase in neutralising antibodies against the Omicron variant after people primed with the Pfizer vaccine received a third (booster) dose of Pfizer.¹³ This study also reported a 2.7-fold increase when AstraZeneca-primed people received a booster dose of AstraZeneca although this was from a cohort from a separate study to the Pfizer vaccine cohort and not directly comparable.¹³

A booster dose of AstraZeneca remains acceptable in those who have a medical contraindication to or who decline a booster dose of mRNA vaccine, based on immunogenicity studies after various primary COVID-19 vaccines.³⁷⁻³⁹

A booster dose of Pfizer or Moderna vaccine induces good protection against symptomatic infection, hospitalisation and death as outlined above²¹, and a preprint study suggests that this protection is equivalent whichever primary vaccine (Pfizer or AstraZeneca) was used.⁴⁰

The Novavax vaccine as booster dose

Novavax is currently registered for use in a primary COVID-19 vaccination course in people aged 18 years or older. An application for the Novavax vaccine for use in Australia as a booster dose is expected to be provided to the TGA shortly. There is currently limited evidence that support the safety and immunogenicity of Novavax used as a homologous or heterologous booster. ATAGI considers Novavax to be acceptable for use as a booster dose in an individual aged 18 or older if no other COVID-19 vaccine is suitable for that individual.

A phase 2 randomised controlled trial investigated a booster dose of Novavax administered 6 months after a primary series of Novavax in healthy adults aged 18-84 years, compared with placebo (n=383 total participants).⁴¹ The likelihood of short term adverse reactions increased with each subsequent dose of this vaccine. Local and systemic adverse events were reported more frequently after the booster dose compared with after the second primary dose (local: 82.5% vs. 70.0%; systemic: 76.5% vs. 52.8%). Following the booster, local and systemic events were mainly mild to moderate in severity and short-lived, with a median duration of 1 to 2.5 days. Both local and systemic events were less frequent and severe in older adults (60 to 84 years) than in younger adults (18 to 59 years). Antibody

levels increased approximately 4.7-fold at 28 days after the booster compared to 14 days after the primary series, with this response higher in older adults. When comparing pre-booster levels (6 months after 2nd dose) to 28-days post-booster, antibody activity increased 61.2-fold against the ancestral SARS-CoV-2 strain and 73.5-fold against the Omicron variant.

Another phase 2 randomised controlled trial in adults aged 30 years or older (N=2,878) investigated a booster dose of Novavax administered approximately 2.5 months after a two dose primary series of AstraZeneca, or approximately 3 months after a two dose primary series of Pfizer in a heterologous vaccine schedule.³⁷ Local and systemic adverse events following a Novavax booster dose were not frequently reported compared to the other booster vaccines investigated; however they were more common in participants who had received an AstraZeneca primary series compared with those who received a Pfizer primary series. Overall, reactogenicity was greater in people aged 30 to 69 years compared to those aged 70 years and older. When comparing pre-booster levels to 28-days post-Novavax booster, antibody levels increased 6.7-fold in the AstraZeneca primary series group (vs. 15.96 with a Pfizer booster) and 3.57-fold in the Pfizer primary series group (vs. 5.71 with a Pfizer booster).

Uncertainties and evidence gaps

The impact, safety and optimal timing of booster doses are continually reviewed by ATAGI, as increasing numbers of Australians without risk factors for severe disease or SARS-CoV2 exposure become eligible.

Other key evidence gaps include: the future epidemiology of COVID-19 in Australia, the duration of protection following booster doses, the protection against severe COVID-19 outcomes in younger individuals, the impact of boosters on transmission, the potential for new variants to emerge and the role of variant vaccines and future booster doses. ATAGI will continue to review emerging international data and continue to meet frequently, updating guidance based on this evidence.

As with all vaccines, ATAGI recommends that receipt of a COVID-19 vaccine booster dose should be recorded in the Australian Immunisation Register. Individuals should be vaccinated as recommended in [ATAGI's advice on being up-to-date with COVID-19 vaccination](#) which will continue to be updated with evidence regarding optimal protection against COVID-19.

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