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ATAGI statement on recommendations on a winter booster dose of COVID-19 vaccine

The Australian Technical Advisory Group on Immunisation (ATAGI) has made recommendations on a winter booster dose of COVID-19 vaccine

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Summary

ATAGI recommends an additional booster dose of COVID-19 vaccine to increase vaccine protection before winter for selected population groups (see Table 1) who are at greatest risk of severe illness from COVID-19 and who have received their primary vaccination and first booster dose. These groups are:

- Adults aged 65 years and older
- Residents of aged care or disability care facilities
- 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)
- Aboriginal and Torres Strait Islander people aged 50 years and older.

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 recommends that the rollout of the additional booster dose for these groups starts from April 2022, coinciding with the rollout of the 2022 influenza vaccination program.

Influenza vaccine can be co-administered with the additional booster dose of COVID-19 vaccine. However, if a person is not yet eligible for their additional booster dose, influenza vaccine could be given ahead of the additional booster dose.

Comirnaty (Pfizer) or Spikevax (Moderna) are the preferred vaccines for COVID-19 booster doses including the additional winter booster dose. Vaxzevria (AstraZeneca) can be used when an mRNA vaccine is contraindicated or a person declines vaccination with an mRNA vaccine. Nuvaxovid (Novavax) can be used if no other COVID-19 vaccine is considered suitable for that person.

For other groups not listed above, there is insufficient evidence of the benefits of an additional booster dose to make recommendations at this time. This includes people younger than 65 years with medical conditions that may increase their risk of COVID-19, individuals with disability and National Disability Insurance Scheme (NDIS) recipients who are not in residential disability care, Aboriginal and Torres Strait Islander people aged 16 to 49, workers at health care or residential care facilities, or younger healthy adults. ATAGI will continue to monitor emerging evidence and may recommend an additional dose for these groups in the future.

Prevention of severe illness from COVID-19 remains the primary goal of the ongoing COVID-19 vaccination program. These recommendations for an additional booster dose focus on protecting the most vulnerable groups against severe disease and reducing the potential burden on the healthcare system over the coming months.

The secondary aims of the COVID-19 vaccination program are preventing infection and preventing transmission of the virus. There is limited evidence at this stage for additional booster doses to prevent transmission. Emerging evidence in relation to prevention of transmission by vaccination will continue to be monitored and additional booster doses may be recommended in additional groups in the future.

All people aged 16 years and older are recommended to receive a first booster dose of COVID-19 vaccine after completing their primary course. For most people, this will be a third dose. The booster dose is important to maintain protection against COVID-19.

For any person aged 16 and older who has not received their first booster yet, ATAGI recommends they receive it as soon as possible.

Protection against infection wanes after the first booster dose. However, protection against severe disease (rather than all infection) is relatively well maintained, especially in young healthy populations.

Target group	Recommendation for additional booster dose	Comments/information gaps/next steps
People aged ≥65 years	Recommended	Recommended from 4 months after the previous booster dose, or from 4 months after previous SARS-CoV-2 infection if this occurred since the previous booster dose.
Residents of aged care or disability care facilities	Recommended	Includes people with disability in group residential care facilities. Includes people in residential aged care or disability care who are aged <65 years. Recommended from 4 months after the previous booster dose, or from 4 months after previous SARS-CoV-2 infection if this occurred since the previous booster dose.
People who are severely immunocompromised aged ≥16 years	Recommended for people with severe immunocompromise, as defined in the ATAGI statement on use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised	This will be a 5th dose as this group is recommended to receive 3 primary doses. Recommended from 4 months after the previous booster dose, or from 4 months after previous SARS-CoV-2 infection if this occurred since the previous booster dose.
Aboriginal and Torres Strait Islander people aged ≥50 years	Recommended	Recommended from 4 months after the previous booster dose, or from 4 months after previous SARS-CoV-2 infection if this occurred since the previous booster dose.
People aged <65 years with medical conditions that may increase their risk of COVID-19 [1]	Not currently recommended. Remains under active consideration	Complete primary schedule. Promote first booster dose, if not already given. ATAGI will continue to evaluate emerging evidence over the coming weeks.
Health care, aged care and disability care workers		Complete primary schedule. Promote first booster dose, if not already given. ATAGI will continue to evaluate emerging evidence over the coming weeks. Maximise up to date vaccination of patients under care.
All others aged 16–64 years		Complete primary schedule. Promote first booster dose, if not already given. ATAGI will continue to evaluate emerging evidence over the coming weeks.
All others aged 5–15 years		Complete primary schedule. ATAGI will evaluate emerging evidence over the coming weeks regarding the first booster dose.

1 except for people who are severely immunocompromised as defined in the ATAGI statement on use of a 3rd primary dose of COVID-19 vaccine

Introduction

The virus that causes COVID-19 (SARS-CoV-2) is now endemic in Australia. The Omicron SARS-CoV-2 variant of concern has become the dominant strain globally.

The first booster doses of COVID-19 vaccine were rolled out in November 2021. The interval between the last primary dose and the booster dose was reduced from 6 months to 3 months by 31 January 2022 as evidence emerged and to maximise the number of people who could be vaccinated with booster doses as the Omicron wave evolved.

While the original BA.1 Omicron wave is now past its peak, the BA.2 subvariant is rapidly replacing BA.1. This subvariant is more transmissible and likely to cause a resurgence of cases.[1] The severity of disease and protection after vaccination appear to be similar between BA.1 and BA.2.[2,3]

As of 13 March 2022, cumulative uptake of the third dose (the first booster dose for most people, except for severely immunocompromised people) is 65.6% of those eligible.[4] ATAGI emphasises the importance of a first booster dose of COVID-19 vaccine for all people aged 16 years and older.

There have been approximately 3 million cases of COVID-19 since 5 December 2021, and the vast majority of cases have been mild in severity.[5,6] Some degree of immunity is to be expected after infection, although the level and duration of this in the context of Omicron infection and protection against future variants is unknown.

Prevention of severe illness from COVID-19 remains the primary goal of the ongoing COVID-19 vaccination program. There is a need to consider how best to use COVID-19 vaccines to protect those most at risk of severe disease, hospitalisation and death. Vaccination program priorities may continue to change in the future based on the emergence of new variants and/or new vaccines.

ATAGI has reviewed the available evidence on the duration of protection given by COVID-19 vaccines (including booster doses) and the epidemiology of SARS-CoV-2, to assess the benefit from and optimal timing of further booster doses in people who are currently up to date with COVID-19 vaccination. ATAGI acknowledges that uncertainties remain regarding the potential for new variants; the benefits, safety and optimal timing of additional doses in different groups; and the potential development of new COVID-19 vaccines.

Recommendations

Based on currently available evidence, ATAGI recommends an additional booster dose of COVID-19 vaccine to increase vaccine protection for winter. This winter booster dose should be available from April 2022 for specified populations who are at increased risk of severe disease. These groups are:

- Adults aged 65 years and older
- Residents of aged care or disability care facilities (including those under 65 years)
- People aged 16 years and older with severe immunocompromise as defined in the ATAGI statement on use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised)
- Aboriginal and Torres Strait Islander adults aged 50 years and older.

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.
- Aboriginal and Torres Strait Islander people aged under 50 years.

ATAGI will actively monitor emerging evidence about booster vaccination in these groups and provide updated advice if needed.

Timing of the additional COVID-19 vaccine booster dose for high-risk populations

The additional booster dose can be given from 4 months or longer since the first COVID-19 booster dose. In people who have had a confirmed SARS-CoV-2 infection (by PCR or rapid antigen test) after receiving their first booster dose, the additional dose should be given from 4 months after the confirmed infection, as infection has been shown to boost immunity. ATAGI recommends that the additional booster dose can be received from April 2022, coinciding with the rollout of the 2022 influenza vaccination program.

In special circumstances, individuals may be vaccinated at a shorter interval from their last dose or infection. Examples include vaccination outreach programs to aged care or disability care facilities, remote communities, or delivering vaccination services in the context of natural disasters, where some flexibility of the minimum interval may facilitate vaccination of a larger proportion of individuals.

The additional booster dose should not be administered less than 3 months from the previous booster dose or SARS-CoV-2 infection.

Choice of vaccine

Choice of vaccine for the additional winter booster dose aligns with current recommendations for COVID-19 vaccine boosters. For more information see ATAGI Clinical Guidance on the use of COVID-19 vaccines in Australia.

Other population groups

ATAGI does not currently recommend an additional booster dose for healthy people who are not in one of the above groups.

ATAGI also does not consider there to be sufficient evidence of benefits to recommend additional boosters in occupational groups, such as workers in aged care, residential care or health care. This is based on evidence suggesting that protection from booster doses against transmission of the Omicron variant may be limited and short-lived. Evidence also suggests that use of appropriate personal protective equipment in the workplace means that exposure of health care workers occurs more frequently in the community than in the workplace. ATAGI considers there to be more evidence to support direct protection from an additional booster dose to those at highest risk of severe disease in these settings – residents and patients. Maintaining infection control procedures by workers at aged care and healthcare facilities remains important to minimise transmission of SARS-CoV-2 between staff, residents and patients.

ATAGI will continue to monitor evidence on the epidemiology of SARS-CoV-2, including the BA.2 subvariant, the potential emergence of new variants, waning of immunity against severe disease after the first booster dose, and protection against Omicron transmission, and will update its advice if required.

Rationale

Key considerations in the review of evidence for a second booster dose included the effectiveness of 3 doses in maintaining protection against severe disease or infection, and whether this changed over time in different population groups, as well as efficacy against onward transmission compared with direct protection against severe disease.

Waning of protection after the first booster dose

Evolving evidence based on early vaccine effectiveness data and analysis of antibody levels after the first booster dose suggest there is gradual waning of immunity against the Omicron variant.[7-10] This is most prominent for vaccine effectiveness against symptomatic infection, which declines from 60–75% at 2–4 weeks after a booster dose of either the Pfizer or Moderna vaccine to 25–40% from 15 or more weeks after the booster.[3]

Vaccine effectiveness against COVID-19 hospitalisation after the first booster dose is high at 88–95% after an mRNA booster,[3,7,8,10] and appears to wane more slowly than vaccine effectiveness against symptomatic infection (vaccine effectiveness against hospitalisation was 75% by 10–14 weeks for Pfizer vaccine[3] and 78% ≥4 months after mRNA vaccine[8]). Data from Qatar show that effectiveness against severe disease remained at >90% after 7 weeks or more after the first booster, although this was in a relatively younger population and may not be directly comparable.[7] Further data on waning vaccine effectiveness against COVID-19 mortality are expected soon, but initial estimates from the United Kingdom are high at >95% immediately after the first booster dose.[3]

Benefits of an additional booster dose

Benefits from a second booster dose are supported by limited pre-print data from Israel, which suggest that in higher-risk people (aged ≥60 years), an additional booster dose of Pfizer vaccine at 4 months after a first booster resulted in a 2-fold lower rate of confirmed infection and 4.3-fold lower rate of severe illness.[11]

Another study in younger people aged ≥18 years showed the additional protection from an additional booster dose to be modest and uncertain. Those who received an additional booster dose were 11–30% less likely to be infected and 31–43% less likely to have symptomatic disease than those who had received only one booster. However, estimates were imprecise due to small numbers of infected people.[12]

Population groups at risk of severe disease

Older age is the strongest risk factor for severe COVID-19 outcomes and forms the basis for providing an additional booster dose to older adults in the coming months.[13] Around 160,000 people aged ≥65 years will be 4 months from their first booster dose as of 1 April 2022.

The age cut-off of 65 years aligns with eligibility for receiving influenza vaccine under the National Immunisation Program, which may facilitate implementation and uptake of the additional booster dose. A 4-month interval also aligns with evidence of waning after the first booster dose, and will allow a large proportion of the eligible population to receive the additional dose before winter. Reducing the burden of COVID-19 in high-risk populations during winter may reduce the strain on the healthcare system.

Some people with disability are at increased risk of severe COVID-19, but this risk can vary widely. The risk is higher for people who live in group residential settings,[14] who may also be more likely to have severe disability, which is itself a risk factor.[15]

Severely immunocompromised people have a suboptimal response to COVID-19 vaccines compared with immunocompetent people, even after 3 primary doses.[16-18] With a lower total antibody level, any waning of protection can leave people more susceptible to breakthrough infections. In severely immunocompromised people, this can result in severe disease and death.[19,20] ATAGI therefore recommends the additional booster dose for these people (aged 16 years and older) based on first principles. However, ATAGI notes that there are no studies to date on the use of a 5th dose of vaccine in this population.

Aboriginal and Torres Strait Islander people aged 50 years and above are recommended for an additional booster dose. Data provided to ATAGI by the National Aboriginal and Torres Strait Islander Advisory Group on COVID-19 showed that, between 15 December 2021 and 13 March 2022 (Omicron wave), crude rates of hospitalisation and death in Aboriginal and Torres Strait Islander people aged 50 years and older were 2.5 to 5 times higher than in the non-Indigenous population. This was despite equivalent vaccine coverage in Indigenous and non-Indigenous people. For other respiratory infections such as influenza and invasive pneumococcal disease, younger Aboriginal and Torres Strait Islander people have comparable risks to older non-Indigenous Australians.[21,22] Therefore, ATAGI recommends this additional booster dose for Aboriginal and Torres Strait Islander people from age 50 years.

Medical co-morbidities, when considered independently from age, have a smaller contribution to an increased risk of severe COVID-19 than age.[13,23] Studies of risk factors have mainly been conducted in the pre-Omicron era, and later studies indicate that Omicron infection is less severe than infection with previous variants.[24-27] ATAGI does not currently recommend an additional booster dose in people with co-morbidities aged under 65 years, but continues to monitor evidence of the risk of severe disease due to the Omicron variant in this group.

Most healthy or lower-risk adults who have received a 2-dose primary course and a single booster dose will have a low likelihood of severe illness from the Omicron variant and are currently not recommended for an additional booster dose.[25,28]

Booster doses and effects on transmission

Early pre-print data suggest that the benefit of first booster doses in preventing onward transmission in breakthrough cases of Omicron may be substantially less than Delta and may be short-lived.[29,30] Data from Israel showed that the additional protection against infection of an additional booster dose may be modest (11–30% reduction compared with those who received only one booster).[12] Up to 30% of second booster recipients who had breakthrough infection were asymptomatic and their virus levels were no different from people who received only one booster, suggesting that the additional booster dose may not significantly reduce onward virus transmission in infected people.[12] Several studies have also suggested that in healthcare workers, COVID-19 infections are more likely to arise from community transmission than exposure in the workplace because of the routine use of appropriate infection control procedures and personal protective equipment in the workplace.[31-33] In one study of 24,749 healthcare workers, no workplace factors were associated with seropositivity, but seropositivity was associated with community COVID-19 contact (adjusted odds ratio 3.5, 95% CI 2.9–4) and community COVID-19 cumulative incidence (OR 1.8, 95% CI 1.3–2.6).[33]

There is insufficient evidence at present to support vaccinating healthy workers in settings such as aged care, disability care and healthcare settings solely on the grounds of reducing transmission to others.

Key areas of uncertainty

ATAGI is continuing to closely monitor scientific data as it becomes available including in key areas of uncertainty.

Epidemiology

The future epidemiology beyond the current rise in BA.2 infections is difficult to predict due to numerous complex factors, including increased immunity in people from past Omicron infection, waning vaccine-derived immunity, relaxation of mask-wearing, physical distancing and other public health measures, and seasonal factors including increased indoor gathering during winter months. ATAGI will continue to monitor changes in epidemiology and impacts on population groups and may update its advice on additional booster doses.

Future variants

The potential remains for new variants of concern to appear and spread rapidly. The timing of this is unpredictable. It is unlikely that a variant-specific vaccine could be developed, tested and produced in sufficient time to counter a new variant. The severity and transmissibility of future variants will not be known until they appear. Severity could range from relatively mild disease (as with Omicron) to severity similar to or greater than the Delta strain. ATAGI will monitor how well current vaccines work to protect again new variants of concern.

New formulations of vaccines

The timeline for availability of variant-based vaccines, their strain composition and evidence of their efficacy/effectiveness is unknown. The incremental benefit of Omicron-specific vaccines or formulations that target multiple variants will need to be studied against Omicron and future variants and compared with extra doses of current vaccines based on the ancestral strain. ATAGI will use this information to determine whether a switch to newer vaccines is warranted.

Potential for reduced efficacy with repeated booster doses at short intervals

Studies of other vaccines (e.g. meningococcal and pneumococcal polysaccharide vaccines) have shown that repeated administration of boosters within a short time frame may result in blunting of vaccine-induced antibody responses.[34] A pre-print study of an inactivated SARS-CoV-2 vaccine (not available in Australia) suggests lower peak antibody levels after a second booster dose compared with the first booster, though whether this may apply to other vaccine platforms is

unclear.[35] ATAGI will monitor data on the kinetics of the antibody response to repeated COVID-19 vaccine doses to ensure that additional doses are not counterproductive to the immune response.

Safety of an additional booster dose

While local and systemic adverse events after a 4th dose appear short-lived and similar to previous doses,[12] data are limited. ATAGI will continue to monitor safety data on more serious adverse events, including myocarditis, to guide whether additional boosters should be recommended in younger people.

Role of therapeutic treatments for COVID-19

ATAGI notes the expanding role and availability of effective intravenous and oral medical treatments (monoclonal antibodies and antivirals) that can reduce the risk of severe illness when given early in COVID-19 infection. ATAGI notes that such treatments could reduce the urgency or the need for a population-wide booster vaccination program to protect high-risk people, if these treatments are readily available, safe and effective. ATAGI continues to monitor the availability and efficacy of therapeutic agents used in the treatment of COVID-19 infection, including the emergence of resistance.

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