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 two vaccination doses for all eligible Australians.

ATAGI recommends booster doses of COVID-19 vaccine for all Australians aged 18 years or older, to mitigate against waning immunity to SARS-CoV-2 and emergence of SARS-CoV-2 variants.

The Delta variant of SARS-CoV-2 has been the predominant circulating strain in Australia in 2021. Omicron was first reported in South Africa on 24 November 2021. The World Health Organization (WHO) declared Omicron to be a SARS-CoV-2 variant of concern on 26 November 2021 and it has since been detected and is now the dominant strain in many countries globally. Cases of COVID-19 due to Omicron, including some acquired in Australia, have been identified in multiple Australian jurisdictions.

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.

Recommendations

Given the likelihood of ongoing transmission of both Omicron and Delta variants, ATAGI now recommends COVID-19 booster vaccination for anyone aged 18 and older who completed their primary course of COVID-19 vaccination 4 or more months ago.

ATAGI advises that based on current evidence, the groups most likely to benefit from booster doses are those with risk factors for severe COVID-19 and/or those at increased risk of COVID-19, notably:

- 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.

- 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.

- People living in jurisdictions with active community transmission of either the Delta or Omicron variant are more likely to benefit from a COVID-19 booster at this point in time. The risk of exposure to SARS-CoV-2, including to the Omicron variant, currently varies significantly between jurisdictions.

The anticipated benefits of ATAGI now recommending the bringing forward of the booster dose from 6 to 4 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 the broader impacts on the community.

These recommendations will continue to be reviewed regularly as the number of people eligible increases and as further evidence regarding the Omicron variant become available.

Both Comirnaty (Pfizer) and Spikevax 50µg (Moderna) COVID-19 vaccines are recommended as a single booster dose, irrespective of the primary COVID-19 vaccine used. Both are preferred over Vaxzevria (AstraZeneca), including for people who received the AstraZeneca COVID-19 vaccine for their primary course. Although not preferred, the AstraZeneca COVID-19 vaccine can be used as a booster dose in the following situations:

- For individuals who have received the AstraZeneca COVID-19 vaccine for their first two doses if there are no contraindications or precautions for use.

- If a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g., anaphylaxis, myocarditis).

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.

Booster doses are not currently recommended for those aged under 18 years. In this age group, severe COVID-19 is uncommon, and the primary course of COVID-19 vaccines generates a strong immune response, so the benefit from additional doses of vaccine is likely to be small. In addition, there are currently only very limited data on the safety of repeated mRNA vaccine doses in this age group. Further guidance will be provided in this group as more evidence becomes available.

Severely immunocompromised individuals aged 18 years and over who have recently been recommended to receive a third dose of a primary COVID-19 vaccine, are also recommended to have a booster dose at 4 months, in line with the timing for the general population.

Pregnant women aged 18 or older who received their primary COVID-19 vaccination course 4 months or more ago are recommended to have a booster dose.
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: Pfizer, Moderna or AstraZeneca COVID-19 vaccines; or one dose of the Johnson & Johnson/Janssen COVID-19 vaccine (which is registered but not available in Australia). Mixed schedules of these vaccines are also included in the definition of an acceptable primary course, as are additional TGA-recognised vaccines\(^1\). For people with severe immunocompromise, a primary course is defined as 3 doses of a COVID-19 vaccine, as recommended by ATAGI.\(^2\)

Summary of evidence:

Benefits of booster doses

Current evidence suggests that humoral immunity to SARS-CoV-2 (measured by virus-specific antibody) wanes, and there is a reduction in protection against infection following vaccination over time.\(^3-5\) Protection against severe disease has been shown to remain high and wane to a lesser degree than against infection or non-severe disease in many studies, including for the Delta variant.\(^3-9\) Protection against transmission from vaccinated individuals who are infected also appears to wane over time.\(^10\)

Administration of a COVID-19 vaccine booster dose 4 months or more after completion of the primary vaccine course has been demonstrated to augment immune responses and is anticipated to increase protection, particularly in older people where waning is more pronounced.\(^11-14\) Data from Israel, where Pfizer COVID-19 vaccine booster doses have been administered to large numbers of people, show reductions in the rate of infection in all eligible age groups, severe disease in those aged ≥40 years, and deaths in those ≥60 years, after the booster dose.\(^15-17\)

The protective effectiveness of a Moderna COVID-19 booster dose has been inferred from a comparison of neutralising antibody titres and seroresponse rates against both the Delta variant and an older strain of SARS-CoV-2, demonstrating that antibody concentrations are higher after the booster dose than after the primary course.\(^18\)

A booster dose may also reduce the potential of infected individuals to transmit the virus to others, although evidence to support this is currently limited.

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.\(^11-14,19,20\) However, there are limited data on the incidence of rare but potentially serious adverse events following booster doses, such as myocarditis and pericarditis which have been particularly associated with second doses of the mRNA vaccines (Pfizer or Moderna) in younger people.\(^17,21-25\) 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.\(^17\)

Choice of vaccine for boosters
Both the Pfizer and Moderna COVID-19 vaccines are recommended as a single booster dose, irrespective of the primary COVID-19 vaccine used.

The Pfizer COVID-19 vaccine was provisionally approved for use as a booster vaccine by the TGA on 27 October 2021 and ATAGI advice published regards its use on 28 October 2021. The Moderna (50µg) COVID-19 booster vaccine was provisionally approved by the TGA on 8 December and ATAGI advice was published on the 12 December 2021.

Both the Pfizer and Moderna (50µg) COVID-19 booster vaccines have already been approved for use as a booster by several 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 COVID-19 vaccination programs.

There are limited data on the rare adverse event of myocarditis rates following a 3rd dose of an mRNA vaccine (Pfizer or Moderna). Data from Israel identified a lower rate of myocarditis following a 3rd dose of the Pfizer vaccine, compared with the second.17 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.

A small study suggests that the AstraZeneca COVID-19 vaccine, when used as a booster, augments humoral and T cell immune responses and is well tolerated14 Although not preferred, the AstraZeneca COVID-19 vaccine can also be used as a booster dose for individuals who have received the AstraZeneca vaccine for their first two doses if there are no contraindications or precautions for use, or if a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g. anaphylaxis, myocarditis).

Uncertainties and evidence gaps

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

Other key evidence gaps include: the degree of protection against the Omicron variant from currently available COVID-19 vaccines, 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 need for variant vaccines, and the need for any future additional 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. However, at this time, evidence is insufficient to support a time, or population in whom, boosters should be strictly required to qualify an individual as fully vaccinated under public health orders. ATAGI may provide further advice on this issue in coming months.
References


