

Recommended use of COVID-19 vaccines

Australian Technical Advisory Group on Immunisation (ATAGI)



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Plain-language summary

COVID-19 is an infectious disease that commonly affects the respiratory system. It is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It spreads through droplets that contain the virus from your nose or throat.

Common symptoms include fever, cough, sore throat or shortness of breath. Most people have only mild or moderate symptoms. Some people are at higher risk of serious disease that means they may need to go to hospital, or that they could die.

In the COVID-19 pandemic between 2020 and 2023, many millions of people around the world became infected or died. Vaccines against COVID-19 became available in 2021.

The Australian Technical Advisory Group on Immunisation (ATAGI) made recommendations for the use of COVID-19 vaccines. These were first published as clinical guidance in 2021, and then added to the <u>Australian Immunisation Handbook</u> in 2023.

ATAGI revised its advice many times because the disease and the vaccines were changing quickly. Now that things have become more stable and will not change as often, ATAGI is asking for public input on the recommendations. This is part of ATAGI's usual process.

This document shows the latest recommendations from ATAGI and a brief summary of the evidence.

ATAGI recommends 1 dose of COVID-19 vaccine for everyone aged 18 years and over who does not have severe immunocompromise. Extra doses are recommended for older adults and people of any age who have medical conditions that increase their risk of severe disease. Other people can choose to get extra doses of COVID-19 vaccine if they want to, based on a risk-benefit assessment. Healthy children and teenagers under 18 years old are not recommended to have a dose of COVID-19 vaccine.

COVID-19 vaccines are free for all people in Australia, including those without a Medicare card.

Summary of recommendations

- Healthy infants, children and adolescents aged <18 years are not recommended to receive COVID-19 vaccine.
- Adults aged ≥18 years are recommended to receive COVID-19 vaccine, and further doses are recommended based on age and risk-benefit assessment.
- People with medical conditions that increase their risk of severe illness from COVID-19 are recommended to receive further doses of COVID-19 vaccine.
- Unvaccinated pregnant women are recommended to receive COVID-19 vaccine.
- Vaccinated pregnant women are not recommended to receive further doses of COVID-19 vaccine during pregnancy.
- People with a history of SARS-CoV-2 infection can receive further doses of COVID-19 vaccine as recommended.
- Serological testing for immunity to SARS-CoV-2 is not recommended before or after receiving a COVID-19 vaccine.

Background and rationale

The Australian Technical Advisory Group on Immunisation (ATAGI) advises the Australian Government on clinical recommendations for vaccination. ATAGI has developed recommendations for the use of COVID-19 vaccines.

These recommendations reflect the current best clinical practice to prevent COVID-19 and its complications. The recommendations are published online in the <u>Australian Immunisation Handbook</u>. Information relating to the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) assessment is published on the <u>National Centre for Immunisation Research and Surveillance (NCIRS) website.</u>

IMPORTANT NOTE ABOUT THIS PUBLIC CONSULTATION

Clinical guidance on COVID-19 vaccines was first published at the start of Australia's COVID-19 vaccine rollout in February 2021 and was regularly updated during the pandemic. The COVID-19 chapter was first published in the Australian Immunisation Handbook in October 2023 to provide a single familiar source of vaccine information for health professionals.

Since then, the chapter has been updated multiple times in response to the changing epidemiology of COVID-19 and the available vaccines. Now that the situation has stabilised and chapter updates are needed less frequently, the public consultation process can be conducted.

Although the COVID-19 chapter has already been published, comments received during this public consultation will still be considered, and any relevant changes will be made to the published version.

COVID-19 epidemiology

COVID-19 is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. It affects people of all ages. Many people have only mild to moderate symptoms, but older adults and people with certain medical conditions have an increased risk of severe disease or death from COVID-19.

The World Health Organization (WHO) declared COVID-19 to be a Public Health Emergency of International Concern on 30 January 2020, and a worldwide pandemic on 11 March 2020. After 3 years of public health measures to tackle the pandemic, the Australian Government determined that COVID-19 was no longer a Communicable Disease Incident of National Significance (CDINS) on 20 October 2023. COVID-19 is now managed like other common communicable diseases in Australia.

According to the WHO, as of 30 March 2025, more than 777 million COVID-19 cases and more than 7 million deaths have been reported globally since the start of the pandemic, with a global case fatality rate of approximately 0.9%.¹

As the virus has evolved over time, waves of infections have been caused by different virus lineages. Since 2024, Omicron is the only variant circulating globally.² Previous variants of

concern (Alpha, Beta, Gamma, Delta) and the ancestral strain have largely disappeared. Numerous sub-lineages of Omicron have caused distinct global waves of infection.³

Since the onset of the pandemic, the incidence of severe illness has declined due to high COVID-19 vaccination coverage, hybrid immunity (that is, immunity from both vaccination and infection), and with changes in dominant variants. There has been a consistent decrease in the incidence of severe illness over time, with smaller peaks of severe illness seen with each subsequent Omicron wave.

COVID-19 vaccines in Australia

During the pandemic, several types of COVID-19 vaccines were available in Australia. These were mRNA vaccines (Pfizer and Moderna), a protein vaccine (Novavax) and a viral vector vaccine (AstraZeneca).

In 2025, the only COVID-19 vaccines available in Australia are Pfizer mRNA vaccines (brand name Comirnaty). There are 6 formulations of these vaccines, which cover different SARS-CoV-2 lineages and are suitable for different age groups:

- Paediatric formulations
 - Comirnaty JN.1 (Pfizer) 6 months to <5 years (yellow cap)
 - Comirnaty JN.1 (Pfizer) 5 to <12 years (light blue cap)
 - Comirnaty Omicron XBB.1.5 (Pfizer) 6 months to <5 years (maroon cap)
 - Comirnaty Omicron XBB.1.5 (Pfizer) 5 to <12 years formulation (light blue cap)
- Adolescent and adult formulations
 - Comirnaty JN.1 (Pfizer) ≥12 years formulation (pre-filled syringe and multidose vial, dark grey cap)
 - Comirnaty Omicron XBB.1.5 (Pfizer) ≥12 years formulation (dark grey cap).

GRADE methods

Evidence on the benefits and harms of COVID-19 vaccines was assessed using <u>GRADE</u> (Grading of Recommendations, Assessment, Development and Evaluations) methods. There were 2 primary research questions for this GRADE assessment, and these focused on the latest vaccine formulations in the context of hybrid immunity.

Question 1: Should people aged 6 months and over receive a single dose of the updated formulation COVID-19 vaccine following a previous dose in the last 6–12 months?

The benefits outcomes considered were:

- vaccine effectiveness against COVID-19-related hospitalisation
- vaccine effectiveness against COVID-19-related death
- vaccine effectiveness against long COVID-19.

The harms outcomes considered were:

- serious adverse events (any and vaccine-related)
- adverse event of special interest: myocarditis (with or without pericarditis) occurring within
 42 days of vaccination

- solicited local adverse events
- solicited systemic adverse events.

Question 2: Should previously vaccinated pregnant women receive a further dose of COVID-19 vaccine during pregnancy to prevent severe outcomes of COVID-19 in themselves (the pregnant women) and in infants aged ≤6 months?

The outcomes considered were:

- vaccine effectiveness against COVID-19-related hospitalisation in infants aged ≤6 months
- vaccine effectiveness against COVID-19 related hospitalisation in previously vaccinated pregnant women
- vaccine effectiveness against COVID-19-related death in infants aged ≤6 months
- vaccine effectiveness against COVID-19-related death in previously vaccinated pregnant women.

For both research questions, the certainty of the evidence for each outcome was determined by assessing the study design, risk of bias, inconsistency, indirectness and imprecision.

Details of the GRADE assessment are published on the <u>NCIRS website</u>. The outcomes of the GRADE assessment underpin ATAGI's recommendations on the use of COVID-19 vaccines.

Recommendations

These recommendations are published in the COVID-19 chapter of the Handbook.

Infants and children

HEALTHY INFANTS, CHILDREN AND ADOLESCENTS AGED <18 YEARS ARE NOT RECOMMENDED TO RECEIVE COVID-19 VACCINE

COVID-19 vaccine is not recommended for healthy infants, children or adolescents who do not have medical conditions that increase their risk of severe illness. This is because the risk of severe illness was extremely low in this cohort over the course of the pandemic, and the benefits of vaccination are not considered to outweigh the potential harms.^{4,5}

Adults

ADULTS AGED ≥18 YEARS ARE RECOMMENDED TO RECEIVE COVID-19
VACCINE, AND FURTHER DOSES ARE RECOMMENDED BASED ON AGE AND
RISK-BENEFIT ASSESSMENT

Adults aged 18–64 years who do not have severe immunocompromise are recommended to receive a single primary dose of COVID-19 vaccine, and can consider

a further dose every 12 months based on individual preference and a risk–benefit assessment. The risk of severe illness from COVID-19 is low in previously vaccinated healthy adults.^{6,7}

Adults aged 65–74 years who do not have severe immunocompromise are recommended to receive a single primary dose of COVID-19 vaccine, and further doses of COVID-19 vaccine every 12 months, and can consider doses every 6 months based on a risk–benefit assessment. A dose every 6 months is most likely to benefit people with medical risk conditions and/or those living in residential care facilities.^{8,9}

All adults aged ≥75 years, including aged care residents, are recommended to receive a single primary dose of COVID-19 vaccine, and further doses of COVID-19 vaccine every 6 months. The risk of severe illness increases significantly with advancing age. 10-12

People with medical conditions

PEOPLE WITH MEDICAL CONDITIONS THAT INCREASE THEIR RISK OF SEVERE ILLNESS FROM COVID-19 ARE RECOMMENDED TO RECEIVE FURTHER DOSES OF COVID-19 VACCINE

For people with relevant medical risk conditions in <u>Table</u>. Example conditions associated with increased risk of severe outcomes from COVID-19, COVID-19 vaccine dose recommendations vary based on age and the presence of severe immunocompromise (which may reduce the immune response to vaccination). See <u>Table COVID-19 vaccine primary and further dose recommendations for people with medical conditions that increase their risk of severe illness and <u>Table</u>. Examples of severely immunocompromising conditions for which additional primary doses of COVID-19 vaccine are recommended or can be considered.</u>

Women who are pregnant or breastfeeding

UNVACCINATED PREGNANT WOMEN ARE RECOMMENDED TO RECEIVE COVID-19 VACCINE

Unvaccinated pregnant women are at increased risk of severe disease and adverse perinatal outcomes from COVID-19.¹³⁻¹⁵ Unvaccinated pregnant women are recommended to receive a primary dose of COVID-19 vaccine, which can be given at any time during pregnancy.

VACCINATED PREGNANT WOMEN ARE NOT RECOMMENDED TO RECEIVE FURTHER DOSES OF COVID-19 VACCINE DURING PREGNANCY

Pregnant women who have previously been vaccinated are not routinely recommended to have a further dose of COVID-19 vaccine. However, they can consider a further dose of COVID-19 vaccine based on presence of underlying risk conditions and/or personal preference.

Previously vaccinated pregnant women who have no conditions that increase the risk of severe illness from COVID-19 have a very low risk of severe illness and pregnancy complications from Omicron infection. However, a dose administered during pregnancy may reduce the risk of COVID-19 infection and hospitalisation in young infants through transplacental passage of antibodies, noting that the risk of severe illness in healthy young infants is extremely low. 18-21

Comirnaty JN.1 and Omicron XBB.1.5-based vaccines can be used in pregnancy. Although the latest mRNA COVID-19 vaccines (Comirnaty JN.1 and Omicron XBB.1.5-based vaccines) have not been formally studied in pregnant women, ATAGI considers them suitable and safe for use.

People with a history of SARS-CoV-2 infection

PEOPLE WITH A HISTORY OF SARS-COV-2 INFECTION CAN RECEIVE FURTHER DOSES OF COVID-19 VACCINE AS RECOMMENDED

There is no recommended minimum interval between a COVID-19 vaccine dose and infection, as it is challenging for many individuals to know if they have had a recent infection. In these circumstances, it is appropriate to proceed with a further dose as per the recommended schedule.

Vaccination is likely to enhance the protection induced by infection, with the combination of the two called 'hybrid immunity'. While there is no harm in having a COVID-19 vaccine soon after infection, a greater interval between infection and vaccination has been shown to enhance hybrid immunity by further boosting the immune response generated following infection.²²

Serological testing for immunity to SARS-CoV-2

SEROLOGICAL TESTING FOR IMMUNITY TO SARS-COV-2 IS NOT RECOMMENDED BEFORE OR AFTER RECEIVING A COVID-19 VACCINE

Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination, including when considering further doses. There are no serological assays that provide a definitive correlate of immunity to SARS-CoV-2.

Evidence for the recommendations

Detailed analysis of the evidence underpinning these recommendations is published on the NCIRS website.

Infection with SARS-CoV-2 occurs in people of all ages. Older age is by far the strongest risk factor associated with morbidity and mortality from COVID-19.^{10-12,23,24} Medical conditions also independently increase the risk of severe disease, but to a lesser extent than age.²⁵

The risk of severe illness from COVID-19 is low in infants, children, adolescents and healthy younger adults. Rates of severe illness in younger age groups have remained relatively low and stable throughout the Omicron wave, not surpassing 1.3 cases per 100,000 population per week since the start of the fifth Omicron wave.²⁶ Primary and additional doses of COVID-19 vaccine are safe and effective in children and adolescents. However, because of the lower incidence of severe illness, the WHO considers healthy children and adolescents aged 6 months to 17 years to be a low priority group for vaccination.²⁷

Unvaccinated pregnant women are at higher risk of severe illness from COVID-19 than pregnant women who are vaccinated.²⁸ However, emerging data indicate that healthy pregnant women who were vaccinated before pregnancy, and their infants aged <6 months, are not at increased risk of severe disease.^{4,5,29-31} Because of the low incidence of severe disease in this group, the benefits of a further dose of COVID-19 vaccine during pregnancy in people who were previously vaccinated are likely to be small.

Benefits and potential risks

Key benefits of these recommendations include the following:

- People at higher risk of severe COVID-19 disease, including older people and those with medical conditions, will continue to be protected against COVID-19 through safe and effective vaccines.
- Healthy adults, including pregnant women, have the option to receive further doses of COVID-19 vaccine based on their own preferences and a risk-benefit assessment, which increases consumer choice.
- Healthy children and adolescents will avoid unnecessary vaccination, as the benefits of vaccination do not outweigh the risks in this age group.

The potential risks that may arise from these recommendations include the following:

- Infants, children and adolescents with undiagnosed medical conditions that increase their
 risk of severe disease may not receive all the vaccine doses that are recommended
 during the time that the condition remains undiagnosed. However, this risk is the same
 for any vaccine and is not specific to COVID-19 vaccines.
- If a variant of concern arises that increases disease severity in children and adolescents, these recommendations will need to be reviewed. ATAGI regularly reviews its recommendations based on COVID-19 epidemiology and available vaccines.
- The number and timing of recommended or optional vaccine doses vary across age
 groups and may not align with other NIP schedule points. This may lead to confusion
 among immunisation providers. Providers are encouraged to check the Handbook to
 ensure they discuss the recommended doses with their patients as part of the shared
 decision-making process.
- People who reach an age or develop a risk condition that changes their recommended COVID-19 vaccine doses may not receive the recommended doses if their immunisation provider is unaware of the change in their circumstances. Providers are encouraged to regularly review the evolving individual needs of their patients.
- Known barriers to vaccine uptake include vaccine fatigue and perceived crowding of the immunisation schedule. However, active recommendation from immunisation providers and effective counselling about co-administration of vaccines can help to reduce these barriers.

Preferences and values

The recommendations for the use of COVID-19 vaccines are in line with best clinical advice. It is expected that these recommendations will result in additional protection for people who are most at risk of serious COVID-19. This is consistent with societal expectations of the best use of vaccines in Australia.

Australians' acceptance of COVID-19 vaccines has been shaped by evolving factors over the course of the pandemic. Initially, vaccine uptake was high, driven by the urgency of protecting public health and ending lockdowns. According to findings of a few surveys published earlier in the pandemic (2021–2022), most Australians supported vaccination efforts, leading to high overall vaccination rates, particularly in areas where the perceived risk of the virus was high especially among elderly people. Pactors such as vaccine fatigue and misinformation have contributed to a decrease in acceptance, but there remains a significant appreciation for the benefits of vaccines among a large segment of the population. Page 19.10.

Findings of previous published surveys in Australia have identified factors that increase the perceived value of vaccination, such as older age, concern about contracting COVID-19, and having a chronic medical condition.^{35,36} However, as the perceived risk of COVID-19 diminishes with fewer cases and the virus becoming endemic, many Australians may feel less urgency to receive further doses.

COVID-19 vaccines are available free to all people in Australia, including those without a Medicare card, under the <u>National COVID-19 Vaccine Program</u>. These recommendations are not funded under the National Immunisation Program.

Additional information in the Australian Immunisation Handbook

The <u>Handbook chapter on COVID-19</u> has the same structure as other Handbook chapters. This includes information on:

- · vaccines, dosage and administration
- contraindications and precautions
- adverse events
- nature of the disease
- clinical features
- epidemiology
- vaccine information
- transporting, storing and handling vaccines
- · public health management
- · variations from product information.

Glossary

A glossary of technical terms is available on the Australian Immunisation Handbook website.

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