Australian Government
Department of Health and Aged Care

ATAGI COVID-19 pandemic statements

March 2021 to November 2023

This document contains COVID-19 vaccines statements from the Australian Technical Advisory Group on Immunisation (ATAGI), produced during the COVID-19 pandemic period.

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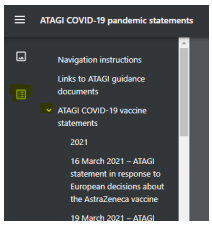

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ATAGI COVID-19 guidance documents

June 2024

The Australian Technical Advisory Group on Immunisation (ATAGI) also produced several guidance documents during the COVID-19 pandemic period. These have been updated over time.

You can find:

- the latest version of each document on health.gov.au
- earlier versions by searching Trove.

Document title	Link to current version	Link to earliest version in Trove
ATAGI – Preliminary advice on general principles to guide the prioritisation of target populations in a COVID-19 vaccination program in Australia	Current version	Earliest version in Trove
Guidance on myocarditis and pericarditis after COVID-19 vaccines	Current version	Earliest version in Trove
ATAGI advice on use of sedation for COVID-19 vaccination	Current version	Earliest version in Trove
ATAGI expanded guidance on temporary medical exemptions for COVID-19 vaccines	Current version	Earliest version in Trove
ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised	Current version	Earliest version in Trove
ATAGI clinical guidance on COVID-19 vaccine administration errors	Current version	Earliest version in Trove
COVID-19 vaccination – Shared decision making guide for women who are pregnant, breastfeeding or planning pregnancy	Current version	Earliest version in Trove

Document title	Link to current version	Link to earliest version in Trove
ATAGI – COVID-19 vaccination – Shared decision making guide for people with immunocompromise	Current version	Earliest version in Trove
COVID-19 vaccination – Shared decision making guide for people receiving palliative care or end-of-life care	Current version	Earliest version in Trove
ATAGI guidance on the use of multi-dose vials for COVID-19 vaccination	Current version	PDF not captured in Trove
COVID-19 vaccination – Site requirements for COVID-19 vaccination clinics	Current version	Earliest version in Trove
COVID-19 vaccination – Site requirements for COVID-19 vaccination in community pharmacies	Current version	Earliest version in Trove
COVID-19 vaccination – Consent form for COVID-19 vaccination (16+)	Current version	Earliest version in Trove
COVID-19 vaccination – Pfizer information and consent form for parents and guardians of children aged 5 to 11 years	Current version	Earliest version in Trove
Pfizer COVID-19 vaccine for children aged 6 months to 4 years – Information for parents and guardians	Current version	PDF not captured in Trove
Children's consent form – Moderna 6 months to 5 years	No longer available	PDF not captured in Trove

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ATAGI statement in response to European decisions about the AstraZeneca vaccine

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding overnight decisions in Europe suspending the use of the AstraZeneca vaccine.

Date published: 16 March 2021

Audience: General public

AstraZeneca clinical update

ATAGI notes the suspension of the AstraZeneca vaccine program in several European countries due to reports of a potential link with thrombotic (clotting) events. Based on evidence to date, ATAGI do not

see any reason to pause use of the AstraZeneca vaccine in Australia.

Thrombotic events occur commonly in the absence of vaccination. It is noted that the rates of thrombotic events are not higher in vaccine recipients than the expected background rate. The Medicines and Healthcare products Regulatory Agency (MHRA) have stated that no signals have been identified in the UK where more than 11 million doses have been administered to date.

The Therapeutic Goods Administration (TGA) is closely monitoring the situation and has been in communication with regulators including the European Medicines Agency (EMA) and the MHRA. Further clinical details of the cases are being reviewed by the EMA with further information expected this week.

No cases of coagulation disorders have been identified following COVID vaccination in Australia. Clotting disorders are designated as 'adverse events of special interest' that are closely monitored.

ATAGI encourages healthcare providers and the public to report any unexpected or serious adverse events, including thrombotic disorders, occurring following any COVID-19 vaccines.

- Read the Chief Medical Officer's statement
- Read the statement from the Therapeutic Goods Administration (TGA).

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement and clinical guidance on AstraZeneca COVID-19 vaccine following European Medicines Agency (EMA) safety review

This statement from the Australian Technical Advisory Group on Immunisation (ATAGI) updates advice previous provided on 16 March. It follows the European Medicines Agency (EMA) safety review of the AstraZeneca COVID-19 vaccine.

Date published: 19 March 2021

Audience: General public

ATAGI notes that the European Medicines Agency (EMA) have completed a preliminary review on 18 March 2021 of reports of thrombotic (clotting) events following AstraZeneca COVID-19 vaccine. They have concluded that the benefits of vaccination using AstraZeneca COVID-19 vaccine continue to outweigh any risk of side effects.

The EMA review has found that the AstraZeneca vaccine is not associated with an increase in the overall risk of blood clots.

Reports of a rare syndrome of blood clots in conjunction with low platelets, or of clots in blood vessels in the brain were also examined. These are conditions which can occur naturally in the absence of vaccination.

Around 20 million people in Europe have received the AstraZeneca vaccine. There have been 18 reports of people who had clots in blood vessels which drain the brain (also called cerebral venous sinus thrombosis or CVST), and 7 reports of people who had blood clots in multiple vessels in the body (also called disseminated intravascular coagulation or DIC). It has not yet been confirmed whether the vaccine caused these events, and ongoing investigation is needed.

ATAGI considers the benefits of vaccination in protecting people in Australia from COVID-19 outweigh the rare potential risk of these rare blood clotting events, and supports the continued rollout of the AstraZeneca vaccine in Australia.

There are no changes to the ATAGI clinical guidance on the use of AstraZeneca at this time.

The only contraindications to vaccination are a history of anaphylaxis to a previous dose of the vaccine, or a component within the vaccine. The preliminary EMA analysis noted that these rare occurrences were mostly in younger women. However, due to the rarity of cases and absence of appropriate comparative data, and the lack of a clear causal link with the vaccine, it did not identify individual patient risk factors or specific population/s for whom the vaccine is not warranted or recommended.

ATAGI will continue to monitor any data on the use of all COVID-19 vaccines, including the AstraZeneca and Pfizer COVID-19 vaccines that emerges globally and data from Australian program.

ATAGI encourages health care providers and the public to report any unexpected or serious adverse events, including thrombotic disorders, occurring following any COVID-19 vaccines.

Read the statement from the Therapeutic Goods Administration (TGA).

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
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ATAGI statement for health care providers on suitability of COVID-19 vaccination in people with history of clotting conditions

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) for health care providers on suitability of COVID-19 vaccination in people with history of clotting conditions.

Date published: 25 March 2021

Audience: Health sector

Following the ATAGI statement of 19 March 2021 on the safety of the AstraZeneca COVID-19 vaccine, ATAGI notes that the World Health Organization (WHO) and regulatory agencies including the European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA) have been reviewing data from tens of millions of people given the AstraZeneca and other COVID-19 vaccines worldwide.

This shows that there is no increase in the rates of general thromboembolic disorders after vaccination over expected rates, noting these conditions occur commonly in the absence of vaccination.

The EMA and others have also been conducting ongoing investigations in Europe regarding reports of a specific type of thrombosis (cerebral venous sinus thrombosis; CVST) following AstraZeneca vaccine.

It is not known whether this condition is linked to vaccination. Cases of CVST reported overseas have mostly occurred 4 to 14 days following the AstraZeneca vaccine and have been rare (varying reports of 1 to 8 per million doses of vaccine given). Further studies in these patients are ongoing to understand if there is a potential link with vaccination. No cases of CVST associated with vaccination have been recorded in Australia to date.

Overall, ATAGI emphasises that the benefits of the COVID-19 vaccine far outweigh this potential risk.

Based on this information, ATAGI considers that there is no evidence of a risk of thrombotic disease after COVID-19 vaccination in people with a history of clotting conditions. ATAGI continues to recommend vaccination with either AstraZeneca or Pfizer (Comirnaty) COVID-19 in such people. This includes those with deep venous thrombosis and/or pulmonary embolism; people with risk factors for thrombosis (such as use of oral contraceptives or smoking); people with thrombocytopenia (low platelets that can occur with clotting conditions); people with known thrombophilic disorders; people on anticoagulants (e.g. warfarin) and people with a history of cardiovascular disease (such as myocardial infarction or stroke).

However, for the time being, ATAGI recommends that vaccination with any COVID-19 vaccine should be deferred for people who have a history of the following rare conditions. This is until further information

from ongoing investigations in Europe is available and is only a precautionary measure:

1. people with a confirmed medical history of CVST; and/or
2. people with a confirmed medical history of heparin induced thrombocytopenia (HIT). HIT is an immune-mediated complication of treatment with heparin that affects platelet function. A HIT-like mechanism is being investigated as a potential, but unconfirmed, pathway to CVST post COVID-19 vaccination.

As for all vaccines, including COVID-19 vaccines, health care providers should be alert for persistent, unexpected and/or severe adverse events following immunisation in their patients, particularly those that occur 1–2 weeks after vaccination.

ATAGI encourages health care providers and the public to report any unexpected or serious adverse events occurring following any COVID-19 vaccines. These should be appropriately investigated and further advice sought from specialist services.

Tags:

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

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ATAGI statement for consumers on a specific clotting condition being reported after COVID-19 vaccination

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) for consumers on a specific clotting condition being reported after COVID-19 vaccination

Date published: 2 April 2021

Audience: General public

Experts are examining a small number of reports of people with unusual clots after COVID-19 vaccination with the AstraZeneca vaccine. Almost all reported cases have been in the United Kingdom and Europe. One probable case was reported in Australia on 2 April 2021. This case is being investigated by the Therapeutic Goods Administration (TGA).

Australian authorities and specialists are keeping a close eye on this condition. The Australian Technical Advisory Group on Immunisation (ATAGI) has issued several statements for clinicians and has been meeting regularly with experts in this area. The TGA has been continuously working with other international regulators including the European Medicines Agency (in Europe) and Medicines and Healthcare Products Regulatory Agency (in the UK) to keep up to date on the status of their investigations.

People who have received COVID-19 vaccines should be aware of common side effects, which include fever, sore muscles, tiredness and headache. These usually start within 24 hours of vaccination and last for 1-2 days. These side effects are expected and are not of concern unless severe or persistent.

The reports of these rare clotting complications have occurred later (between day 4 and 20 after vaccination) and have generally been severe, requiring hospitalisation. Consumers should be particularly alert to severe, persistent headaches that are different to their "usual" pattern and do not settle with paracetamol or other painkillers. If these symptoms occur consumers should seek medical advice as soon as possible. Anyone attending their GP or a hospital with any concerns should let their treating clinician know the details of the vaccine they received.

Tags: Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on COVID-19 vaccination and a reported case of thrombosis

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on COVID-19 vaccination and a reported case of thrombosis.

Date published: 2 April 2021

Audience: General public

The Australian Technical Advisory Group on Immunisation (ATAGI) notes that a case of an unusual thrombosis following the AstraZeneca vaccine has been reported. This is one case in more than 400,000 doses given to date.

We have issued communication for consumers and clinicians on the significance of this condition and to be alert for the symptoms and signs of thromboses.

Regulatory agencies in the European Union and United Kingdom, where more cases have been reported and many millions of doses of vaccine have been administered, have not made recommendations to broadly restrict the use of the AstraZeneca vaccine.

However, some countries, including Canada, have made precautionary recommendations to limit the use of AstraZeneca vaccine in some groups.

ATAGI has not changed its advice on the use of the AstraZeneca vaccine at this time.

ATAGI and the Therapeutic Goods Administration (TGA) are currently investigating this case and working with international experts and regulators to provide advice on the optimal use of the AstraZeneca vaccine.

We plan to meet again on Wednesday 7 April 2021 when we anticipate more information from international regulators and when the outcomes of ongoing investigations of this case will be available that will enable us to assess the risks and benefits of this vaccine for the Australian population.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

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ATAGI statement on AstraZeneca vaccine in response to new vaccine safety concerns

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on the AstraZeneca COVID-19 vaccine in response to new vaccine safety concerns.

Date published: 8 April 2021

Audience: General public

Summary

- ATAGI notes further evidence of a rare but serious side effect involving thrombosis (clotting) with thrombocytopenia (low blood platelet count) following receipt of COVID-19 Vaccine AstraZeneca
- ATAGI recommends that the COVID-19 vaccine by Pfizer (Comirnaty) is preferred over COVID-19 Vaccine AstraZeneca in adults aged under 50 years. This recommendation is based on the increasing risk of severe outcomes from COVID-19 in older adults (and hence a higher benefit from vaccination) and a potentially increased risk of thrombosis with thrombocytopenia following AstraZeneca vaccine in those under 50 years.
- COVID-19 Vaccine AstraZeneca can be used in adults aged under 50 years where the benefits are likely to outweigh the risks for that individual and the person has made an informed decision based on an understanding of the risks and benefits.
- People who have had the first dose of COVID-19 Vaccine AstraZeneca without any serious adverse effects can be given the second dose, including adults under 50 years.

Background – Thrombosis with thrombocytopenia syndrome and COVID-19 Vaccine AstraZeneca

ATAGI recommends that all adults are vaccinated against COVID-19. The COVID-19 pandemic is continuing to cause severe disease around the world, with many lives being lost. The Australian population remains vulnerable to COVID-19 and most Australians have not yet been vaccinated and are not immune.

ATAGI advised on 25th March 2021 that there was a potential safety concern being investigated overseas, involving cases of thrombosis (blood clots) and thrombocytopenia (low blood platelet count) occurring after COVID-19 Vaccine AstraZeneca. On 2 April 2021 ATAGI reported that a probable case had been reported in an Australian vaccine recipient, and issued an updated advice for healthcare providers.

This 'thrombosis with thrombocytopenia syndrome' (TTS) is a newly described serious condition, with unusual blood clots in the brain (cerebral venous sinus thrombosis) or in other parts of the body, associated with low platelet levels. Some researchers have provisionally called this condition 'vaccine induced prothrombotic immune thrombocytopenia' (VIPIT). However, the causal relationship and exact mechanism leading to this condition is not yet understood. Some people have antibodies which activate platelets (anti-PF4 antibodies). These antibodies have been detected in another disorder triggered by the drug heparin, which has a similar presentation.

ATAGI and other Australian officials continue to consult with the WHO, UK, European and other regulatory agencies in countries where use of the AstraZeneca COVID-19 vaccine has been widespread. Further information from the UK and Europe is still emerging. The European Medicines Agency (EMA) stated on 7 April 2021 that a causal relationship between the AstraZeneca vaccination and thrombosis in combination with thrombocytopenia is plausible.

In the UK, where approximately 20.2 million doses of AstraZeneca COVID-19 vaccine have been administered, their regulatory agency, the MHRA have advised that the evidence of a link is stronger but more work is still needed.

ATAGI is aware of more cases of TTS being reported from other countries, and has reviewed all available data and research provided by AstraZeneca, as well as independent expert groups.

Some countries that are using the AstraZeneca COVID-19 vaccine have made precautionary decisions about pausing or limiting its use based on the potential risk of this serious adverse event. These decisions are also informed by the local risk for COVID-19, how much of the population is already immune from vaccination and in what age groups, and whether they have an alternative supply of vaccines.

The risk-versus-benefit assessment for the use of AstraZeneca COVID-19 vaccine will be different for Australia compared to other countries, such as those with widespread transmission. This includes countries in our region such as those currently experiencing very serious outbreaks of COVID-19, such as Timor Leste, Papua New Guinea and others.

Key Considerations

The following information has been considered by ATAGI in relation to its new recommendations:

Local epidemiology:

- While Australia currently has very low or no community transmission of COVID-19, this could change, particularly in the context of high global transmission rates, including of new variants of the virus. The risk of serious disease and death in Australia remains, even as borders controls and other measures continue.
- Although Australia has had few deaths from COVID-19 in young adults until now, large outbreaks in other countries have caused many thousands of deaths in young adults, indicating that the risk for serious outcomes exists across the age spectrum.

Vaccine availability and uptake:

- The AstraZeneca vaccine is highly effective at reducing the risk of death or severe disease from COVID-19 across all adult age groups. At the present time, the AstraZeneca vaccine is the only vaccine option for reducing this risk for many Australians, since the global availability of alternative vaccines is highly constrained.
- ATAGI recognises this safety concern will likely impact on confidence in being vaccinated with AstraZeneca vaccine in all age groups.
- Until the Government can increase supply of COVID-19 vaccines other than AstraZeneca, overall coverage under Australia's COVID-19 vaccine program will likely be reduced. This will likely

impact the time frame to which the Australian population is protected against COVID-19.

- In the short term, delays in vaccine uptake increase the vulnerability of the Australian population to outbreaks of COVID-19 and the attendant risk of death and serious morbidity, especially among older Australians.

Evidence regarding TTS:

- The AstraZeneca vaccine appears likely to be causally-linked with a risk of this newly recognised thrombosis with thrombocytopenia syndrome.
- There is currently uncertainty in, and different reported rates of risk, for this adverse event.
- Studies have suggested it may occur in approximately 4 - 6 people in every one million people in the 4-20 days after the first dose of vaccine. However, higher rates have been reported in Germany and some Scandinavian countries.
- Some evidence suggests the risk of this condition occurring may be somewhat higher in people of a younger age, however a small number of cases have been reported in people of different ages (including older adults).
- While there have been more reports of TTS in women in some settings, this may be because more vaccine doses have been given to women. In one country the reported rate of TTS (number of cases adjusted for the number of men and women vaccinated) was similar in men and women.
- TTS can cause serious long term disability or death (with death occurring in approximately 25% of reported cases).
- So far no specific biological risk factors or pre-existing medical conditions have been found to modify (i.e. increase or decrease) the risk of TTS occurring after AstraZeneca vaccine.
- We do not yet know to what extent earlier recognition of this syndrome and improved treatments will improve patient outcomes. More cases can be expected to occur, albeit rarely.
- Comirnaty (the Pfizer COVID-19 vaccine) does not appear to carry a risk of TTS.

Benefit-to-risk assessment:

- ATAGI consider that the individual benefit-to-risk balance of vaccination with COVID-19 vaccine AstraZeneca in Australia varies with age. The risk of ongoing health issues and death from COVID-19 is highest in older age groups, particularly rising from 50 years of age. By comparison, the rate, and thus possibility of disability and death from TTS may be higher in younger people. This age-specific benefit-to-risk balance is demonstrated in an analysis from the UK.
- Younger people with certain underlying medical conditions are also at increased risk of severe outcomes from COVID-19, which affects their individual benefit-to-risk balance.
- ATAGI respects a person's choice to make an informed decision on whether to accept the risk of COVID-19 vaccination with the AstraZeneca vaccine. ATAGI recognise that it is difficult for people to assess their personal risk where there is uncertainty about the short and long term risk of severe COVID-19 in different age groups, and the evidence around benefit and risk of the AstraZeneca vaccine is changing quickly.
- In the context of the ongoing risk of COVID-19 in Australia, ATAGI considers that the benefit-to-risk balance is favourable for use of AstraZeneca vaccine in all older adult age groups.
- ATAGI also consider that population coverage under Australia's COVID-19 vaccine program will likely be impacted until such time that an increased supply of alternative safe and effective vaccines can be secured.

Recommendations

ATAGI recommends that:

- At the current time, use of Comirnaty COVID-19 vaccine (Pfizer) is preferred over AstraZeneca COVID-19 vaccine in adults aged < 50 years who have not already received a first dose of AstraZeneca vaccine. This is based both on the increased risk of complications from COVID-19 with increasing age (and thus increased benefit of vaccination), and the potentially lower, but not zero, risk of TTS with increasing age.

- COVID-19 Vaccine AstraZeneca can be used in adults aged under 50 years where the benefits are likely to outweigh the risks for that individual and the person has made an informed decision based on an understanding of the risks and benefits.
- People who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse effects can be given their second dose. This includes adults under 50 years of age. People who have had blood clots associated with low platelet levels after their first dose of COVID-19 Vaccine AstraZeneca should not be given their second dose.
- That the Department of Health further develop and refine resources for informed consent that clearly convey the benefits and risks of AstraZeneca vaccine for both immunisation providers and consumers of all ages.

This advice may be revised as more information becomes available or if the epidemiological situation changes, particularly if there is, or is likely to be significant community transmission.

ATAGI supports the Australian Government's ongoing efforts to procure more or bring forward the delivery of alternative COVID-19 vaccine brands to replace the use of AstraZeneca COVID-19 vaccine that would have been administered to persons under 50 years of age. Where possible, onshore manufacturing of alternative safe and effective vaccines should be considered.

ATAGI intends to review other current COVID-19 vaccine recommendations as soon as practicable. This includes recommendations on vaccination for those who have a past history of heparin induced thrombocytopenia (HIT), central venous sinus thrombosis (CVST), and/or have other thrombosis risk factors, and those who are pregnant.

Further data and outcomes of investigations from the UK, Europe and other countries will continue to be reviewed over the coming days to weeks. ATAGI recommendations may change as a result of this ongoing assessment of new and emerging evidence over coming days and weeks.

Definitions

- **Thrombosis with thrombocytopenia syndrome (TTS)** is a rare and new syndrome which has been reported after being given the AstraZeneca COVID-19 vaccine. It may be caused by this vaccine. The condition involves blood clots (occurring in body sites like the brain or abdomen) together with low platelet levels.
- **Thrombosis** is the formation of a blood clot, which prevents blood flowing normally through the body.
- **Thrombocytopenia** is a condition in which you have a low blood platelet count. Platelets (thrombocytes) are blood cells that help blood clot. Platelets stop bleeding by clumping and forming plugs in blood vessel injuries.

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI reinforce recommendations on use of COVID-19 vaccines following review of vaccine safety data and benefits

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on use of COVID-19 vaccines following review of vaccine safety data and benefits.

Date published: 23 April 2021

Audience: General public

Vaccination remains the best way to protect against severe illness and death from COVID-19 and is a core element of the pandemic response.

ATAGI is continuing to monitor local and international data on a rare and new condition that occurs after AstraZeneca COVID-19 vaccine called thrombosis with thrombocytopenia syndrome (TTS).

ATAGI has reviewed the additional 3 cases of TTS confirmed by the TGA on 22 April 2021 in Australia, bringing the total confirmed cases to six. Of these cases, 5 people were under 50 years of age. All had received their first dose of AstraZeneca COVID-19 vaccine between 4 and 26 days before the onset of symptoms.

Cases have varied in severity but included one fatal case. People who have had TTS can make a full recovery, although some may have ongoing organ damage, including to the brain (similar to stroke) and to abdominal organs, that can result in long term health impacts.

These TTS cases have occurred amongst approximately 730,000 individuals administered an AstraZeneca COVID-19 vaccine prior to the 11th April 2020. ATAGI estimates that the overall rate of TTS is about 6 cases per million people vaccinated, but the rate is currently estimated to be higher (20-40 cases per million) in those under 50 years of age. However, Australian-estimated age-specific incidence rates are imprecise due to small numbers and will be updated as further information become available.

ATAGI have made previous recommendations on this issue, most recently on 8 April.

ATAGI reinforces its previous advice that:

- Comirnaty (Pfizer) is preferred over AstraZeneca COVID-19 vaccine in people under the age of 50 years. The AstraZeneca COVID-19 vaccine can still be given to adults under 50 years if Comirnaty is not available, if the benefit of vaccination is likely to outweigh risk, and where informed consent has been obtained.
- In people aged 50 years and over, the benefits of AstraZeneca COVID-19 vaccine outweigh the risks associated with vaccination. This is due to the ongoing potential for COVID-19 outbreaks, the widespread susceptibility of the Australian population, and the strong relationship of severe COVID-19 and mortality with increasing age.
- Overseas, cases of TTS have occurred in people of all ages, but the risk of TTS appears to be lower in those 50 years and over than in younger adults. The TGA and ATAGI are continuing to monitor the rates of cases in this age group and will advise as more data becomes available.

People who are considering vaccination with AstraZeneca COVID-19 vaccine should be aware of this potential complication as part of providing informed consent. Those who choose to delay vaccination until a vaccine other than AstraZeneca COVID-19 vaccine is available should be aware that they may not be protected against COVID-19 for many months. ATAGI acknowledges the challenges of decision making as information continues to emerge.

ATAGI continues to recommend that people who have received a first dose of AstraZeneca COVID-19 vaccine without serious adverse events can be given a second dose. Current data suggest that the risk of TTS following a second dose is considerably lower than with a first dose (with one case reported from more than 2 million second doses given in the UK to 14 April 2021), and there are no studies of the effectiveness of mixed schedules of different vaccine types. ATAGI will continue to review evidence on this issue.

Background

ATAGI notes that a total of 168 cases of thrombosis with thrombocytopenia following AstraZeneca vaccine have been reported in the UK as of 14th April 2021, out of a total of 21.2 million first doses and 2.3 million second doses given. Additional cases have been reported in Europe but total case numbers are not clear.

The assessment and advice provided by ATAGI is specific to the context of no current but potential future community transmission of COVID-19 and will need to be reviewed should circumstances change. Other considerations were noted in ATAGI's previous statement on 8 April.

ATAGI notes the potential for incursion of COVID-19 in the Australian community remains high with the worsening global situation, including in many countries in our region. The risk-benefit assessment and advice will be different in situations with higher community incidence of COVID-19.

Resources for providers and consumers will be updated in the coming days.

Definitions

- **Thrombosis with thrombocytopenia syndrome (TTS)** is a rare and new syndrome which has been reported after being given the AstraZeneca COVID-19 vaccine. It may be caused by this vaccine. The condition involves blood clots (occurring in body sites like the brain or abdomen) together with low platelet levels.
- **Thrombosis** is the formation of a blood clot, which prevents blood flowing normally through the body. While thrombosis is usually a normal response to prevent bleeding (e.g. following injury), in this case this process is abnormal.
- **Thrombocytopenia** is a condition in which you have a low blood platelet count. Platelets (thrombocytes) are blood cells that help blood clot. Platelets stop bleeding by clumping and forming plugs in blood vessel injuries.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
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Joint statement between RANZCOG and ATAGI about COVID-19 vaccination for pregnant women

Joint statement between RANZCOG and ATAGI about COVID-19 vaccination for pregnant women.

Date published: 9 June 2021

Audience: General public

RANZCOG and ATAGI recommend that pregnant women are routinely offered Pfizer mRNA vaccine (Comirnarty) at any stage of pregnancy. This is because the risk of severe outcomes from COVID-19 is significantly higher for pregnant women and their unborn baby.

Global surveillance data from large numbers of pregnant women have not identified any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy. Furthermore, there is also evidence of antibody in cord blood and breastmilk, which may offer protection to infants through passive immunity.

Pregnant women are encouraged to discuss the decision in relation to timing of vaccination with their health professional.

Women who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination.

Tags: Immunisation | Pregnancy, birth and baby | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on revised recommendations on the use of COVID-19 Vaccine AstraZeneca, 17 June 2021

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on the AstraZeneca COVID-19 vaccine in response to new vaccine safety concerns.

Date published: 17 June 2021

Audience: General public

Summary

The Australian Technical Advisory Group on Immunisation (ATAGI) recommends the COVID-19 Pfizer vaccine (Comirnaty) as the preferred vaccine for those aged 16 to under 60 years. This updates the previous preferential recommendation for Comirnaty over COVID-19 Vaccine AstraZeneca in those aged 16 to under 50 years. The recommendation is revised due to a higher risk and observed severity of thrombosis and thrombocytopenia syndrome (TTS) related to the use of AstraZeneca COVID-19 vaccine observed in Australia in the 50-59 year old age group than reported internationally and initially estimated in Australia.

For those aged 60 years and above, the individual benefits of receiving a COVID-19 vaccine are greater than in younger people. The risks of severe outcomes with COVID-19 increase with age and are particularly high in older unvaccinated individuals. The benefit of vaccination in preventing COVID-19 with COVID-19 Vaccine AstraZeneca outweighs the risk of TTS in this age group and underpins its ongoing use in this age group.

People of any age without contraindications who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events should receive a second dose of the same vaccine. This is supported by data indicating a substantially lower rate of TTS following a second COVID-19 Vaccine AstraZeneca dose in the United Kingdom (UK).

Background

The Australian COVID-19 vaccination program has the overarching goal of protecting all people in Australia from the harm caused by the novel coronavirus SARS-CoV-2.

On 8 April 2021, ATAGI recommended that Comirnaty was the preferred vaccine for people under the age of 50 years due to local and international reports of thrombosis and thrombocytopenia syndrome (TTS) following COVID-19 Vaccine AstraZeneca.

Based on available international data at that time, the estimated risk of TTS was 4-6 per million cases following a first dose of COVID-19 Vaccine AstraZeneca. Given the ongoing risk of COVID-19 outbreaks,

low vaccine coverage, and increasing rate of severe COVID-19 outcomes in older individuals, it was considered that the benefits of COVID-19 Vaccine AstraZeneca outweighed the risk in those over 50 years. As such, no preferential recommendation for either vaccine was made in this age group. This advice was reinforced on 23 April 2021 and has been reviewed weekly by ATAGI since then.

Principles underpinning the revised recommendations

In making the decision to revise the previous recommendation, ATAGI has considered several factors that have been monitored closely, including:

- The potential risk of severe illness and death from COVID-19 over the coming months
- Minimising harms to people due to adverse events following immunisation
- Australian data on the age-specific risks and severity of TTS following COVID-19 Vaccine AstraZeneca
- The expected vaccine supply over the months ahead
- The impacts of any change in recommendation on the COVID-19 vaccine program.

The benefits of vaccination to prevent COVID-19

There is an ever-present risk of COVID-19 in Australia while the population remains largely susceptible to infection. Recent events in Victoria have demonstrated how rapidly outbreaks can spread despite intensive contact tracing and public health action. As at 16 June 2021, 63% of people aged 70 years and older and 25% of those aged 18 years and older have received at least one dose of a COVID-19 vaccine.

The risk of severe COVID-19 is strongly related to increasing age. In 2020, for every 100 people with COVID-19 aged between 50-59 years, around 14 were hospitalised and 3 required admission to an intensive

care unit (ICU). One in every 600 people with COVID-19 in this age group died. In contrast, for every 100 people aged 70-79 years with COVID-19, around 38 were hospitalised, 7 were admitted to ICU and 4 died (ie. 24 deaths in 600). Therefore, the benefit of vaccination in preventing COVID-19 is greater in older people. If an outbreak occurred comparable to the first wave in Australia, the benefits in preventing severe COVID-19 would outweigh the risks of TTS due to COVID-19 Vaccine AstraZeneca in older adults, as illustrated in Weighing up the potential benefits against the risk of harm from COVID-19 Vaccine AstraZeneca.

ATAGI acknowledges the difficulty in balancing the small risk of a clinically significant adverse event related to vaccination with COVID-19 Vaccine AstraZeneca against the need to protect individuals and the community against the ongoing threat of COVID-19, together with ongoing limitations and uncertainties about the supply of alternative COVID-19 vaccines. ATAGI emphasises that this advice is specific to the context that there is currently no or limited community transmission in most of Australia and would be different in other countries.

The risks of TTS after COVID-19 Vaccine AstraZeneca

From early April to 16 June 2021, 60 cases of confirmed or probable TTS have been reported in Australia. This includes an additional seven cases reported in the past week in people between 50-59 years, increasing the rate in this age group from 1.9 to 2.7 per 100,000 AstraZeneca vaccine doses. The revised estimates of risk associated with first doses of COVID-19 Vaccine AstraZeneca are listed in the table below.

Age	Estimated risk of TTS per 100,000 AstraZeneca vaccine doses (first dose)
<50 years	3.1
50-59 years	2.7
60-69 years	1.4
70-79 years	1.8
80+ years	1.9

TTS is a serious condition in a proportion of individuals who develop it. The overall case fatality rate in Australia (3%; 2 deaths among 60 cases) is lower than has been reported internationally. This is likely to reflect increased detection due to heightened awareness, as well as early diagnosis and treatment. A spectrum of severity of illness has been reported in Australia, from fatal cases and those with significant morbidity, to relatively milder cases. TTS appears to be more severe in younger people.

There are different ways in which the severity of TTS can be measured. The US Centers for Disease Control and Prevention (CDC) defines "tier 1" cases as clots involving unusual sites, such as the veins of the brain (cerebral venous sinus thrombosis) or abdomen (splanchnic thrombosis); these are generally more severe and may potentially lead to long term health complications. In those under 60 years, 52% of TTS episodes are occurring in tier 1 sites compared with 28% in those 60 years and older. Other markers of severity include the requirement for intensive care (33% of TTS in those under 60 years; 15% of TTS cases in those 60 years and older), and fatal cases (both occurring in those < 60 years).

Second dose recommendations for COVID-19 Vaccine AstraZeneca

ATAGI supports completion of a two-dose schedule with COVID-19 Vaccine AstraZeneca, based on current evidence. The risk of TTS following a second dose of COVID-19 Vaccine AstraZeneca is much lower than the risk following a first dose. The UK has reported 23 TTS cases in 15.7 million people after receiving a second dose, an estimated rate of 1.5 per million second doses (compared to a reported risk of 14.2 per million first doses in the UK).

People of any age without contraindications who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events should receive the second dose.

Recommendations

- ATAGI advises that Comirnaty is preferred over COVID-19 Vaccine AstraZeneca from the age of 16 to under 60 years. This is based on recent data regarding TTS cases in Australia and a reassessment of current age-specific risks and benefits of vaccination.
- ATAGI considers the benefit of vaccination in preventing COVID-19 with COVID-19 Vaccine AstraZeneca outweighs the risk of TTS in people aged 60 and above. For this age group, the benefits of receiving a COVID-19 vaccine are greater than in younger people. The risks of severe outcomes with COVID-19 increase with age and are particularly high in older unvaccinated individuals.
- COVID-19 Vaccine AstraZeneca can be used in adults aged under 60 years for whom Comirnaty is not available, the benefits are likely to outweigh the risks for that individual and the person has made an informed decision based on an understanding of the risks and benefits.
- People of any age without contraindications who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events should receive the second dose.
- ATAGI reinforces the importance of providing clear communications to people who have received or are considering COVID-19 Vaccine AstraZeneca, and notes guidance documents for consumers, for primary care and for hospitals are being continually revised to accommodate this new recommendation.

Next steps

ATAGI is continuing to monitor the evidence regarding the risks of TTS and the epidemiology of COVID-19, and will continue to review recommendations. Further modifications may be recommended as additional COVID-19 vaccine supply and emerging evidence become available. ATAGI reinforces that due to the ongoing risk of COVID-19, maximising vaccine coverage is a priority, particularly in those at greatest risk of severe COVID-19.

ATAGI is currently working with general practitioners, emergency physicians and haematologists to update clinical advice on TTS for consumers and primary care.

Tags:

Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on use of COVID-19 vaccines in an outbreak setting

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of COVID-19 vaccines in an outbreak setting.

Date published: 13 July 2021

Audience: General public

ATAGI recommendations on the use of COVID-19 vaccines are stated in the Clinical guidance on use of COVID-19 vaccine in Australia in 2021[1]. ATAGI has reviewed its clinical advice in the setting of increasing community COVID-19 cases in Australia. Recommendations for non-outbreak settings remain unchanged.

This statement addresses the specific application of these recommendations in the setting of a significant COVID-19 outbreak involving the Delta variant. This includes:

1. the re-assessment of benefits versus risks of COVID-19 Vaccine AstraZeneca for adults under 60 years old
2. updated advice about the optimal interval between the two doses of COVID-19 Vaccine AstraZeneca in an outbreak setting.

Recommendations on the use of Comirnaty, the Pfizer COVID-19 vaccine, are unchanged. The jurisdiction(s) where the COVID-19 outbreak occurs will determine when and where these recommendations are applicable, i.e. the response should be based on current epidemiology of the disease.

Recommendations

1. ATAGI reinforces that the benefits of vaccination with COVID-19 Vaccine AstraZeneca strongly outweigh the risks of adverse effects in those ≥60 years, and that vaccination is essential for this group in the context of an outbreak.
2. Every effort should be made to support vaccination of people in priority groups (e.g., older people, healthcare workers, disability and aged care workers, and those with listed medical comorbidities).
3. In the context of a COVID-19 outbreak where the supply of Comirnaty (Pfizer) is constrained, adults younger than 60 years old who do not have immediate access to Comirnaty (Pfizer) should re-assess the benefits to them and their contacts from being vaccinated with COVID-19 Vaccine AstraZeneca, versus the rare risk of a serious side effect.
4. While the recommended interval between the first and second doses of COVID-19 Vaccine AstraZeneca is between 4 and 12 weeks, in outbreak situations an interval of between 4 and 8 weeks is preferred. Therefore, people in an outbreak situation who received their first dose of COVID-19 Vaccine AstraZeneca more than 4 weeks ago should contact their vaccine provider to arrange their second dose as soon as possible. In non-outbreak settings, the preferred interval between doses of COVID-19 Vaccine AstraZeneca remains at 12 weeks.

5. All people who receive COVID-19 Vaccine AstraZeneca should be provided with information about common and rare but serious side effects, including the symptoms and signs of the thrombosis with thrombocytopenia syndrome (TTS). They should be advised that if they experience any signs or symptoms consistent with TTS, they should seek immediate medical attention.
6. Any additional unallocated supplies of both Comirnaty (Pfizer) and COVID-19 Vaccine AstraZeneca should be prioritised to populations and areas of greatest risk of COVID-19.
7. Recommendations around the use of Comirnaty (Pfizer) remain unchanged in outbreak settings.

Background

Vaccination is a key public health intervention to prevent infection, transmission and severe disease. In the context of the current COVID-19 outbreak with the new more transmissible Delta (B.1.617.2) variant, ATAGI has reviewed its previous advice on the use of COVID-19 vaccines, along with new information regarding the virus. Currently in Australia, the supply of Comirnaty (Pfizer) remains constrained, while access to COVID-19 Vaccine AstraZeneca is relatively easier.

The Delta variant is more infectious than other strains of SARS-CoV-2. It is unclear if the Delta variant causes more severe disease. Some countries have reported that infections with this variant are associated with higher risk of hospitalisation, need of intensive care, and death, even after differences in age or other factors are accounted for.[2,3] In Australia, more infections in the community means that there will be more people with COVID-19 requiring hospitalisations and intensive care unit (ICU) admissions. In addition, the effectiveness of vaccination against infection with a single dose of COVID-19 vaccine, either Comirnaty (Pfizer) or COVID-19 Vaccine AstraZeneca is notably lower against infections with the Delta variant compared with other strains. A two-dose course of vaccination offers optimal protection against both infection and hospitalisation.

Benefits and risks of COVID-19 Vaccine AstraZeneca in outbreak situations

The benefits to the individual of being vaccinated include avoiding severe COVID-19 outcomes, such as hospitalisation, intensive care unit admission and death, as well as chronic post-COVID-19 conditions ('long COVID'). Other benefits of vaccination including reducing the risk of passing the virus to close contacts including family, friends and work colleagues, and the potential to help reduce community spread of the virus. In outbreak settings, the benefits of COVID-19 Vaccine AstraZeneca are increased compared with non-outbreak settings. When the virus is spreading in the community it is critical that as many people as possible are vaccinated as quickly as possible.

In both outbreak and non-outbreak situations, ATAGI considers the benefits of COVID-19 prevention to outweigh the small risk of adverse events including TTS in those 60 years or older. ATAGI therefore reinforces the benefits of vaccination with COVID-19 Vaccine AstraZeneca in these individuals.

In outbreak settings, such as that currently occurring in Sydney, the benefits of vaccination are greater. Given the changes to the risk-benefit equation, ATAGI recommends adults under 60 years who do not have immediate access to Comirnaty (Pfizer) should re-assess the need for vaccination with AstraZeneca given these greater benefits. This changing risk-benefit balance is illustrated in previously published scenarios.[4] For context, the current cumulative risk of COVID-19 for residents of Sydney to 11 July 2021 is approximately 10 per 100,000 and is increasing by 2 additional cases per 100,000 per day. Although overall this is comparable to the Australian first wave (cumulative incidence 29 per 100,000), the ongoing risk would be considerably greater in some parts of Sydney and for specific populations. For example, in Fairfield Local Government Area, the cumulative risk to date is >100 per 100,000 and has increased by >10 cases per 100,000 per day in the past week.

COVID-19 Vaccine AstraZeneca is associated with a small but significant risk of adverse events following immunisation. The most important of these is TTS, a rare but potentially serious adverse event.[5] ATAGI has previously advised that it is important to: a) weigh up the benefits of

vaccination, when compared with the risks of harm of TTS from COVID-19 Vaccine AstraZeneca and b) be aware of the symptoms and signs of TTS in order to get prompt and effective treatment in the rare situation that TTS occurs. The latest cumulative estimates of the rates of TTS by age group, and a discussion of the spectrum of severity of TTS are available in the ATAGI update following weekly COVID-19 meeting – 7 July 2021 and the Therapeutic Goods Administration COVID-19 vaccine weekly safety report.[6,7]

Recommended interval between COVID-19 Vaccine AstraZeneca doses in outbreak situations

Earlier trials of COVID-19 Vaccine AstraZeneca suggested that there is a trend towards a higher vaccine efficacy with a longer interval between the two doses of this vaccine. The protective efficacy against symptomatic COVID-19 was 55% (95% confidence intervals [CI]: 33, 70%) when the two doses were given 4 weeks apart, compared to 81% (95% CI: 60, 91%) when given 12 weeks apart.[8] On this basis, ATAGI recommends a routine preferred interval of 12 weeks between the first and second dose of COVID-19 Vaccine AstraZeneca, but noted that "shortening the interval from 12 weeks to no less than 4 weeks between doses is acceptable and may be appropriate in certain circumstances, for example, imminent travel or anticipated risk of COVID-19 exposure."[1]

The protection of vaccines against infection and hospitalisation with the recently-emerging Delta variant have been studied internationally. A single dose of COVID-19 Vaccine AstraZeneca reduces the risk of symptomatic infection by around 30% (95% CI: 24%, 35%) and hospitalisation by 71% (95% CI: 51, 83%).[9] However, two doses of COVID-19 Vaccine AstraZeneca reduces the risk of symptomatic infection even further, by 67% (95% CI: 61%, 72%), and the risk of hospitalisation by 92% (95% CI: 75, 97%).[9] Thus, shortening the gap between first and second doses will bring forward short term protection, which is expected to be beneficial in outbreak situations. On this basis, an interval of between 4 and 8 weeks between the first and second doses of COVID-19 Vaccine AstraZeneca is preferred in an outbreak situation. In non-outbreak settings, the preferred interval between doses of COVID-19 Vaccine AstraZeneca remains at 12 weeks.

A similar incremental benefit in protection following second doses of Comirnaty (Pfizer) is observed but given the short dosing interval (of 3 to 6 weeks), these recommendations are unchanged in outbreak and non-outbreak settings.

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Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI Statement – Response to NSW COVID-19 outbreak – 24th July 2021

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) in response to the NSW COVID-19 outbreak.

Date published: 24 July 2021

Audience: General public

Summary

All individuals aged 18 years and above in greater Sydney, including adults under 60 years of age, should strongly consider getting vaccinated with any available vaccine including COVID-19 Vaccine

AstraZeneca. This is on the basis of the increasing risk of COVID-19 and ongoing constraints of Comirnaty (Pfizer) supplies. In addition, people in areas where outbreaks are occurring can receive the second dose of the AstraZeneca vaccine 4 to 8 weeks after the first dose, rather than the usual 12 weeks, to bring forward optimal protection.

Detail

ATAGI continues to closely monitor the epidemiology of COVID-19 in New South Wales, Victoria and South Australia. The outbreak in NSW continues to grow and the risk of disease, particularly in the greater Sydney area, is likely to continue to be significant over coming weeks.

ATAGI reaffirms our previous advice that in a large outbreak, the benefits of the COVID-19 Vaccine AstraZeneca are greater than the risk of rare side effects for all age groups.

In the context of the current risk of COVID-19 in NSW and with the ongoing constraints on Comirnaty (Pfizer) vaccine supplies, all adults in greater Sydney should strongly consider the benefits of earlier protection with COVID-19 Vaccine AstraZeneca rather than waiting for alternative vaccines

Maximal protection requires two doses of vaccine, but even a single dose of either vaccine provides substantial protection (by more than 70%) against hospitalisation. A single dose of COVID-19 Vaccine AstraZeneca partially reduces transmission by around half and therefore may also benefit close contacts and the community. It should be noted that there is a delay of 2-3 weeks after receiving a first dose of vaccine and being protected from COVID-19.

A second reason for ATAGI to recommend that individuals strongly consider vaccination at this time is emerging data about severity of disease. The Delta variant may be more severe than the original SARS-CoV-2 strain. The proportion of people less than 60 years requiring hospitalisation appears to be higher than was reported in outbreaks with the original SARS-CoV-2 strain. This reinforces the benefit of protection with any available vaccine.

People considering vaccination should be informed of the benefits and risks and give informed consent. People who receive COVID-19 Vaccine AstraZeneca should be aware of the symptoms of thrombosis with

thrombocytopenia syndrome (TTS), and when to seek prompt medical attention. Early detection of TTS means that people can get treatment and this can improve their outcomes.

ATAGI has previously issued advice recommending a shorter interval between the first and second doses of COVID-19 Vaccine AstraZeneca of 4-8 weeks in an outbreak (versus the routine 12 week interval) so that maximal protection against COVID-19 can be achieved earlier.

ATAGI also reinforces that the interval between the first and second doses of Comirnaty (Pfizer) is 3-6 weeks, providing flexibility in managing available supplies of vaccines, whilst also noting two doses are required for optimal protection. Spacing Comirnaty (Pfizer) to a routine interval of 6 weeks would allow limited vaccine supplies to be redirected to obtain first dose protection in outbreak areas of greatest need.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement regarding COVID-19 vaccines in the setting of transmission of the Delta variant of concern

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding COVID-19 vaccines in the setting of transmission of the Delta variant of concern.

Date published: 2 August 2021

Audience: General public

Summary

The increased transmissibility and possible increased severity of the Delta variant of SARS-CoV-2 underscores the importance and immediate benefits of achieving the highest possible COVID-19 vaccine uptake, especially in outbreak areas.

ATAGI suggests that several strategies could maximise first dose vaccine coverage. Achieving higher levels of first dose vaccine coverage as soon as possible, especially in those most likely to transmit SARS-CoV-2 or develop severe disease from COVID-19, complements broad and effective public health measures.

ATAGI reinforces a second dose of COVID-19 vaccine is required for durable protection and so first dose recipients should continue to be reminded to book in for their second doses.

The risk posed by the Delta Variant

ATAGI re-iterates the importance of COVID-19 vaccination as a key component of COVID-19 control with the overarching goal of protecting all people in Australia from the harm caused by SARS-CoV-2.

Outbreaks of the Delta variant have additional implications compared to previous COVID-19 outbreaks due to the original strain or other variants:

- The greater transmissibility of the Delta variant makes control of outbreaks using public health measures more difficult and increases the risk of seeding additional COVID-19 outbreaks.
- Some evidence suggests that infections with the Delta variant may be associated with more severe disease, as indicated by hospitalisations, particularly in younger people.

ATAGI reaffirms previous advice that in a large outbreak, the benefits of the COVID-19 Vaccine AstraZeneca are greater than the risk of rare side effects for all age groups.

ATAGI reiterates that all adults in greater Sydney should strongly consider the benefits of earlier protection with COVID-19 Vaccine AstraZeneca rather than waiting for alternative vaccines. ATAGI continues to recommend a shorter interval of 4 to 8 weeks between the first and second doses of COVID-19 Vaccine AstraZeneca in an outbreak (versus the routine 12-week interval that provides optimal longer-term protection) so that maximal protection against COVID-19 can be achieved earlier.

ATAGI notes the significant risk that the Delta variant poses to COVID-19 control and therefore continues to recommend COVID-19 vaccination for all adult Australians. ATAGI notes there is an increasing risk of outbreaks in places other than greater Sydney and therefore the benefits and risks may change. People considering vaccination should be informed of the changes in benefits and risks and give appropriate informed consent. People who receive COVID-19 Vaccine AstraZeneca should be aware of the symptoms of thrombosis with thrombocytopenia syndrome (TTS), and when to seek prompt medical attention. Early detection of TTS means that people can get treatment and this can improve outcomes.

Additional strategies to optimise first dose vaccine coverage

Providing a first dose of COVID-19 vaccine promptly to as many people as possible is likely to reduce hospitalisations and deaths from COVID-19. Protection against severe outcomes is substantial after a single dose of either vaccine. A first dose-prioritisation strategy has been employed in many other countries.

In addition to strict public health measures, providing a first dose of COVID-19 vaccine will contribute to interrupting transmission in affected areas. Evidence suggests that a first dose reduces symptomatic infection and transmissibility, with the protective effect starting 2-3 weeks after vaccination.

Strategies that could expand access to those in outbreak areas using available vaccine supplies include:

1. Increasing the interval between first and second doses of Comirnaty (Pfizer) from 3 to 6 weeks to facilitate earlier access to

first doses in areas of greatest risk of COVID-19.

2. Prioritisation of any available and additional supplies of both Comirnaty (Pfizer) vaccines and COVID-19 Vaccine AstraZeneca to populations residing in areas of greatest risk of COVID-19 and those at risk of transmitting the virus.
3. Addressing barriers to access to COVID-19 vaccines.

ATAGI also emphasises that for both vaccines completion of two doses is still required to attain optimal and durable protection. All people should ensure they complete a two-dose schedule.

In outbreak areas, efforts are required to address barriers to vaccination. This should include targeted communications and community engagement, education appropriate to specific populations, and vaccination centres and outreach services in accessible locations.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on considerations for establishing drive-through COVID-19 vaccination clinic sites

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on considerations for establishing drive-through COVID-19 vaccination clinic sites

Date published: 9 August 2021

Audience: General public

The requirements for COVID-19 vaccination sites generally remain unchanged for drive-through COVID-19 vaccination clinics.

Careful and comprehensive planning is strongly recommended to establish a drive-through vaccination clinic, including:

- Identifying a suitable site with sufficient space to meet site requirements (ideally identified in consultation with local government)
- Planning traffic flow, ideally in consultation with logistics experts
- Implementing clear processes for clinic flow, particularly identifying patients at higher risk for reactions immediately post-vaccination
- Ensuring all requirements for post-vaccination precautions and observations regarding safety are met in principle and are implemented
- Ensuring sufficient IT equipment and support
- Planning for contingencies and incidents.

Co-location of drive-through COVID-19 vaccination clinics with COVID-19 testing sites is not preferred due to the risk of exposing staff at vaccination clinics to COVID-19. Where co-location is being considered as separate sites are not feasible, special precautions and additional infection control measures are required.

General principles for drive-through COVID-19 vaccination clinics

The requirements for COVID-19 vaccination sites generally remain unchanged for drive-through COVID-19 vaccination clinics and are considered feasible to implement. The requirements for vaccinating sites are listed in the Appendix and have been slightly modified to account for logistical differences between ambulatory and drive-through vaccination clinics.

Careful and comprehensive planning is strongly recommended to establish a drive-through vaccination clinic. The challenges unique to drive-through clinics, compared with ambulatory clinics, are largely logistical, particularly traffic flow. The set-up and traffic flow of the

clinic must be carefully planned, with advice sought from local government and other relevant sectors on the suitability of vaccination sites and clinic arrangements.

Careful consideration should be given to ensuring requirements for post-vaccination safety precautions and observation can be met. Clinic processes and flow, particularly identifying patients who are higher risk for reactions immediately post-vaccination and methods for monitoring patients, must be clearly detailed and communicated to all staff. Prior to commencing mass vaccination, sites should consider conducting pilot testing, as this may help to determine throughput time per patient and identify and rectify bottlenecks in clinic flow and any other potential issues that may arise.

Below are some considerations for setting up a drive-through vaccination clinic. These are not absolute requirements, but considerations to help ensure that clinics are set up to be effective and efficient, and to mitigate safety issues.

Considerations for selecting a suitable site for drive-through vaccination clinics

Drive-through vaccination site selection will be restricted by the space requirements. Health authorities should ensure there is sufficient space available for line up, registration, vaccination and observation post-vaccination. Where possible, a separate area for consultation with an immunisation provider (for patients who wish to have a longer discussion prior to vaccination) may be considered to avoid congestion in traffic flow within the clinic.

Health authorities are strongly recommended to consult with local government and others with experience in arranging and managing complex logistical events. Ensuring proper traffic flow while ensuring the safety of staff and patients is imperative for running a drive-through vaccination clinic successfully. Site selection should consider traffic flow within the clinic as well as entrances to and exits from the site. Consultation with local government can help to identify a suitable

site, e.g., ensuring that a vaccination site is not established in an area where traffic build up may affect traffic in surrounding areas or where extensive roadworks are planned.

Sites should be selected to ensure that the vaccinating area is protected from the weather elements, with staff provided with adequate shelter and heating and/or cooling.

Drive-through vaccination sites that are not located within or adjacent to a health facility are likely to experience more logistical challenges and require more space, due to the requirements regarding storage and preparation of vaccine doses. Ensuring proper cold chain management will be important, particularly if drive-through clinics are to be used in warmer weather. Ultra-cold temperature storage is not needed at drive-through vaccination clinics.

The transportation of pre-prepared syringes to drive-through vaccination sites is generally not recommended. Sites must have sufficient space to prepare vaccine doses on-site. There may be exceptions on rare occasions; in these cases, the principles detailed in the guidance on multi-dose vial use must be adhered to.

Experience from previous drive-through mass vaccination clinics has found that additional information technology equipment and support is required. Ideally, sites would have a wireless network that allows electronic data entry and suitable IT support available.

Co-location with COVID-19 testing sites

It is preferable not to co-locate drive-through vaccination clinics with COVID-19 testing or respiratory infection clinic (RIC) sites, wherever possible. This is predominantly due to infection control risks, e.g., the increased risk of infection to staff in vaccination clinics, given the potential for patients to inadvertently drive into the vaccination clinic instead of the COVID-19 testing clinic. In addition, different levels of PPE are required in vaccination and testing clinics.

In some settings where an additional site for drive-through vaccination is not feasible, very clear directions to the different entities will be required. Consideration may also be given to utilising the testing site

as a vaccination clinic on different days, although the risk of patients seeking COVID-19 testing driving into a vaccination clinic is still present. There would need to be clear signage and guidance to minimise the risk of a patient driving into the wrong clinic. Additional infection control measures to minimise the risk of staff at vaccination clinics being exposed to COVID-19 should also be considered, such as additional PPE requirements for staff in first contact with patients.

Considerations for ensuring safety in drive-through vaccination clinics

All requirements for post-vaccination precautions and observation should be met in principle and implementation in a drive-through vaccination setting. There are three concerns regarding safety unique to this context:

Post-vaccination observation and safety events

Clinics must ensure there is sufficient space for patients to be observed as per clinical recommendations. Clear protocols and communication must be implemented for identifying patients who experience an adverse event, with abundant signage to inform patients what action, if any, they need to take (e.g. use their horn to get staff's attention).

Processes for identifying patients at risk of post-vaccination events who require a longer observation period must be in place. Sites should consider the feasibility of having a separate area for patients who are identified as high risk for syncope post-vaccination, so that they may go directly to that area and park prior to receiving vaccination. This is to reduce the risk of syncope while driving from the spot where vaccine is administered to the observation space. Patients with certain medical histories (e.g. serious allergic reactions, past reaction to a vaccine, syncope post-vaccination) may be advised at the time of booking their appointment to bring an accompanying person with them as an additional precaution.

Shoulder injury related to vaccine administration (SIRVA)

SIRVA is a rare event, and the risk is not considered to be higher in a drive-through clinic setting as long as there is clear access to the deltoid muscle. In most instances, vaccination through the car window is acceptable. In some cases, where there is a large vehicle, patients may need to step out of the car to receive the vaccine. A separate space with seating should be considered for these patients but is not required.

Staff safety

Logistics planning should account for staff safety, given staff will be moving around to run the clinic in an area with vehicles. Planning should account for ways to reduce needlestick injuries, such as having sharps bins on wheels available. Steps should also be taken to minimise staff's exposure to vehicle exhaust fumes (e.g. asking patients to turn off their engines when stationary).

Additional considerations for planning drive-through vaccination clinics

Administration of different COVID-19 vaccines

Clinics may choose to administer different brands of COVID-19 vaccines at the same drive-through vaccination clinic. This would allow families with people of different ages (and therefore eligible for different vaccines) to be vaccinated at the same time. However, the ability to do this should be assessed on a case-by-case basis, given the increased risk of administering the wrong vaccine brand to a patient. Planning should include consideration of measures to mitigate this risk.

Incident management and contingency planning

Preparing for establishing a drive-through clinic requires contingency and incident management planning. Some scenarios include technological issues or 'downtime', car accidents, staff absences (particularly in the winter season), and workplace injuries. This is especially important for larger and new clinics with staff that have limited experience running drive-through vaccination clinics.

Appointments

While not required, it is recommended that attendance at drive-through clinics for COVID-19 vaccination be by appointment only, due to the potentially large demand. Clinics may still accept patients without an appointment, if capacity allows.

Additional resources needed for drive-through mass vaccination clinics

The following are not absolute requirements but are considerations to enhance the efficiency of a drive-through vaccination clinic.

- Additional staff/volunteers for various tasks such as directing patients and documentation. Additional personnel may include a logistics/flow manager (particularly for large clinics), volunteers to manage flow, traffic control personnel (line attendants, flaggers) and IT support.
- IT equipment and support – e.g. laptops/tablets, wireless internet, tech support
- Clear signage to direct flow
- Information resources for patients
- Markers or coloured cards to flag patients who require longer waiting times
- Tents (depending on clinic location and set up)

- Sharps containers on wheels (to reduce sharps-related injuries to staff)
- Portable fridges, eskies or other appropriate container(s) to store and move vaccine doses within the clinic

Resources for planning drive-through vaccination site

The following resources may assist in planning and setting up a drive-through COVID-19 vaccination clinic. Additional, unpublished resources are available from WA and VIC (Monash) where drive-through vaccination clinics were set up in 2020.

- NSW guidance for GPs considering vehicle-based influenza vaccination clinics (2020)
- UCHealth mass vaccination playbook
- CDC guidance for planning vaccination clinics held at satellite, temporary or off-site locations
- CDC checklist
- CDC considerations for planning curbside/drive-through vaccination clinics
- Drive-through efficiency: How to prepare for and execute a mass vaccination event (UCHealth) – commentary in the NEJM Catalyst (includes practical information and tips to improve efficiency)

Checklist for COVID-19 vaccination sites

Workforce requirements

- Adequate well-trained staff are allocated for clinics (the required number will depend on the anticipated size of the clinic or patient volume, with provisions for emergency scenarios), including:
    - Vaccinators to prepare and administer vaccines

    - Authorised immunisation provider (e.g. medical officer or fully trained immunisation registered nurse/nurse practitioner to assess patients and authorise other appropriately trained clinical staff (vaccinator) to administer the vaccine)
    - Concierge or team leader (to direct clinic flow)
    - Clerical staff
    - First aid staff, additional to vaccinating staff as per jurisdictional requirements
    - Security staff (if required)
- There are sufficient medical officers or fully trained immunisation providers with authority to vaccinate, especially if supervising vaccinators who have not completed a specific training course in immunisation
- All immunisation providers have received adequate specific training, including regarding the use of multi-dose vials (documentation of training required)
- Have access to and have a clear understanding of the clinical guidelines for administering COVID-19 vaccines from multi-dose vials.

Set up of the physical environment

- Have adequate space for patients waiting to be vaccinated that is not congested, observes physical distancing requirements, and is sheltered from weather elements
- Have a private space for consultation with patients and vaccinator (including obtaining informed consent, answering patient questions and assessment of any conditions that may preclude vaccination or require further assessment) – recommended, but not required, for drive through clinics
- Have a dedicated, clean, well-lit space for administration of the vaccine to patients, including a desk and chairs for vaccinator(s)
- For drive through clinics: have the site layout designed to allow space for patients to be observed for the required duration without having to move the vehicle post vaccination.
- Have safe, risk free and directed access in clinical areas to allow movement of staff between areas while minimising the risk of workplace incidents (e.g. moving doses from preparation area to

patient administration area, accessing refrigerators or cool boxes, etc.) – in drive-through setting, traffic flow should be carefully planned

- Have a dedicated clean and well-lit area, separate from areas that provide other clinical services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration
- Adequate handwashing facilities for staff, and antimicrobial hand sanitisers available
- Have antimicrobial /disinfectant wipes to clean stations between patients
- Have visual reminders and cues in place to reduce the risk of errors
- Have a process in place to safely dispose of unused vaccines, in accordance with TGA and other regulatory requirements
- Have adequate sharps disposal bins, appropriate for the volume of patients, and securely placed and spaced to mitigate the risk of needlestick injuries.

Cold chain management

- Have adequate number and capacity of refrigerators to store vaccines for the vaccine to be used
- Able to monitor the temperatures of the refrigerator(s) and freezer(s) where vaccines are stored, including appropriate equipment and systems to monitor temperatures according to national vaccine storage guidelines
- Have an appropriate policy and protocol in place to respond to temperature breaches, including relocating vials to another refrigerator/freezer and responding at times where clinic may not have any staff present
- Have appropriate refrigerators and opaque containers to store vaccine syringes that have been prepared for administration under appropriate temperature conditions and protected from light from the time they are prepared till the time they are administered.

Immunisation record keeping and reporting to the Australian Immunisation Register (AIR)

- Have a clear procedure for identifying individual vaccine recipients, checking to confirm any record of previous receipt of any COVID-19 vaccine doses (including date and brand product received), and recording immunisation encounters (electronic records are preferable)
- Have a process of labelling syringes when they are drawn up from multi-dose vials, including date and time of preparation and of expiry
- Have access to AIR via Provider Digital Access (PRODA)
- Have a process to manage vaccination data and report immunisation records to AIR
- Have a process to record vaccines used and those discarded, including reasons for discarding
- Have a process of obtaining informed consent.

Management of the clinic

- Standardised screening process to exclude patients who display symptoms of COVID-19 disease, and refer for appropriate assessment for COVID-19 or other conditions (as per guidance provided in the ATAGI Guiding Principles for Maintaining Immunisation Services During the COVID-19 Pandemic
- Standardised screening process for contraindications, receipt of previous doses of COVID-19 vaccines and/or receipt of other vaccines (observing any interval requirements)
- Clear record of patients vaccinated (to inform ordering of vaccines)
- Clear assignment of duties and responsibilities of all staff and clear plan of workflow, particularly regarding drawing up from a multi-dose vial and administering individual vaccine doses drawn from a particular vial for each clinic session
- Knowledgeable about procedures and able to report adverse event following immunisation to the appropriate health authorities

- Incident management in place, with staff knowledgeable about procedures and able to report any clinical incident (e.g. injury in workplace) to the appropriate health authorities
- Has process in place to manage injuries to workforce (e.g. needlestick injury)
- Process in place to prevent and manage violence or aggression in the workplace.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on COVID-19 vaccines in adolescents.

Date published: 27 August 2021

Audience: General public

This statement was originally published on 27 August 2021, and has now been updated.

The Australian Technical Advisory Group on Immunisation (ATAGI) has previously recommended that adolescents from 12 years of age belonging to the following groups be prioritised for vaccination using Comirnaty (Pfizer):

- Individuals with specified underlying risk conditions, including NDIS participants
- All Aboriginal and Torres Strait Islander children
- All children in remote communities, as part of broader community outreach vaccination programs.

ATAGI has reviewed the evidence and now supports COVID-19 vaccination in all adolescents from 12 years of age.

Vaccination against COVID-19 is recommended for all people from 12 years of age, extending the current recommendation for those 16 years and older.

A two dose schedule using Pfizer or Spikevax (Moderna) is recommended.

ATAGI has developed these recommendations following careful consideration of the relevant benefits, risks, uncertainties and evidence on this topic, including:

- Safety, efficacy and effectiveness of COVID-19 vaccines in adolescents from clinical trials and overseas vaccination programs
- Epidemiology of COVID-19 in adolescents including disease severity and complications and their role in transmission in the population
- The potential for indirect benefits of vaccination, such as on family and adolescent wellbeing and participation in education
- Evidence of potential acceptance of vaccination in this age group.

ATAGI notes that supply of Pfizer and Moderna remains constrained, and so the timing of inclusion of adolescents in the national COVID-19 vaccination program needs to be balanced against access to vaccine in other populations.

The timing for inclusion of adolescents in the COVID-19 vaccination program may also vary depending on local epidemiology, including outbreaks. It should be noted that there is a delay of 2-3 weeks after

receiving a first dose of vaccine to gaining protection from

COVID-19.

Further detail regarding this ATAGI recommendation is available here.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement about the need for additional doses of COVID-19 vaccines

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) about the need for COVID-19 vaccine booster shots.

Date published: 23 September 2021

Audience: General public

At this point in the National COVID-19 vaccine rollout, Australian Technical Advisory Group on Immunisation (ATAGI) strongly recommends maximising first and second dose vaccine uptake across the community without delay in line with current prioritisation and outbreak response strategies.

Two doses of any of the vaccines available in Australia have been shown to protect an individual from COVID-19 and its complications, as well as protecting the community.

At this time, the Therapeutic Goods Administration (TGA) has not yet received a registration application for the administration of additional doses of any COVID-19 vaccines.

ATAGI is closely monitoring local and international data about the frequency and severity of COVID-19 in fully vaccinated individuals. ATAGI is also reviewing the international data on the efficacy, effectiveness and safety of additional doses for specific high-risk patient populations, including immunocompromised individuals, and the population more generally. These data will inform future strategies regarding additional vaccine doses.

Additional doses can be defined as:

- Third doses: Additional COVID-19 doses required as part of the primary course to reach a comparable (optimal) level of protection
- Booster dose: Additional COVID-19 doses required at a broader population level, to optimise protection due to waning of immunity (loss of protection) over time, with booster doses also leading to improved immune memory.

ATAGI anticipates that a relatively small cohort of individuals, such as those with severely immunocompromising conditions, are likely to require a third dose as part of their primary course of vaccination to ensure optimal vaccine effectiveness. Advice on the need for third doses in this group is anticipated in the next few weeks.

ATAGI anticipates that additional booster doses for other populations may be required in the future. Additional doses are currently being considered but no recommendation has yet been made for the general population at this stage. In addition to the severely immunocompromised, evidence for use in selective cohorts is being actively considered. Detailed advice will be provided as the review progresses. The following points are worth noting in this regard:

- First and second dose coverage in yet to be vaccinated adults and adolescents remains a priority, as high primary COVID-19 vaccine coverage is expected to have the largest impact on

protection against severe disease both directly (by direct protection) and indirectly (by prevention of transmission).

- Currently available international data suggests that protection from two doses is maintained against severe COVID-19 disease, including both hospitalisation and intensive care unit (ICU) admissions. This is further supported by the Australian data suggesting that severe COVID-19 following full vaccination is uncommon in the current Delta outbreak.
- The duration of protection provided by additional 'booster' doses is not yet clear. Timing of booster doses to cover anticipated future peaks will be an important consideration.
- Data on the balance of efficacy and safety of third doses of mRNA vaccines is still emerging, so ongoing monitoring of the international experience will be important.
- Consideration is required as to the timing and the type of vaccine to be used as boosters and the potential for newer vaccine types (e.g. protein subunit vaccines [e.g. Novavax], variant vaccines) to become available.

ATAGI is expecting to provide preliminary advice on the need and timing of additional doses in the broader population by the end of October.

ATAGI notes that current procurement arrangements between the Australian Government and vaccine providers are sufficient to provide for first, second and additional doses as required over the next 2 to 3 years.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

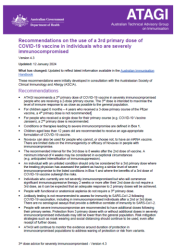
Australian Government
Department of Health and Aged Care

ATAGI statement on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Audience: General public

The referred fact sheet provides the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.



ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on SARS-CoV-2 Omicron variant and COVID-19 booster doses

The Australian Technical Advisory Group on Immunisation (ATAGI) has noted the emergence of a new SARS-CoV-2 variant of concern, which has been named the Omicron variant.

Date published: 3 December 2021

Audience: General public

At this stage, there is no evidence to suggest that earlier booster doses of current COVID-19 vaccines will augment protection against the Omicron variant.

ATAGI will continue to closely monitor the epidemiology and emerging data on the likely impact of vaccination on this variant and update recommendations in the near future.

Background

Omicron was first reported in South Africa on 24 November 2021. The World Health Organization (WHO) declared Omicron to be a COVID-19 variant of concern.

At the current time, very little is known about the characteristics of this variant. Specifically, it is still to be determined whether it is more transmissible, causes more (or less) severe disease, and whether immunity following natural infection or immunisation has an impact on infection and severe disease following exposure to this variant.

Over the coming weeks, more evidence will emerge from laboratory studies, studies of virus transmission, age-specific case-hospitalisation and case-fatality ratios, and studies of breakthrough infections after previous infection and/or vaccination. These studies are underway globally and in Australia.

Vaccine manufacturers have also signalled they are examining the need for and potential development of COVID-19 vaccines that may be more effective against new variants.

A booster dose is currently available to anyone in Australia aged 18 years and over who has completed their primary course of vaccination at least six months ago.

At this stage, there is no evidence to suggest that earlier booster doses of current COVID-19 vaccines will augment protection against the Omicron variant.

ATAGI advises that in certain circumstances, the routine six-month interval for booster doses may be shortened to five months for logistical reasons, for example:

- for patients with a greater risk of severe COVID-19 in outbreak settings;

- if an individual is travelling overseas and will be away when their booster dose is due; or
- in outreach vaccination programs where access is limited.

It should be noted that there are very limited data on benefit for boosters given prior to 20 weeks after completion of the primary course, and the duration of protection following boosters is not yet known. More information is available in ATAGI's Clinical Guidance.

In addition, a third dose is recommended for anyone with immunocompromising conditions, a minimum of two months after their second dose. Refer to ATAGI's statement on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Providers should use their clinical judgement to determine whether it is appropriate to administer the dose early.

Tags: Immunisation | Travel health | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

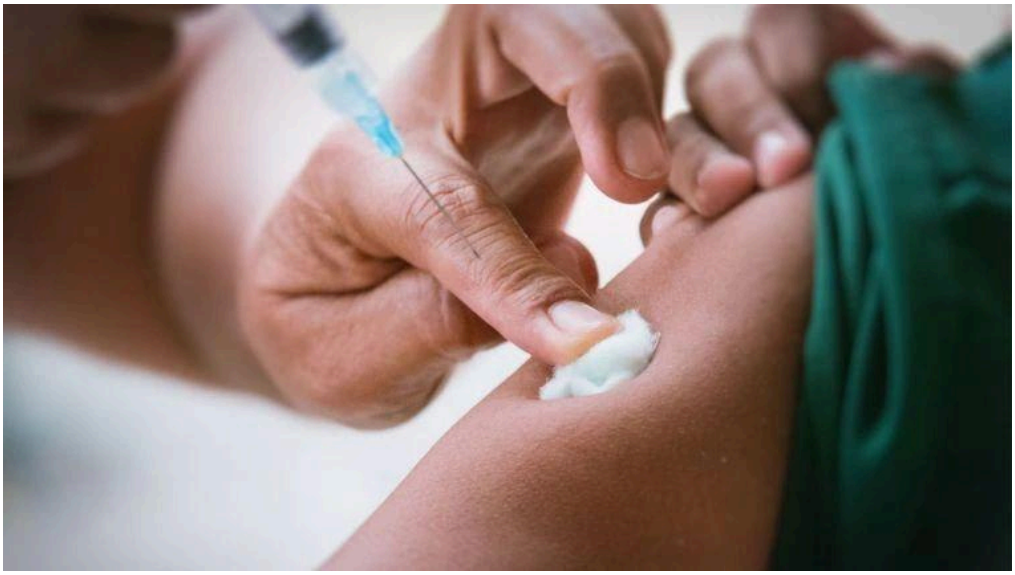
Australian Government
Department of Health and Aged Care

Updated ATAGI advice on the administration of seasonal influenza vaccines in 2021 (December 2021)

As international borders open, the Australian Technical Advisory Group on Immunisation (ATAGI) has issued updated advice for the rollout of influenza vaccines.

Date published: 7 December 2021

Audience: Health sector



The Australian Technical Advisory Group on Immunisation (ATAGI) has released updated advice for influenza vaccination in 2021. Seasonal influenza virus' may start to re-emerge and circulate in Australia with the opening of international borders.

Due to the COVID-19 public health and social measures in Australia and internationally, the seasonal pattern of influenza was different in 2020 and 2021 from previous years, with considerably lower influenza virus circulation. Influenza vaccine coverage in Australia in 2021 has been lower compared to 2020.

With borders reopening from November 2021 and greater population movement, a resurgence of influenza activity is expected (outside of the usual influenza season).

Influenza vaccination with the 2021 vaccine is recommended for anyone aged 6 months and over who has not had an influenza vaccine this year, particularly those in higher risk groups.

It is also recommended those planning international travel receive the 2021 influenza vaccination before departure.

Co-administration with COVID-19 vaccines

Influenza vaccines can be co-administered with COVID-19 vaccines. Subject to availability of influenza vaccines, an ideal time to vaccinate could be on the same day as a COVID-19 booster vaccine.

Expiry of 2021 influenza vaccines

2021 influenza vaccines should continue to be offered as long as valid, unexpired vaccine is available. Some vaccine brands now have expiry dates up to late February 2022.

Immunisation providers should check a vaccine's expiry date before administration and not issue expired vaccines.

The full ATAGI statement contains further detail.

Tags:

Immunisation | Influenza (flu) | Advisory Committee on Vaccines (ACV) | National Immunisation Program | Communicable diseases

Australian Government
Department of Health and Aged Care

Response to ATAGI advice about vaccinating 5 to 11-year-olds against COVID-19

The latest phase in our COVID-19 vaccination rollout program – to vaccinate children aged 5 to 11 years from 10 January 2022 – continues to be based on the best medical and scientific advice available.

Date published: 10 December 2021

Audience: General public

Extending the vaccination program to this age group has been approved by Australia's medicines regulator, the Therapeutic Goods Administration (TGA) and recommended by Australia's vaccines experts on the Australian Technical Advisory Group on Immunisation (ATAGI).

The TGA's provisional approval of the Pfizer vaccine for 5 to 11-year-olds was based on an evaluation of available data to support its safety and efficacy among this age group.

ATAGI's considerations before recommending the Pfizer vaccine be extended to this age group built on the work of the TGA and included a careful review of the "real world" experience in other countries where vaccinations had already been administered to this cohort.

Clinical trials have demonstrated the vaccine to be more than 90 per cent effective at preventing laboratory-confirmed symptomatic COVID-19 from seven days after a person has had their second dose. The vaccine was demonstrated to be well tolerated, with most adverse effects being mild and transient.

The experts on ATAGI considered the low numbers of children – approximately one in 3,000 – who get COVID-19 and go on to develop an immunological condition called paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 (PIMS-TS, also known as multisystem inflammatory syndrome in children, or MIS-C). Children who develop this condition can become very sick for months.

ATAGI also took into account the benefits that vaccinating this age group would have for the broader community through reduced transmission levels and greater protection for older and more vulnerable Australians.

The Australian Government is working with state and territory governments, and health professionals, to prepare for the rollout to be extended to children aged 5 to 11 years from 10 January 2022.

The Australian Health Protection Principal Committee, ATAGI and the TGA are constantly monitoring the COVID-19 pandemic and the emerging evidence on vaccines – both domestically and internationally – and will continue to provide expert, independent advice to the Government.

For people who want more information about the Pfizer vaccine for children.

Read the ATAGI advice

Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

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

Spikevax (Moderna), also referred to as the Moderna COVID-19 vaccine, has been provisionally approved for use as a COVID-19 booster vaccine in people aged 18 years and older by the Therapeutic Goods Administration (TGA).

Date published: 12 December 2021

Audience: General public

Introduction

Spikevax (Moderna), also referred to as the Moderna COVID-19 vaccine, has been provisionally approved for use as a COVID-19 booster vaccine in people aged 18 years and older by the Therapeutic Goods Administration (TGA). The dosage for use as a booster dose is 50µg (0.25mL), i.e. half of the recommended dose of the Moderna COVID-19 vaccine used for the primary course.

Recommendations

ATAGI previously recommended that Comirnaty (Pfizer), also referred to as the Pfizer

COVID-19 vaccine, was the preferred vaccine for use as a COVID-19 booster, regardless of the vaccine used for the primary course. Following review of recently available data on the safety and immunogenicity of the Moderna COVID-19 booster vaccine and its TGA approval, ATAGI now recommends that:

1. The Moderna (50µg) COVID-19 vaccine can be used as a booster dose for people who completed their primary COVID-19 vaccine course 5 or more months ago with a COVID-19 vaccine registered or recognised by the TGA.
2. ATAGI considers the Moderna (50µg; 0.25mL) and Pfizer COVID-19 vaccines to be equally acceptable as booster vaccines for all people aged 18 years and older, including pregnant women.

3. Both mRNA COVID-19 vaccines are preferred over the AstraZeneca COVID-19 vaccine for the booster dose, including for people who received the AstraZeneca vaccine for their primary course. The AstraZeneca vaccine is not yet TGA approved as a booster but can be used as a booster for people who have contraindications to mRNA COVID-19 vaccines or who had AstraZeneca for their primary course.
4. Severely immunocompromised people who are receiving a third primary dose of the Moderna COVID-19 vaccine should receive a 100µg dose. A booster dose is not yet recommended for this cohort. ATAGI will provide advice on the timing of a booster soon.
5. A booster dose is not currently recommended for people aged under 18 years, and there are currently no vaccines approved for use as a booster in this age group.

The implications of the newly emerged Omicron variant have been reviewed by ATAGI and need and timing for booster doses revised. Refer to the ATAGI statement on the Omicron variant and timing of COVID-19 booster vaccination.

Background

Benefits of a Moderna booster dose

ATAGI notes that the benefits of the Moderna COVID-19 vaccine booster dose have been inferred from immunogenicity studies.

The safety and efficacy of a primary course of the Moderna COVID-19 vaccine to prevent-COVID-19 was demonstrated in a large randomised controlled clinical trial in adults aged 18 years and older.[1] A cohort of 1,080 participants from this trial were randomly selected as the comparison group for a booster study.[2] 50µg (0.25mL) of the Moderna COVID-19 vaccine was administered to 344 participants 12 years and older who had received a two-dose primary course of either 100µg or 50µg of the Moderna COVID-19 at least 6 months prior.

The protective effectiveness of a booster dose was inferred from a comparison of neutralising antibody titres and seroresponse rates against both the Delta variant and an older strain of SARS-CoV-2 measured 28 days after a single 50µg booster dose, compared to 28 days after the second 100µg primary series dose (day 57). The

geometric mean ratio (GMR) in the booster cohort compared with the unboosted cohort was 1.8 (95% CI 1.5 – 2.1), suggesting that antibody concentrations are higher after the booster dose than after the primary course. The difference between the seroresponse rate (defined as 4-fold titre rise) between the boosted and unboosted group was -5.3% (95% CI: -8.8%, -2.9%). The lower bound of the 95% CI at -8.8% met the prespecified success criterion of a non-inferiority margin of 10%.

Safety of a Moderna booster dose

Evidence of the safety of the Moderna booster COVID-19 vaccine is derived predominantly from clinical trials as well as limited post-implementation safety surveillance. The Moderna 50µg booster dose was safe and well tolerated among the 344 boosted participants, which included both 100µg and 50µg primary dose recipients.[2] Rates of adverse events within the booster group were comparable to those observed after dose 2 of the primary series, with pain at the injection site the most common solicited local adverse event in both groups. Headache, fatigue and myalgia were reported as systemic adverse events equally across both groups. Axillary swelling or tenderness was the only adverse event more common in booster dose recipients, being reported in 21% (69/330) of participants following a booster dose, compared with 14.2% (2,092/14,687) of participants following their second primary dose.[2] No grade 4 adverse events, or vaccine-related serious adverse events or deaths were reported in the booster trial.

Considerations in the choice of booster vaccine brand

Safety and immunogenicity of heterologous booster vaccination with Moderna COVID-19 vaccine

The safety and immunogenicity of a 100µg booster dose of Moderna COVID-19 vaccine was analysed in an open label phase I-II study of healthy adults ⩾ 18 years who had completed their primary course with the Janssen (n=53), Moderna (n=51) or Pfizer (n=50) COVID-19 vaccines[3].

Regardless of the initial vaccine primary course, boosting with 100µg of the Moderna COVID-19 vaccine resulted in a significant increase in neutralising antibody titres, including against the Delta variant. No unexpected safety signals occurred, but approximately 60% of participants who received a primary course with an mRNA vaccine reported systemic adverse events following their booster dose with Moderna (mild to moderate malaise, headache and nausea), which was more frequent than participants who received Janssen as their primary vaccine course. No deaths or SAEs were reported following the booster dose in any of the participants.

A phase 2 study from the UK also analysed healthy adults ⩾ 30 years who received AstraZeneca COVID-19 vaccine (n=112), or Pfizer/BioNTech (n=111) for their primary course. Trial participants were boosted with **100µg** of the Moderna vaccine (compared with placebo and boosting with other vaccines).[4] The 100µg Moderna booster resulted in the greatest increase in neutralising antibody titres and slightly increased reactogenicity compared to boosting with other vaccines.

Comparison of immunogenicity and efficacy between the Moderna COVID-19 vaccine and other vaccines used as booster

There are no published studies that directly compared the immunogenicity of the Moderna 50µg booster dose with other vaccines used as booster. In an open label study where Moderna 100µg was given as a booster at 6 months after the second primary dose, participants achieved neutralisation GMTs at least >3.8 times higher at 2 weeks post-booster compared with 1 month post dose 2 against wild-type, Beta, Gamma, and Delta variants.[5] By comparison, the Pfizer COVID-19 vaccine, given as a booster at 6 to 9 months post dose 2 produced neutralisation GMTs 3.29 to >5 times higher after the booster dose than after the second primary dose.[5]

Comparison of safety between Moderna and other vaccines used as booster

Active vaccine safety surveillance data from the USA has shown that both Pfizer and Moderna booster doses have generally lower rates of local and systemic adverse events than the second primary dose of each vaccine. [6] Local and systemic adverse event rates were generally

higher with the Moderna booster than with the Pfizer booster, regardless of the brand of mRNA vaccine given for the primary course. The majority of the reported adverse events were non-serious.

Myocarditis and pericarditis occur rarely after vaccination with Moderna COVID-19 vaccine, more commonly after the second compared with the first dose and in young adult and adolescents, particularly males.[7–9] These conditions occur more commonly following COVID-19 itself however, highlighting the benefits of vaccination over risk. While still rare, these conditions have been reported more frequently following the Moderna COVID-19 vaccine (100µg) compared with Pfizer COVID-19 vaccine, when used in a primary course.[10,11] Early observational data from Israel (where only the Pfizer vaccine is used in the booster program) showed that a lower rate of myocarditis and pericarditis was reported after a booster dose of the Pfizer vaccine than after dose 2 of the Pfizer primary course.[12]

Insufficient data are yet available to establish the rates of myocarditis or pericarditis specifically after a booster dose of the Moderna COVID-19 vaccine. In this context, it will be important to monitor rates of myocarditis and pericarditis, particularly in younger males, and when the Moderna COVID-19 vaccine is used as a booster. ATAGI will monitor these data as they emerge from Australia and internationally and will update these recommendations if required. Refer to Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines for further information.

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Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on the Omicron variant and timing of COVID-19 booster vaccination

The COVID-19 vaccines used in Australia are critical in protecting against COVID-19 due to all variants, including the newly emerged Omicron variant.

Date published: 12 December 2021

Audience: General public

Recommendations

Given the likelihood of ongoing transmission of both Omicron and Delta variants, ATAGI recommends COVID-19 booster vaccination for anyone aged 18 and older who completed their primary course of COVID-19 vaccination 5 or more months ago.

Timely receipt of a booster dose is particularly important for people with increased exposure risk (e.g. occupational risk or outbreak areas) or who have risk factors for severe disease.

Either Comirnaty (Pfizer) or Spikevax (Moderna) are recommended for use as a booster vaccine, and are considered equally acceptable.

ATAGI reiterates that a third (primary) dose of COVID-19 vaccine is also recommended for anyone with immunocompromising conditions, a minimum of two months after their second dose.

Background

ATAGI are closely examining all data on the epidemiology of COVID-19 and COVID-19 vaccine impact, in particular emerging data on the new Omicron SARS-CoV-2 variant.

On 28 October 2021, ATAGI recommended boosters for all Australians aged 18 and older from 6 months after their primary course, or from 5 months in specific circumstances. ATAGI now advises a routine interval of 5 months.

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 in over 50 countries globally. Cases of COVID-19 due to Omicron, including some acquired in Australia, have been identified in multiple Australian jurisdictions.

Evidence is still incomplete on the transmissibility, capacity to cause severe disease and overall impact of the Omicron variant. While data suggest that past infection with an earlier variant does not provide significant protection against infection, it remains unclear whether prior infection may reduce severity.[1] Early data suggest that the protection

provided by COVID-19 vaccination against infections with the Omicron variant is impaired compared to those with the Delta variant, but further data are required on the effectiveness against severe disease.

The virus has been isolated in several laboratories, including those in Australia, and laboratory, clinical and epidemiological studies are underway globally and in Australia to understand its potential impact. Preliminary data suggest that the increased antibody levels generated following a COVID-19 vaccine booster dose may offer improved protection against the Omicron variant. However, the correlation between antibody levels in laboratory studies and protection against infection and severe disease is not yet established.

Rationale

As of the 11 December 2021, the weight of evidence suggests that a booster vaccine increases antibody levels substantially and this will likely offer protection against both Delta and the new Omicron variant. However, there is limited evidence to inform the optimal interval between primary and booster doses. Although registered for use from 6 months after primary vaccination, there are considerable data on the effectiveness and safety of boosters from 5 months from the Israeli program.[2,3]

The anticipated benefits of bringing forward the booster dose include earlier protection, particularly against severe disease in those at risk, and improved protection against COVID-19 due to the Omicron variant. The relative benefit of a booster vaccination increases with the duration since primary COVID-19 vaccine course and for those living in regions with community transmission of SARS-CoV-2. There remains uncertainty about the duration of protection following a booster dose, and the potential emergence of future new variants.

Vaccine manufacturers have also signalled they are examining the need for and potential development of COVID-19 vaccines that may be more effective against new variants, however this is expected to take several months.

More information is available in ATAGI recommendations on the use of a booster dose of COVID-19 vaccine and ATAGI's Clinical guidance on COVID-19 vaccine in Australia.

Immunocompromised people have been recommended to receive a third primary dose since 8 October 2021, two months after their second dose. Both the Pfizer and Moderna COVID-19 vaccines can be used for this third dose. ATAGI is reviewing the timing of a later dose (i.e., a post dose 3 booster dose) in this specific population and will issue advice on this in the near future. Refer to ATAGI's statement on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

ATAGI will continue to review emerging evidence on the optimal interval between primary and booster COVID-19 vaccine and will provided updated advice in future as required.

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Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on Omicron variant

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) about the COVID-19 Omicron variant.

Date published: 17 December 2021

Audience: General public

ATAGI notes that several outbreaks in Australia have now been attributed to the SARS-CoV-2 Omicron variant. With the relaxation of border restrictions in most jurisdictions, there are likely to be increasing numbers of COVID-19 cases due to the Omicron variant. In addition to the rapid spread of the Omicron variant in South Africa, this new variant is also becoming dominant in the UK and Denmark.

ATAGI notes the increasing use of booster doses of vaccine, with more than 130,000 doses administered on 16 December 2021. Approximately 1,117,020 booster doses have been delivered overall and 430,000 of those have been delivered since ATAGI recommended shortening the

interval at which people become eligible between booster doses and the primary schedule bringing it forward from 6 months to 5 months on 12 December 2021.

ATAGI recognises that some flexibility may be required in recommendations for those who are due booster doses during the holiday period.

Recommendations

- At this stage, ATAGI has not changed the recommendation for commencement of eligibility of COVID-19 booster vaccination for anyone aged 18 and older who completed their primary course of COVID-19 vaccination 5 or more months ago.
- To ensure timely provision of boosters, ATAGI recommends that those who become eligible for a COVID-19 booster dose before or during the December and New Year holiday period (i.e. up to 3 January 2022) can receive them earlier than 5 months.
- ATAGI reinforces that timely receipt of a booster dose is particularly important for who have risk factors for severe disease (particularly older age and those with underlying medical conditions) or people with increased exposure risk (e.g. occupational risks or outbreak areas). ATAGI recommends that providers encourage and enable those at greatest risk to receive timely COVID-19 boosters.
- Both Comirnaty (Pfizer) or Spikevax (Moderna- 50µg) are recommended for use as a booster vaccine, and both are considered equally acceptable.
- ATAGI reiterates that a third (primary) dose of COVID-19 vaccine is also recommended for anyone with severe immunocompromise, a minimum of two months after their second dose.

ATAGI recognises that the epidemiological situation and evidence regarding boosters is evolving rapidly and will frequently review the timing of booster doses.

Rationale

Since last week, further laboratory studies have confirmed a reduction in antibody binding to the Omicron variant in post-vaccination sera. This appears to be at least partially overcome by the higher antibody concentrations in those who have received boosters 5-6 months after the primary course.[1–6] UK data suggest that cases with the Omicron variant have a higher secondary crude attack rate in households than cases with the Delta variant.[7] It seems likely that the rapid spread of Omicron relates to immune evasion rather than a major increase in transmissibility compared to previous strains.

A South African study noted a higher risk of reinfection due to Omicron variant than had been seen in previous waves of infection.[3] Very limited data suggest that primary courses of COVID vaccines provide lower protection against infections due to Omicron than those due to Delta.[8] It is noted that the UK data suggesting a higher vaccine effectiveness following booster doses are based on very small numbers of Omicron cases in vaccine recipients. There are not yet data on the age specific case-hospitalisation or case-fatality ratios (particularly in the elderly) or estimates of vaccine effectiveness against severe disease. There are not yet robust data on the safety or incremental effectiveness of booster doses if given earlier than 5 months, although small studies to date have not raised specific safety concerns.

There remain several uncertainties to inform the optimal interval between primary and booster/third doses of vaccine. The protection provided by two vaccine doses against severe disease due to Omicron is not yet clear. It remains uncertain whether a booster will provide additional protection against severe disease.

More information is available in ATAGI recommendations on the use of a booster dose of COVID-19 vaccine and ATAGI's Clinical guidance on COVID-19 vaccine in Australia.

Immunocompromised people have been recommended to receive a third primary dose since 8 October 2021, 2 months after their second dose. Both the Pfizer and Moderna COVID-19 vaccines can be used for this third dose. ATAGI is reviewing the timing of a later dose (i.e., a booster dose after the third primary dose) in this specific population and will issue advice on this in the near future. Refer to ATAGI's statement on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

ATAGI will continue to review emerging evidence regarding the optimal timing of booster doses and provide updated advice as required.

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI Statement on the Omicron variant and the timing of COVID-19 booster vaccination

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) about the COVID-19 Omicron variant and the timing of COVID-19 booster vaccination.

Date published: 24 December 2021

Audience: General public

ATAGI notes that the course of the COVID-19 pandemic has significantly changed in recent weeks. Case numbers of COVID-19 due to the Omicron variant are rapidly increasing and this variant now dominates in some regions of Australia. Internationally, the Omicron variant has become dominant in several countries with case numbers growing rapidly in some. Preliminary data from large superspreading events in New South Wales involving younger people suggested that two doses of vaccine did not provide any significant protection against SARS-CoV-2 infection due to the Omicron variant.

Strong evidence has accumulated over the past two weeks to indicate that booster doses of COVID-19 vaccines are likely to increase protection against infection with the Omicron variant. Although some early data suggest that the risk of hospitalisation due to disease caused by the Omicron variant is lower than that with the Delta variant, this difference would not be enough to offset the impact of high case numbers on the health system.

There are now reassuring data on the safety of early booster doses in tens of millions of people, with no new safety signals identified in the United Kingdom where more than 21 million booster doses have been delivered.

ATAGI expects that booster vaccination alone will not be sufficient to avert a surge due to Omicron. However, maximising booster coverage by expanding eligibility and encouraging high uptake, in combination with enhanced public health and social measures, may prevent a large surge in case numbers, hospitalisations and deaths. ATAGI also acknowledges the demands that the booster and paediatric COVID-19 vaccination programs will have on the immunisation workforce.

Recommendations

- In light of emerging evidence, ATAGI now recommends that the eligibility for COVID-19 booster vaccination be expanded for adults aged 18 and older.
- ATAGI recommends bringing forward the minimum interval between the primary course and the booster dose from 5 months to 4 months as soon as practical, noting the holiday period. It is understood that this is achievable from 4 January, although some providers may have flexibility to administer before that time.
- As soon as practical, ATAGI recommends providing boosters to all eligible adults from a minimum of 3 months following the second dose of the primary course.
- Pregnant women aged 18 or older who received their primary COVID-19 vaccination course ≥ 4 months ago are recommended to have a booster dose. When practical and in line with the broader community, this interval should be brought forward to 3 months.
- Immunocompromised individuals who have received 3 primary doses of a COVID-19 vaccine are also recommended to have a booster dose in line with the timing for the general population, i.e., currently a 4-month interval from their primary course, and when capacity permits, 3 months.
- ATAGI reinforces that timely receipt of a booster dose is particularly important for:
    - people with risk factors for severe disease (including those aged ≥60 years, those with underlying medical conditions, those in aged/disability care and Aboriginal and Torres Strait Islander peoples); and
    - people with increased risk of exposure to SARS-CoV-2. This may include those in an outbreak area, or those with a high risk of occupational exposure. The impact of occupational risks is magnified in settings where workers may transmit the virus to others with increased risk of severe disease, such as aged/disability care facilities.
- ATAGI recommends that providers and jurisdictional immunisation program coordinators encourage and facilitate access for those at greatest risk to receive COVID-19 boosters as a priority.
- Both Comirnaty (Pfizer) or Spikevax (Moderna- 50µg) are recommended for use as a booster vaccine, and both are considered equally acceptable. AstraZeneca can be used for people who have contraindications to the Pfizer and Moderna vaccines.
- ATAGI recommends that anyone aged 12 or older who is unvaccinated should receive a COVID-19 vaccine as soon as possible.

Background and considerations

ATAGI has been closely monitoring the epidemiology and characteristics of COVID-19 caused by the Omicron variant as well as emerging data on the need, potential benefits and optimal timing of a vaccine booster dose to prevent COVID-19 due to this variant. There is now sufficient evidence to support bringing forward the interval from 5 months after the primary course, as recommended on 17 December 2021, to 4 months and when capacity permits, to 3 months, in order to provide greater protection, particularly for higher-risk groups.

Epidemiology of COVID-19 due to the Omicron variant

The Omicron variant was first designated a variant of concern on 26 November 2021. Since then, large numbers of cases have been reported in many countries where the Omicron variant is now dominant. The rapid growth in case numbers relative to the Delta variant, as well as studies of contacts of cases demonstrating its higher secondary attack rate provide evidence that Omicron can spread rapidly even in populations where there has been widespread infection and/or COVID-19 vaccination.

In Australia, case numbers of Omicron have continued to increase sharply. As of 22 December 2021, 547 confirmed cases due to the Omicron variant have been reported in Australia, but a substantial number of suspected unconfirmed cases are also likely to be due to the Omicron variant (awaiting confirmation via sequencing). In New South Wales, the Omicron variant is thought to be dominant in all regions, and community transmission of the Omicron variant is occurring in all jurisdictions apart from Western Australia.

A preliminary analysis of superspreading events in New South Wales involving the Omicron variant has suggested very low vaccine effectiveness, with the proportion of cases who received two doses of vaccine similar to the proportion of other attendees at the venue who were not infected. Notably, these events involved younger people, the majority of whom received two doses of vaccine relatively recently.

Anticipated benefits of an earlier booster dose for protection against COVID-19 due to Omicron

An earlier booster dose is expected to reduce the risk of symptomatic infection, severe illness and death from COVID-19. 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.

Preventing symptomatic disease

Strong evidence suggests that booster doses of COVID-19 vaccines may enhance protection against symptomatic disease due to the Omicron variant. This is primarily based on in vitro studies of neutralising antibodies demonstrating that the decreased binding seen with the Omicron variant compared with ancestral strains can be overcome by increasing antibody concentrations with a booster dose. Multiple studies have shown a 2 to >20-fold decrease in neutralising antibody titre against Omicron compared with wild type and/or Delta variant in sera after the primary vaccination course. Studies demonstrate that neutralising antibody titres are higher against Omicron following a booster dose of an mRNA vaccine.[1,2]

A mathematical modelling study has examined the relationship between neutralising antibody titres and vaccine effectiveness estimated in epidemiological studies. The investigators predicted that six months after primary immunisation with an mRNA vaccine, efficacy for Omicron is estimated to have waned to around 40% against symptomatic disease, and 80% against severe disease (36.7% [95% CI: 7.7-73], 70.9% [95% CI: 32.9-91.5] and 81.1% [95% CI: 42.1-96] for the AstraZeneca, Pfizer and Moderna vaccines, respectively). A booster dose with an mRNA vaccine has the potential to increase efficacy for Omicron to 86.2% (95% CI: 72.6-94%) against symptomatic infection and 98.2% (95% CI: 90.2-99.7%) against severe infection.[3]

A recent pre-print study from the UK suggested that protective effectiveness against symptomatic COVID-19 due to the Omicron strain was not observable after 2 doses of the AstraZeneca vaccine and was only approximately 35% at about 4 to 6 months (from 15 weeks onwards) after 2 doses of the Pfizer vaccine. Although the number of cases who had received booster doses was small (10 cases receiving a booster after primary AstraZeneca vaccination and 16 cases after primary Pfizer vaccination), the protective effectiveness against symptomatic disease was estimated at about 70–75% after receiving a Pfizer booster dose for both groups.[4] Further data from the UK and Europe comparing vaccine effectiveness against the Omicron and Delta strain are anticipated in coming weeks.

Reducing transmission of SARS-CoV-2 in the community

The effectiveness of a booster dose to prevent onward transmission of Omicron from infected persons, and the duration of protection afforded by a booster are currently unclear. It is expected a reduction in symptomatic infection will parallel a reduction in transmission. ATAGI will continue to closely monitor emerging data regarding these evidence gaps.

Reducing severe COVID

Despite key uncertainties, it is reasonable to assume that protection against severe disease is likely to be enhanced by a booster dose, particularly in those with risk factors for severe COVID-19. However, it is not yet known to what degree boosters may provide additional protection against severe disease, hospitalisation or intensive care admissions.

Firstly, the severity of COVID-19 caused by the Omicron strain is not yet known. Early data from South Africa suggest that the odds of hospitalisation with Omicron are around 80% lower than that observed in previous waves.[5] Similar data from Scotland suggest that the risk of hospitalisation due to Omicron is reduced by two-thirds compared to Delta.[6] It should be noted that in these countries, some protection may have been provided by infection with previous strains, which may limit the generalisability of these findings to Australia where prior infection is much less common. However, high case numbers would still translate into substantial numbers of hospitalisations even if Omicron causes much less severe disease than Delta.

Second, protection against severe disease is generally higher than against symptomatic infection. The modelling study discussed above validated neutralising antibody titres against vaccine effectiveness against symptomatic infection [3]. This study suggests that protection against severe disease due to Omicron is also likely to be significantly impaired, particularly when waning protection over time is accounted for, and would be restored by a booster dose of an mRNA vaccine.

Reducing impacts on the healthcare system

Mathematical modelling of the Australian context also suggests that maximising booster doses for all adults may contribute to mitigating the peak number of severe cases of COVID-19 due to Omicron expected in the coming few months. When expanded (and earlier) delivery of booster doses are used in combination with more extensive public health and social control measures, the most major impacts of Omicron on severe health outcomes and on the Australian healthcare system could be mitigated.

Reduced illness in healthcare workers would also be expected to preserve the capacity of the healthcare system to deliver services. Similarly reduced illness in the community would mitigate against the broader impacts of disease caused by the highly transmissible Omicron variant.

Safety of a booster dose given 3 months after a primary course

Common adverse events

Local and international data provide reassurance that booster doses are well tolerated and safe.

There are now considerable data characterising the expected systemic and local adverse event profile in countries where boosters have been administered after 5-6 months. The AusVaxSafety active surveillance system has collated data from more than 92,000 respondents who received booster doses. In this system, the proportion reporting common systemic and local reactions were similar after the booster dose compared with after the second primary dose. No safety issues of concerns have been noted in the USA where millions of booster doses of mRNA vaccines have been administered. Local and systemic reactions and health impacts were reported less frequently following a booster dose than dose 2 of the primary series, and the nature of these reactions were similar to those after a primary series.[7]

There are more limited data on the expected adverse events when boosters are administered earlier than 5 months. A UK study found that AstraZeneca, Moderna and Pfizer COVID-19 vaccines given as booster doses around 3 months after a primary course of either the AstraZeneca or Pfizer vaccine were all generally well tolerated.[8] The most common systemic reactions for all booster vaccines were fatigue and headache, and the most common local reaction was injection site pain. Adverse events were more common in those who received a Moderna booster (compared with a Pfizer booster), in those who had a different brand of booster vaccine than what was used for the primary course (compared with those who had the same vaccine brand for all doses), and in younger (compared with older) participants.

Vaccine associated myocarditis

The impact of reducing the interval between the primary course and booster dose to 3 months on the risk of myocarditis is not yet known. Data from the UK, where more than 21 million booster doses have been administered, have not identified any new safety signals.[9]

It should be noted that myocarditis appears to be more common after second doses in younger males. As of 12 December 2021, the overall rate of myocarditis for all ages reported to the Therapeutic Goods Administration (TGA) is 1.6 (95% CI 1.5 – 1.7) per 100,000 doses of Pfizer COVID-19 vaccine and 2.5 (95% CI 1.8 – 3.3) per 100,000 doses of Moderna COVID-19 vaccine given. Preliminary data from people who

received a Pfizer booster vaccine at least 5 months after a Pfizer primary course suggest that the risk of myocarditis is not higher after the booster dose than after the second dose.[10]

There are currently no data on the risk of myocarditis after a booster dose of the Moderna vaccine, but this is expected to be available in coming weeks. More information on myocarditis and pericarditis after mRNA vaccines is available here.

Implications for the rollout program and Omicron control

ATAGI does not anticipate that shortening the booster interval alone will be sufficient to suppress the rapid spread of the Omicron variant, and additional non-pharmaceutical public health measures are likely to be required to prevent continued rapid growth in case numbers.

As a result of the shortened recommended interval between the COVID-19 primary course and booster dose, a large number of people are currently eligible or will soon become eligible for a booster dose. Currently, around 4 million people are eligible for boosters at 5 months; this would increase to around 7.2 million if the eligibility interval was brought forward to 4 months, and to 11 million if brought forward to 3 months. ATAGI is conscious of the burden of a sharp increase in demand will have on immunisation service providers, particularly over the holiday period. Bringing forward eligibility in stages, initially from 5 months to 4 months, then later to 3 months will achieve the goal of maximising booster coverage as quickly as possible. However, it will also implicitly prioritise the higher risk populations who received their primary vaccines first. ATAGI recommends that all possible measures be undertaken to facilitate timely access to a booster dose for people with increased risk of severe disease, i.e., provide enhanced direct protection. ATAGI recognises some flexibility may be required for operational reasons, particularly in high-risk settings such as remote communities and within aged/disability care facilities.

Uncertainties and evidence gaps

As noted above, the severity of disease caused by the Omicron variant remains uncertain. While few people have been hospitalised with COVID-19 due to Omicron in Australia to date, this may reflect the expected lag between diagnosis and progression to severe disease; it may also reflect the younger population in whom the Omicron variant was first detected.

There is still little evidence on the incremental benefit of booster doses in protecting against severe disease or reducing onward transmission of Omicron variant of SARS-CoV-2, and on the duration of protection provided by COVID-19 booster doses.

ATAGI will continue to closely monitor the situation and review data that informs these key evidence gaps and will update recommendations accordingly.

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on the use of Novavax COVID-19 vaccine (Nuvaxovid)

Novavax COVID-19 vaccine, also known as Nuvaxovid (Biocelect Pty Ltd/Novavax Inc) has been provisionally approved by the Therapeutic Goods Administration (TGA) for use in a primary course of vaccination in people aged 18 years and older.

Date published: 24 January 2022

Audience: General public

Novavax COVID-19 vaccine, also known as Nuvaxovid (Biocelect Pty Ltd/Novavax Inc) has been provisionally approved by the Therapeutic Goods Administration (TGA) for use in a primary course of vaccination in people aged 18 years and older. Novavax COVID-19 vaccine is a spike protein-based vaccine. Each 0.5mL dose contains 5 micrograms of the of SARS-CoV-2 spike protein and 50 micrograms of Matrix-M as an adjuvant. Novavax COVID-19 vaccine has been demonstrated to be highly effective in preventing symptomatic COVID-19 in adults in a primary schedule, based on phase II-III clinical trials involving over 45,000 participants.

Novavax COVID-19 vaccine is not currently registered by the TGA for use as a COVID-19 booster vaccine.

ATAGI recommendations

- ATAGI recommends that Novavax COVID-19 vaccine can be used for the primary course of COVID-19 vaccination in people aged 18 or older.
- The recommended schedule for administration is 2 doses, a minimum of 3 weeks apart.
- Contraindications to vaccination are anaphylaxis to a previous dose of Novavax COVID-19 vaccine or to a component of the vaccine (e.g. polysorbate 80).
- There are no specific precautions for the use of Novavax COVID-19 vaccine.
- Novavax COVID-19 vaccine can be administered to pregnant and breastfeeding women. ATAGI notes that unlike the Pfizer and Moderna vaccines for which there are substantial data on their safe use in pregnancy and with breastfeeding, there are no immunogenicity or safety data for these groups with the Novavax COVID-19 vaccine. However, there are no theoretical safety concerns relating to use in pregnancy, since the Novavax COVID-19 vaccine, similarly to other COVID-19 vaccines, is not a live vaccine.
- Novavax COVID-19 vaccine can be administered to people with a prior history of SARS-CoV-2 infection, in line with recommendations for other COVID-19 vaccines.
- People with severe immunocompromise are recommended to receive 3 primary doses of COVID-19 vaccine, and Novavax

COVID-19 vaccine can be used for this purpose. Refer to the ATAGI statement on the use of a 3rd primary dose which is recommended at an interval of 2 months after the 2nd dose.

- Novavax COVID-19 vaccine can be administered as part of a heterologous (mixed) primary schedule to people who have received one or more doses of another COVID-19 vaccine, including as a third dose for people with severe immunocompromise.
- Novavax COVID-19 vaccine is not currently recommended for use as a booster vaccine.
- Novavax COVID-19 vaccine can be co-administered with other vaccines if required.

Background

Vaccine efficacy

Two phase III trials, conducted in the USA/Mexico and in the UK, assessed the efficacy of Novavax COVID-19 vaccine.[1,2] Across these trials approximately 27,000 participants received the full 2 doses of vaccine, and approximately 17,000 received a placebo. A phase II trial conducted in South Africa included over 4000 participants and provided data on vaccine efficacy against the Beta variant of SARS-CoV-2.[3]

Vaccine efficacy (VE) against PCR-confirmed symptomatic mild, moderate or severe COVID-19 in serologically negative adults, with onset at least 7 days after 2nd dose was 90.4% (95% CI 82.88 - 94.62) in the US/Mexico trial, and 89.7% (95% CI 80.2 - 94.6%) in the UK trial.[1,2] The estimated VE against moderate or severe COVID-19 was 100% (95% CI 80.9 - 100) in the USA/Mexico trial, and 86.9% (95% CI 73.7 - 93.5%) in the UK trial.[1,2] In the South African phase II trial, VE among HIV-negative adults was 60.1% (95% CI 19.9 – 80.1%) overall, and specifically against the Beta variant was estimated at 51% (95% CI -0.6 to 76.2).[3] The significant difference in VE estimates between the American/UK trials and the South African trial has been attributed to the prevalence of the Beta variant in South Africa during the study period, however other contributory factors cannot be excluded.

Special populations

Vaccine efficacy in several pre-specified subgroups was generally consistent with the overall study population. VE in adults aged 65 years or older was 88.9% (95% CI 20.2 – 99.7), and in adults with a comorbid medical condition was about 91% (95% CI 70.4 – 95.9%).[1,2]

Pregnant and breastfeeding women were excluded from the Novavax clinical trials, however animal studies have not indicated any direct or indirect harmful effects relating to pregnancy or embryonic/foetal development.[4]

There are limited data on the safety and immunogenicity of Novavax COVID-19 vaccine in people with immunocompromise. In the South African phase II trial, among 2684 participants, 6% were HIV positive.[3] When including all participants, vaccine efficacy was 49.4% (95%CI 6.1-72.8), however when HIV positive participants were excluded, vaccine efficacy was 60.1% (95%CI 19.9-80.1).[3] Neutralising antibody geometric mean titres for HIV-positive participants were comparable in HIV-positive and HIV-negative participants. No safety concerns were highlighted for the HIV positive participants.

Co-administration

A small sub-study (n = 431) of the UK phase III trial assessed the impact of co-administering the first dose of Novavax COVID-19 vaccine or placebo with either a quadrivalent cell-based influenza vaccine (for those aged 18-64) or a trivalent adjuvanted influenza vaccine (in those aged 65 years or older).[5]

Vaccine efficacy against laboratory-confirmed symptomatic COVID-19 was 87.5% (95%CI –0.2 to 98.4) in the co-administration group aged 18 to 64 years, compared with an efficacy of 89.8% (95%CI 79.7 to 95.5) in the main study for participants aged 18 to 64 years who received Novavax COVID-19 vaccine alone.[5] SARS-CoV-2 binding antibody responses were approximately 0.6-fold lower in participants who received the co-administered vaccines compared with those who received Novavax COVID-19 vaccine alone. There were no significant differences in the immune responses to influenza vaccines in the group who received co-administered Novavax COVID-19 vaccine compared with those who received the influenza vaccine with placebo. It is not yet known whether the impact of co-administration on immunogenicity translates to any difference in clinical protection, or duration of

protection against COVID-19. Post-introduction assessment of real-world vaccine effectiveness, as for all COVID-19 vaccines, should be conducted to assess clinical protection.

Adverse events were reported more frequently in the co-administration compared with the COVID-19 only vaccine group but were overall mild and of brief duration.

There are currently no data available on the co-administration of Novavax COVID-19 vaccine with other vaccines, but there are no significant theoretical concerns regarding co-administration, which is permissible for all COVID-19 vaccines as per current ATAGI clinical guidance.

Vaccine safety

Safety data from the three phase II-III clinical trials included approximately 34,000 participants.[4] Safety monitoring was conducted after each vaccine dose with a median follow up period of around 70 days. In the larger (US/Mexico) phase III trial, local adverse events were reported in around 58% of Novavax COVID-19 vaccine recipients after the first dose, and in around 79% after the second dose.[2] The most commonly reported local adverse events were injection site tenderness and pain. Local adverse events were more frequent among younger (age 18-64 years) participants compared with older participants.

Systemic adverse events were reported in 47.7% of Novavax COVID-19 vaccine recipients following dose 1 compared with 69.5% following dose 2.[4] The most common solicited systemic adverse events were headache, myalgia, fatigue and malaise, with a median duration of events of 2 days or less.

Serious adverse events were rare. There was a numerical imbalance in the reported incidence of hypertension in older adults during the 3 days following vaccination (1% in Novavax COVID-19 vaccine recipients vs 0.6% in placebo recipients).[4]

A total of three cases of myocarditis were reported in the two phase III trials, of which 2 occurred in the vaccine group and 1 in the placebo group.[4] Of the two cases in the vaccine group, one was a young healthy participant with onset 3 days after dose 2, and the other was a participant aged over 65 years. There is currently no published additional information on these cases. Based on this very small number

of cases with limited information and the overall number of trial participants, which is inadequate for detection of very rare adverse events such as myocarditis, it is not possible to determine if there is a causal relationship or to estimate the risk of myocarditis associated with this vaccine. The occurrence of these cases is not necessarily attributable to this vaccine. It is recommended that all COVID-19 vaccine recipients should be aware of the potential signs and symptoms of myocarditis or pericarditis, and should be counselled about when to seek medical attention. For more information see ATAGI guidance on Myocarditis and Pericarditis.

ATAGI will continue to evaluate further data on the safety and efficacy of Novavax COVID-19 vaccine as it emerges, including in special populations and as a booster vaccine, and will provide updated recommendations as required.

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Tags: Immunisation | Communicable diseases | Emergency health management | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI recommendations for use of Pfizer COVID-19 vaccine as a booster dose in adolescents aged 16-17 years

The Australian Technical Advisory Group on Immunisation (ATAGI) has made recommendations for use of Pfizer COVID-19 vaccine as a booster dose in adolescents aged 16-17 years.

Date published: 3 February 2022

Audience: General public

Introduction

Comirnaty (Pfizer) was registered by the TGA on 28 January 2022 for use as a booster in the 16–17 year age group. ATAGI now extends the recommendation of a booster dose to include all individuals aged 16-17 years. This clinical recommendation aims to maximise protection for this age group who are at a critical point in their secondary education and early working lives. People in this age group are also very mobile and may engage in increased social mixing. Comirnaty (Pfizer) is the only vaccine registered for use as a booster for people aged 16–17 years at present.

Evidence demonstrates that waning of protection against the Omicron variant occurs after a two-dose primary vaccination schedule and a booster dose is required to increase protection against infection and severe disease. For more information see: ATAGI advice on the omicron variant and the timing of COVID-19 booster vaccination.

Recommendations

- ATAGI recommends a booster vaccination with the 30 microgram **Comirnaty (Pfizer)** COVID-19 vaccine, for **all adolescents aged 16-17 years** who have previously received any TGA approved or recognised vaccines for their primary vaccine schedule, from **3 months** after receiving their last primary dose. This includes those who were aged under 16 years when they received their last primary dose and are now aged 16 years.
- Adolescents aged 16-17 years who are severely immunocompromised and have received a third primary dose of COVID-19 vaccine (Refer to ATAGI advice) should also receive a booster dose (4^{th} dose) of the Pfizer vaccine when they become eligible from 3 months after receiving their third primary dose.
- Adolescents with risk factors for severe disease or those in work or environmental settings that place them at higher risk of exposure (e.g., healthcare, aged care, disability care), are recommended to receive their booster dose as soon as they become eligible (Refer to risk factors in ATAGI clinical guidance).
- Adolescents who have recently had SARS-CoV-2 infection and are now eligible for a booster are still recommended to receive their booster dose. This booster dose can be administered

immediately after recovery from acute illness or can be deferred for up to 4 months. (Refer to detailed ATAGI advice for considerations regarding timing of booster doses after SARS-CoV-2 infection).

- Adolescents eligible for a booster who have previously developed myocarditis or pericarditis after a primary dose of mRNA vaccine (Pfizer, Moderna) should discuss the benefits and risks of a COVID-19 vaccine booster dose with their cardiologist and/or treating doctor to determine whether they should receive a booster or defer vaccination. Refer to ATAGI advice on myocarditis and pericarditis after mRNA COVID-19 vaccines. People with previous anaphylaxis to an mRNA vaccine are contraindicated to receive a Pfizer COVID-19 vaccine booster dose.
- Pfizer vaccine is the only brand currently registered for use as a booster dose in this age group. ATAGI will update this advice if other vaccines are approved.

Rationale

ATAGI supports the extension of booster dose recommendations to include individuals aged 16-17 years, as an extension of previous booster recommendations for all those aged 18 years and over. This recommendation is based on a review of COVID-19 epidemiology, disease burden, health benefits directly to individuals and indirectly to the community, and safety considerations in this age group described in sections below.

ATAGI notes that the 16-17 year old COVID-19 vaccine program commenced on the 30 August 2021 for healthy adolescents and over 90.8% of this age group nationally have completed a two-dose primary schedule (as of 23 January 2022). A large proportion were vaccinated in the first 3 months of eligibility and these recommendations result in approximately 65% of adolescents aged 16-17 now becoming eligible for a booster dose from 1 February 2022.

Epidemiology

There is currently widespread community transmission of SARS-CoV-2 in most jurisdictions in Australia. The Omicron variant has greater transmissibility and is able to partially evade immunity from either prior

infection with earlier variants and/or two-dose COVID-19 vaccination. These factors have led to Omicron rapidly becoming the dominant variant, largely replacing the Delta variant.

There has been a rise in the proportion of COVID-19 cases observed in younger age groups compared to previous variants that is related to relatively lower vaccination rates in this age group, removal of movement restrictions prior to the Omicron wave and higher mobility and social mixing among younger people. In New South Wales (NSW) between 26 November 2021 and 8 January 2022, infections in those aged 10-19 years (49,312 cases) comprised 13% of all cases, the age group with the third highest number of cases behind those aged 20-29 years (116,604 , 31% of all cases) and 30-39 years (71,240 cases, 19% of all cases).[1]

Individuals aged 16-17 years old will likely have increased mixing with the start of the school year which may lead to an increased number of cases. UK data from the REACT-1 study, which assesses SARS-CoV-2 prevalence in 100,000 volunteers, show that for the period 5 January to 20 January 2022 (after resumption of school in the UK) the overall prevalence in adults in England decreased, while prevalence in children increased, noting that only high risk 5–11-year-olds are recommended to be vaccinated in the UK and two-dose vaccine coverage in adolescents is lower than in Australia.[2]

Severe disease and hospitalisation

Despite a large increase in the numbers of cases, COVID-19 remains predominantly a mild disease in adolescents aged 16-17 years, with only 3.2% of Australian cases in this age group between 1 January 2021 and 21 November 2021 (pre-Omicron) requiring hospitalisation; no deaths were recorded during this period.[3] Approximately 6.3% of cases among Aboriginal and Torres Strait Islander people in this age group required hospitalisation, suggesting a higher rate of severe disease than in the non-Aboriginal population of this age group.[3]

More recent NSW data suggest a modest decrease in the proportion hospitalised during the early period of the Omicron epidemic from 26 November 2021 to 8 January 2022. Only 2% of notified COVID-19 cases in adolescents aged 10-19 years were hospitalised. Severe disease or death occurred in 0.01% of adolescents who had received two doses of vaccine compared with 0.05% who were unvaccinated, [1] noting most adolescents hospitalised had underlying conditions that increase their

risk of severe COVID-19 compared to healthy individuals.[4] Studies have shown that the severity of Omicron infection is likely to be reduced compared to the Delta variant with a reduced requirement for emergency department presentation, hospitalisation, or ICU admission in adults and children. However, as seen in Australia and worldwide, the absolute number of hospitalisations due to this variant is higher due to higher infection rates, impacting both individuals, the community and healthcare capacity overall.[5-8]

Reduced effectiveness of two dose vaccination schedule against recent COVID-19 variants with an increase after a booster

The Omicron variant possesses numerous mutations in the receptor binding domain of the spike protein.[9] These changes have led to much higher transmissibility and resulted in escape from immunity due to previous infection or vaccination. Viral neutralisation studies demonstrate greatly reduced neutralisation by sera from both vaccinated individuals and previously infected individuals.[10-12] Early estimates of vaccine effectiveness in all individuals aged ≥16 years against infection have similarly indicated lower initial vaccine effectiveness from two doses of Pfizer or AstraZeneca vaccine (36 – 88%)[13-15] against the Omicron variant which then wanes rapidly to quite modest effectiveness (0-34% by about 4 months, and 0-10% by 6 months[15] post dose 2). A Pfizer COVID-19 vaccine booster dose restores moderate levels of effectiveness against symptomatic Omicron infection (54-76%).[13-16] Vaccine effectiveness against hospitalisation with Omicron shows a similar pattern of waning (25-57% pre-booster) but rises to 88-90% after a booster dose.[15,17] There appears to be some waning after the booster dose with estimates of effectiveness against infection of 40% from 15 weeks after a Pfizer booster dose.[15]

Similar patterns of waning protection are seen when comparing adults and adolescents[18] in both immunogenicity[19] and vaccine effectiveness studies against the Delta variant.[20] Studies of vaccine effectiveness with the Omicron variant specific to adolescents are not yet available, but would be estimated to be comparable to that for young adults.

Efficacy of booster dose in adolescents 16-17 years old

Pfizer conducted a randomised blinded placebo-controlled trial of approximately 10,000 participants aged ≥16 years, including 78 aged 16-17 years. The study included people who had completed a two-dose primary schedule of Pfizer vaccine at least 6 months prior. The relative vaccine efficacy against infection across all ages was 95.3% (95% CI: 89.5%, 98.3%) for boosted compared to non-boosted participants during a period of Delta variant circulation. Only two COVID cases occurred in the 16-17 year age cohort, both in the placebo non-booster group.[21]

Potential effect on transmission

It is anticipated that booster doses for 16-17 year olds will have some effect on reducing transmission of SARS-CoV-2 both directly by preventing infection in these individuals and potentially via a smaller effect in reducing onward transmission from infected individuals who are vaccinated. Such effects have been demonstrated from primary vaccination against Alpha and Delta variants, although no data are yet available for Omicron.[22]

Booster vaccination after previous COVID-19

Prior COVID-19 due to other variants such as Delta does not reliably prevent reinfection with Omicron.[23,24] Data on how long Omicron infection may protect from re-infection with Omicron are not yet available, and the lack of genomic testing for every case means it is not possible to differentiate Omicron and Delta past-infection in most cases. Therefore, booster vaccination is still advisable in all previously infected individuals. Vaccination is recommended at any time from recovery after infection but should be given by 4 months after infection. For considerations regarding when best to be vaccinated in this situation, refer to the ATAGI clinical guidance on People with a past SARS-CoV-2 infection.

Safety

The Pfizer vaccine has a satisfactory safety profile including when given as a booster dose. Clinical trial data from Pfizer's unpublished study in individuals aged ≥18 years of age demonstrated an adverse event profile after booster doses consisting of similar known reactogenicity events seen after primary vaccination.[25] An Israeli preprint study in adults (aged ≥18 years) demonstrated self-reported systemic reactions after the third dose of Pfizer vaccine were a similar pattern to that seen after the second dose.[26]

However, Pfizer and Moderna mRNA COVID-19 vaccines have both rarely been associated with myocarditis, with the highest rates in adolescent and young adult males aged 16-19 years after the second primary dose. In studies of primary Pfizer vaccination, conducted in the US and Israel, estimated myocarditis rates in young males aged 16-19 years after the second primary dose were between to 6.9 to 15.1 per 100,000 people / doses administered.[27,28]

Preliminary evidence from the Pfizer COVID-19 vaccine booster program in Israel, where individuals aged ≥12 years have received Pfizer vaccine boosters, indicates that the rate of myocarditis after the booster dose in individuals aged 16-19 years was similar in females and lower in males than after a second primary dose (6.5 per 100,000 in males and 1.6 per 100,000 in females after the third dose compared to 15.3 and 0.9 per 100,000 respectively after dose 2).[29] However, myocarditis rates were higher than that seen after the first dose in this age group (1.2 per 100,000 in males and 0 per 100,000 in females).

Data from Israel were predominantly from recipients who received their booster after a 5-month interval from their second dose. In the United Kingdom, where over 36 million doses of booster vaccine (as of 19 January 2022) have been administered, most with a 3-month interval, the adverse event reporting rate for third doses is lower than that for all doses combined. However, there are no studies that directly compare rates of myocarditis after vaccination with a booster at 3 months compared to 5 months. ATAGI will continue to monitor any differences in adverse event reporting when shorter intervals have been recommended. No additional safety concerns have been raised following booster doses and there is no indication that myocarditis or pericarditis events have been more serious after boosters.[30]

Heterologous schedules (different brands of vaccine for primary and booster doses):

A Pfizer booster is considered acceptable in patients who have had a primary series of any other TGA approved or recognised vaccine, including Moderna vaccine. This is based on an immunogenicity study in adults which has shown that heterologous booster schedules elicit a good neutralising antibody response at least comparable to homologous schedules and an adequate safety profile.[31]

There are a lack of studies reporting on the specific risks of myocarditis after heterologous booster schedules (e.g. Moderna primary vaccination with Pfizer booster), however, safety monitoring is actively occurring in this context. ATAGI will continue to monitor evidence in this area and update its guidance as required.

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Tags:

Young people's health

Australian Technical Advisory Group on Immunisation (ATAGI)

COVID-19

Australian Government
Department of Health and Aged Care

ATAGI recommendations on the use of Spikevax (Moderna) COVID-19 vaccine in children aged 6 to 11 years

The Australian Technical Advisory Group on Immunisation (ATAGI) has made recommendations for the use of the Moderna COVID-19 vaccine in children aged 6 to 11 years.

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Audience: General public

Introduction

ATAGI currently recommends COVID-19 vaccination of children aged 5-11 years with paediatric Comirnaty (Pfizer COVID-19 vaccine for children).

On 17 February 2022, Spikevax (the Moderna COVID-19 vaccine) was provisionally approved by the Therapeutic Goods Administration (TGA) for a two-dose schedule of 50µg per dose in 6 to 11 year old children.

The Pfizer children's vaccine continues to be the only COVID-19 vaccine approved for children who are 5 years of age.

ATAGI Recommendations and Rationale:

ATAGI recommends Spikevax (Moderna) COVID-19 vaccine can be used for primary vaccination in children aged 6-11 years.

- A clinical trial conducted by Moderna demonstrated that Spikevax produces a strong immune response in children and reduced the likelihood of children developing COVID-19.
- However, ATAGI notes that evidence outside of clinical trials regarding the safety and effectiveness of this vaccine in children in this age group is not yet available.
- The Pfizer COVID-19 vaccine continues to be available and recommended for 5-11 year old children. The Moderna COVID-19 vaccine is an alternative option for children aged 6-11 years. Pfizer remains the only vaccination available for children who are 5 years old. There are currently no vaccines licensed for children aged 4 years and under.
- Side effects reported following the Moderna COVID-19 vaccine have been mild to moderate and transient but may be more common than those following Pfizer COVID-19 vaccine.

ATAGI recommends that immunisation providers are vigilant for the potential for dosing errors with the Moderna vaccine for children.

- There is no paediatric-specific formulation for the Moderna vaccine, there is a risk of dosing, including over-dosing, errors with the Moderna vaccine for children.
- The Moderna 6-11 years dose is half that of the dose used for the primary course for people 12 years and older; but the same as the booster dose (50µg per dose; 0.25mL) for adults.

Schedule:

- The recommended schedule for Moderna vaccination in children 6-11 years is 2 doses (50µg per dose; 0.25mL), 8 weeks apart.
- The interval can be shortened to a minimum of 4 weeks, for children at risk of moderate to severe COVID-19 in special circumstances (as outlined in ATAGI Clinical guidance on the use of COVID-19 vaccines).
- A third COVID-19 vaccine dose is recommended for children aged 5 and older who are severely immunocompromised. An mRNA COVID-19 vaccine (either Moderna or Pfizer) is recommended for this third dose (either Pfizer for children 5 years and older or Moderna for children 6 years and older. This dose is recommended to be administered from 2 months after the second dose.
- Children who turn 12 years of age after their first dose should receive the adolescent/adult dose (0.5mL; 100µg) of the Moderna COVID-19 vaccine to complete their primary vaccine course.
- There are currently no published data regarding mixed primary vaccination schedules for children aged <12 years. ATAGI do not recommend the use of mixed primary schedules in this age group. ATAGI will monitor and update this recommendation as evidence evolves.

Co-administration

- Paediatric COVID-19 vaccines, including the Moderna vaccine, may be co-administered with other vaccines. Parents and guardians should be aware that this may increase the likelihood of mild to moderate side effects.

Restrictions based on vaccine status

- While vaccination is recommended for children, ATAGI does not support restricting activities for children aged 6 – 11 years who are not vaccinated, or have only received one dose of a COVID-19 vaccine.

Rationale for recommending vaccination

In children aged 6-11 years, SARS-CoV-2 infection is generally asymptomatic or causes a brief illness with mild symptoms.[1,2] Children at increased risk of severe outcomes from COVID-19 include those with pre-existing obesity, chronic pulmonary disease, congenital heart disease and neurological disease, as well as those with neurodevelopmental disorders or epilepsy.[1,3,4] In addition, SARS-CoV-2 infection may be complicated by paediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS, also known as MIS-C), a rare and potentially life-threatening syndrome that occurs in approximately 1 in 3,000 children after SARS-CoV-2 infection.[2,5] There is emerging evidence to suggest vaccination in children and adolescents may protect against PIMS-TS.[6,7]

The Moderna COVID-19 vaccine demonstrated comparable immunogenicity (for both neutralising antibody and binding antibody) in the pivotal clinical trial in children 6 to 11 years of age (50 mcg per dose) when compared to immunogenicity data in young adults (18 to 25 years, 100 mcg per dose) in a clinical trial demonstrating efficacy. An evaluation of efficacy as a secondary endpoint in the 6 to 11 years Moderna COVID-19 vaccine trial also suggested good protection against COVID-19, noting the overall number of cases available for evaluation was small.

There are currently limited data on the effectiveness of SARS-CoV-2 vaccines in preventing transmission or asymptomatic infection in children. In addition to an anticipated reduction in illness (which is mostly mild), vaccination is also indirectly expected to reduce the need for isolation in children, disruption to education and social activities, and potentially a reduction in parental absenteeism.

At a population level, several modelling studies conducted for earlier SARS-CoV-2 variants have suggested that a vaccination program in young children may indirectly reduce COVID-19-related hospitalisations, admissions to intensive care units (ICU) and deaths in the overall population.[8–10] More details on the indirect and direct benefits of COVID-19 vaccination in children are provided here. In December 2021, ATAGI recommended the use of an mRNA vaccine, the Pfizer (Comirnaty) vaccine, for prevention against COVID-19 in children aged 5-11 years, based on these anticipated direct and indirect benefits.

The paediatric formulation of the Pfizer COVID-19 vaccine (Comirnaty) was the first vaccine to be provisionally approved by the Therapeutic Goods Administration for children aged 5 to 11 years in Australia, and has been available since 10 January 2022. As at 17 February 2022, 48.1% of children aged 5-11 years have received at least one dose of the Pfizer COVID-19 vaccine. Provisional data from AusVaxSafety suggest that this is a well-tolerated vaccine; noting approximately 1 in 4 children have reported at least one adverse event following the first dose. Such side effects were generally mild with pain, swelling, and redness at the vaccination site being the most commonly reported side effects.[11]

The Moderna COVID-19 vaccine provides an alternative vaccine for children aged 6 to 11 years, administered as a two-dose schedule of 50µg (0.25 mL) per dose, 8 weeks apart. Preliminary data suggest that this vaccine elicits strong antibody responses, and that most side effects are mild to moderate and transient in nature, similar to those observed in children who have received the Pfizer vaccine.

Safety

The Pfizer and Moderna clinical trials differed in how they were designed and how they monitored for side effects which makes it difficult to directly compare the rates of side effects after each vaccine. Side effects were reported more commonly overall in the Moderna COVID-19 vaccine trial compared with the Pfizer trial, but participants who received a placebo dose in the Moderna trial also reported side effects more commonly. A direct comparison of these two paediatric vaccine formulations within a single clinical trial is not yet available.

To help with decision-making parents/carers and health care providers should be aware the short-term adverse events that were more common in the Moderna trial included:

- injection site pain
- lymph node swelling and tenderness
- fever
- headache
- nausea occurred

For example, following the second dose of vaccination with Moderna, 1 in 4 children (24.1%) had a fever, compared to 6.5% of children in the Pfizer trial; and almost 1 in 4 (23.9%) children experienced nausea and vomiting (compared to 1.9% in the Pfizer trial). Furthermore, approximately half (54.2%) of the children experienced headache following their second vaccination in the Moderna trial (compared with 28.0% in the Pfizer trial).

While no cases of myocarditis or pericarditis were reported in the clinical trial of this vaccine conducted by Moderna, this trial was conducted on a relatively small number of children, and this vaccine has not been rolled out broadly in paediatric populations internationally.

Rationale for an extended dosing interval

The manufacturer's recommended schedule for the paediatric Moderna vaccine is two doses, 28 days apart.

In keeping with the principles outlined in ATAGI's advice regarding administration of the other mRNA vaccine recommended young children (Comirnaty, the Pfizer vaccine), ATAGI recommends a schedule of two doses of Moderna vaccine be administered 8 weeks apart for children aged 6-11 years. This extended interval may improve immunogenicity and vaccine effectiveness following the second dose, based on data obtained in adults.[12,13] In addition, this longer dosing interval may reduce the risk of myocarditis and pericarditis, as suggested by a Canadian study among older age groups.[14] Myocarditis and pericarditis are very rare adverse events linked to the

use of an mRNA COVID-19 vaccine. Data on the rate of these conditions in young children following Moderna vaccination are not available, but rates of myocarditis and pericarditis in this age group are likely to be lower than that in adolescents. Indeed, real-world evidence using the Pfizer vaccine reveals that for every million doses of Pfizer vaccine administered in male children and adolescents in the US, there are approximately 46 cases of myocarditis in boys aged 12-15 years, compared to only 4 cases for boys aged 5-11 years.[15]

It is appropriate to consider shortening the interval in special circumstances to a minimum of 4 weeks, including in those needing a 3rd dose as part of their primary course due to significant immunosuppression, those at high risk of severe COVID, including NDIS participants, and pre-international travel. Parents and providers are encouraged to weigh up the benefits of earlier protection with the benefit of having a longer dose interval. A dose interval of 8 weeks may improve protection and longevity of protection from the vaccine. A longer interval may also reduce the risk of rare adverse events such as myocarditis.

Issues relating to vaccine administration: Minimising vaccine error risk

The same formulation of the Moderna vaccine is used for adults, adolescents, and children aged 6-11 years; however, the dosage is lower (50µg; 0.25mL) for children under 12 years.

The Moderna vaccine is supplied in multidose vials each containing 5mL providing 10 doses for use for adolescents and adults for a dose of 100µg (0.5mL per dose), or a maximum of 20 doses for use in children aged 6-11 years for a dose of 50µg (0.25mL per dose) for each dose of the primary course. Note, this dose is the same as the dose of 50µg authorised for a booster dose in adults.

It is therefore important to note the risk of dosing, including particularly over-dosing errors with the Moderna COVID-19 vaccine when used in children. Inadvertent administration of a 100µg dose to a child 6-11 years of age is likely to result in an increased risk of adverse reactions, as was observed in the first (dose-finding) part of the clinical

trial conducted by Moderna. Should this occur, an adverse event following immunisation (AEFI) report should be submitted using established mechanisms. All AEFI reports are reviewed by the Therapeutic Goods Administration (TGA).

It is also important to note that Moderna is not currently registered for use in children who are under 6 years of age. Therefore, for children who are 5 years old, the only registered vaccination is the paediatric Pfizer vaccine.

Uncertainties and evidence gaps:

At present, there are limited real-world use data available pertaining to the efficacy and safety of the Moderna vaccine in large populations of children, noting that this vaccine has not been used extensively overseas for this age group. Data on immune responses to the Moderna vaccine for children aged 6-11 years, and real-world data on adults immunised with the Moderna vaccine, together indicate that Moderna is likely to be very effective at reducing the likelihood of severe COVID-19 in children, including against the Omicron variant.[16]

Preliminary data from older age groups suggest that myocarditis may occur at increased frequency following vaccination with the mRNA vaccines (including the Moderna vaccine),[17] although the absolute risk remains low. Further detail regarding myocarditis and pericarditis following mRNA vaccination is available here.

ATAGI will closely monitor data that may become available regarding the use of the Moderna vaccine in children from both overseas and within Australia and will continue to update recommendations based on the latest available evidence.

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

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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Audience: General public

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 3 months after a confirmed SARS-CoV-2 infection, if infection occurred since the person's first COVID-19 booster dose.

The additional winter booster dose is now available to coincide with 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 3 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 3 months after previous SARS-CoV-2 infection if this occurred since the previous 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

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 3 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 3 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 is available 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 3 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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Tags:

Immunisation
Australian Technical Advisory Group on Immunisation (ATAGI)
Communicable diseases
Emergency health management
COVID-19
COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on use of booster doses in adolescents aged 12-15 years

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) on booster doses in adolescents aged 12-15 years.

Date published: 8 April 2022

Audience: General public

ATAGI notes on 8 April 2022, the Therapeutic Goods Administration (TGA) approved a booster dose of Comirnaty (Pfizer) COVID-19 vaccine for use in adolescents aged 12-15 years.

ATAGI has reviewed evidence on the benefits and risks of a booster dose of Pfizer COVID-19 vaccine in adolescents in Australia aged 12-15 years. Current data suggest that COVID-related serious illness is very rare in adolescents aged 12-15, particularly after completion of a primary series of COVID-19 vaccination.

At this time, ATAGI does not recommend that adolescents aged 12-15 years need to receive a booster dose of Pfizer COVID-19 vaccine and will continue to review international evidence on efficacy of a booster in this age group.

ATAGI continue to strongly recommend vaccination of all young people aged 5 to 15 years with 2 primary doses of a COVID-19 vaccine, including those who may have previously had COVID-19; 3 primary doses are recommended for those in this age group who are severely immunocompromised.

ATAGI will continue to review and consider new evidence on the benefits and risks of any additional doses in 12-15 year olds, including for those with underlying medical conditions.

Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

Expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19

The Australian Technical Advisory Group on Immunisation (ATAGI) have expanded their recommendations on the use of additional (booster) doses of COVID-19 vaccine.

Date published: 25 May 2022

Audience: General public

Read the media release.

Executive summary

The primary goal of the Australian COVID-19 vaccine program is to minimise the risk of severe disease, including hospitalisation and death, from COVID-19.

Currently, the COVID-19 vaccination program is targeted at preventing severe disease, by providing additional protection to those with risk factors for severe disease. On 25 March 2022, ATAGI recommended an additional winter booster dose (4th dose for most people) for the highest risk groups: people aged 65 years and above, residents of aged care or disability care facilities, people with severe immunocompromise and Aboriginal and Torres Strait Islander people aged 50 years or above.

In this updated advice, an additional winter booster is now also recommended for other people at increased risk, to be given 4 months after their first booster dose. This applies to people aged 16-64 who have:

- A medical condition that increases the risk of severe COVID-19 illness (see Table 1 for expanded groups).
- People with disability with significant or complex health needs or multiple comorbidities which increase risk of poor outcome from COVID-19.

Healthy people aged 16 to 64 years, who do not have a risk factor for severe COVID-19, are **not** recommended to receive an additional winter booster dose at this time, as their risk of severe illness after their first booster dose is likely to remain very low. This includes healthy people from occupational groups such as healthcare workers. Pregnant women who do not have an additional risk factor for severe disease (such as in Table 1) and who have received three doses of COVID-19 vaccine are also **not** currently recommended for a winter booster dose at this time.

As per previous advice, if an individual has had a recent confirmed SARS-CoV-2 infection, they should delay their winter booster dose until 3 months after their infection.

Comirnaty (Pfizer, from age 16 years) or Spikevax (Moderna, from age 18 years) are the preferred vaccines for a COVID-19 booster dose. Vaxzevria (AstraZeneca) can be used in people aged 18 or older when an mRNA vaccine is contraindicated, or where a person declines vaccination with an mRNA vaccine. Nuvaxovid (Novavax) can be used in people aged 18 or older if no other COVID-19 vaccine is considered suitable for that person.

ATAGI also encourages people to be vaccinated against Influenza. 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.

Background

ATAGI emphasises the importance of the first booster dose and notes that a substantial proportion of eligible people aged 16 years and older (approximately 30% as of 21 May 2022) have not yet received their first booster dose. These eligible people are strongly encouraged to receive their first booster dose promptly to maximise protection prior to winter against SARS-CoV-2 infection. It is important that all people are up-to-date with COVID-19 vaccination.

Since ATAGI's initial recommendations for an additional winter booster dose in selected populations (on 25 March), ATAGI has continued to review evidence on the need for additional doses in other population groups. While there is relatively preserved protection against severe

disease after a primary COVID-19 vaccine course and a first booster dose, an additional booster dose (4th dose for most people) provides a further increase in the level of protection against severe disease and death. This increased protection is of greatest benefit to people at high risk of severe disease.[1-3]

ATAGI now advises that additional population groups are recommended to receive a winter booster dose (see below).

Recommendations

The following groups are recommended to receive a winter booster dose of COVID-19 vaccine:

Groups recommended previously (advice from 25 March)

ATAGI recommends that people in these groups who have not yet received their winter booster should get one as soon as possible, factoring in timing of first booster and infection (if applicable).

- adults aged 65 years and older
- residents 16 years and older of aged care or disability care facilities
- 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.

Additional groups recommended (from 25 May 2022)

- People aged 16-64 years who have complex, chronic or severe conditions that are considered to increase their risk of severe illness from COVID-19 (Refer to Table 1).

Table 1: Additional groups recommended for a winter booster dose as of 25 May 2022

People in these groups are likely to have an ongoing increased risk of severe COVID-19 even after primary vaccination. These examples are not exhaustive and providers may include individuals with conditions similar to those listed below, based on clinical judgment

Category	**Examples**
Immunocompromising conditions	
Cancer	Non-haematological cancer including those diagnosed within the past 5 years or on chemotherapy, radiotherapy, immunotherapy or targeted anti-cancer therapy (active treatment or recently completed) or with advanced disease regardless of treatment. Survivors of childhood cancer.
Chronic inflammatory conditions requiring medical treatment with disease modifying anti-rheumatic drugs (DMARDs) or immune-suppressive or immunomodulatory therapies.	Systemic lupus erythematosus, rheumatoid arthritis, Crohn's disease, ulcerative colitis, and similar who are being treated.
Chronic lung disease	Chronic obstructive pulmonary disease, cystic fibrosis, interstitial lung disease and severe asthma (defined as requiring frequent hospital visits or the use of multiple medications).
Chronic liver disease	Cirrhosis, autoimmune hepatitis, non-alcoholic fatty liver disease, alcoholic liver disease.
Severe chronic kidney disease (stage 4 or 5)	

Category	Examples
Chronic neurological disease	Stroke, neurodegenerative disease (e.g dementia, motor neurone disease, Parkinson's disease), myasthenia gravis, multiple sclerosis, cerebral palsy, myopathies, paralytic syndromes, epilepsy.
Diabetes mellitus requiring medication	
Chronic cardiac disease	Ischaemic heart disease, valvular heart disease, congestive cardiac failure, cardiomyopathies, poorly controlled hypertension, pulmonary hypertension, complex congenital heart disease.
People with disability with significant or complex health needs or multiple comorbidities which increase risk of poor outcome from COVID-19	Particularly those with trisomy 21 (Down Syndrome) or complex multi-system disorders.
Severe obesity with BMI ≥ 40 kg/m^2	
Severe underweight with BMI < 16.5 kg/m^2	

Younger people (aged 16 to under 40 years) with conditions that increase their risk of severe COVID-19 may consider discussing the potential risks and benefits of a second booster dose with their treating doctor. There is a very rare risk of myocarditis and pericarditis after mRNA vaccines which is highest in this age group, particularly in males.[4] It is anticipated that this cohort may have an increased risk of myocarditis or pericarditis following the second booster, compared with other population groups (see ATAGI advice on Myocarditis and Pericarditis after mRNA COVID-19 vaccines).

The following groups are currently not yet recommended to receive an additional winter booster dose:

- healthy people aged 16 to 64 years of age who do not have any risk factors for severe COVID-19
- women who are pregnant without any other comorbidity that increases their risk of severe COVID-19
- people from occupational groups, such as healthcare workers, who do not have any other comorbidity that increases their risk of severe COVID-19.

Rationale

Anticipated benefits of 4th doses in adults with risk factors

Accumulating evidence suggests that the greatest benefit from a second booster dose of COVID-19 vaccine is in people at highest risk of severe disease outcomes. Studies from Israel show that the relative vaccine effectiveness in people aged ≥60 years of a second booster compared with a first booster dose given ≥4 months previously was 68% (95% CI, 59 to 74) against COVID-19–related hospitalisation and 74% (95% CI, 50 to 90) against COVID-19–related death.[3]

A second study in Israel in people aged ≥60 years reported that the incremental benefit from a fourth dose (second booster) against infection peaked at 3 weeks after vaccination, with a relative vaccine effectiveness of 64% (95% CI: 62.0%-65.9%) compared with after a third dose. The relative vaccine effectiveness against infection declined to 29.2% (95% CI: 17.7%-39.1%) by the end of the 10-week follow-up period. However, protection against severe COVID-19 was maintained at a high level (>73%) throughout the 9-week follow-up period.[2]

Evidence to define additional risk groups

Older age remains the strongest risk factor for severe outcomes from COVID-19, including death.[5,6] Compared with individuals aged 18-39 years, the risk of death was 6.1 times higher in people aged 65-74 years and 8.66 times in those aged ≥75 years in a study conducted prior to COVID-19 vaccine availability.[6] This relationship with age exists as a continuum, with a systematic review finding that case mortality increases by 7.4% per year of age.[7] This relationship persists even with high levels of primary vaccination in Australia, as indicated by the

Australian population mortality rate during the Omicron wave, ranging from 0.2 per 100,000 in those aged 18-29 years compared to 388.8 in those aged ≥90 years.[8]

Studies conducted prior to vaccine availability found associations between numerous co-morbid medical conditions and severe COVID-19.[5,9] However, in general the increased risk of severe outcomes related to comorbidities has been less than that due to advancing age.[5,9] More recently, studies have reported on risk factors in individuals who have received 1 or 2 doses of a primary course of COVID-19 vaccination, noting this current ATAGI advice is for individuals who have received 3 doses of vaccine rather than 1 or 2 in many of the studies.[10,11] While the absolute risk (i.e., rate) of severe disease is lower in vaccinated than in unvaccinated individuals, studies investigating risk factors in the vaccinated population indicate a similar pattern of contribution to risk from increasing age, and to a smaller extent, from comorbidities. The number of comorbid conditions and risk factors also cumulatively increases an individual's risk of severe disease.[5,9,11,12]

A US study of risk factors in individuals after primary vaccination found immunosuppression, respiratory disease, chronic liver disease, chronic kidney disease, neurological disease, poorly controlled diabetes, and cardiac disease were all associated with increased adjusted odds ratios (aOR) for severe COVID-19 outcomes after primary vaccination, ranging from 1.44 to 1.91. This compared to age ≥65 years which showed an aOR of 3.22 compared to those aged 18-39 years.[11] This study did not evaluate risk based on degree of immunocompromise, and included cancer within the definition of immunocompromise.

A UK study found the incidence of COVID-19 mortality in individuals who had received 1 or 2 doses of vaccine was increased with various comorbid conditions including immunosuppression, HIV/AIDS, cirrhosis, neurological conditions, chronic kidney disease, blood cancer, epilepsy, chronic obstructive pulmonary disease, cardiovascular and peripheral vascular disease, and type 2 diabetes (aOR ≥1.2). The risk was particularly high in Trisomy 21 (Down syndrome) (12.7-fold increase), kidney transplantation (8.1-fold), and care home residency (4.1-fold). Significant underweight and obesity were both associated with an increased risk of COVID-19 mortality.[10]

Other studies have also identified a higher risk of breakthrough infection leading to hospitalisation among vaccinated people with immunocompromise or cancer.[13-16] A cohort study which included 45,253 vaccinated found a significantly increased risk for breakthrough infections in patients with cancer vs patients without cancer (HR, 1.24; 95% CI, 1.19-1.29), and a high risk of hospitalisation and mortality in those with breakthrough infection (31.6% and 3.9%, respectively).[16] A retrospective cohort study of 664,722 US vaccinated patients found that immunocompromised patients (including people with rheumatological conditions and cancer) had higher rates of breakthrough infection in the post-Delta period (8.6-15.7 per 1000 person-months) than non-immunocompromised patients (7.1 per 1000 person-months) and that rates of hospitalisation (20.7%) and severe outcomes (2.1%) were also higher than the non-immunocompromised population (14.8% and 0.7%) respectively.[15]

Rationale for not including other groups

While studies have shown that unvaccinated pregnant women are at higher risk of severe outcomes compared to non-pregnant women[17], these studies were from early in the pandemic. There is a relative lack of data on severe outcomes during the Omicron wave and in vaccinated or boosted individuals. In a small study which included 135 pregnant women (70 having received 2 doses and 13 with 3 or more doses) infected with the Omicron variant, 0% of vaccinated versus 9.6% of unvaccinated women had moderate (lower respiratory tract involvement) or severe infection (reduced blood oxygen levels or lung infiltrates on imaging).[18] While there are no particular maternal or fetal safety concerns from use of COVID-19 vaccines in pregnant women, ATAGI considers that currently there is insufficient evidence of incremental benefit from second boosters to recommend routine administration of this dose at this point in time. ATAGI will continue to monitor emerging evidence in this population.

Additional boosters are not currently recommended for people aged 16-64 years who do not have any conditions associated with increased risk of severe COVID-19, nor for people based on occupation, e.g. healthcare workers. In particular, studies have shown that healthcare workers have a greater risk of acquiring SARS-CoV-2 infection in community settings than through exposure at work.[19,20] People in these groups without comorbidity have been demonstrated to retain good protection against severe illness from SARS-CoV-2 several months out from their first booster dose. Data from the United

Kingdom shows vaccine effectiveness against hospitalisation specific to severe respiratory disease was still high at 76% at ≥105 days after first booster and 88% against COVID-19 related mortality at ≥10 weeks.[21]

As outlined in ATAGI's previous statement on recommendations on a winter booster dose of COVID-19 vaccine, an additional booster is likely to provide only modest and transient protection against infection with the Omicron variant and onward transmission. ATAGI recognises that in the context of very high rates of SARS-CoV-2 circulation, vaccination of additional groups at lower risk of severe disease may be warranted in the future, in order to prevent milder infection and reduce transmission in the short term. ATAGI will continue to monitor disease modelling and the epidemiology of SARS-CoV-2 and may recommend wider vaccination to combat rapid increases in disease transmission in the future if the need arises.

Safety considerations

Though data are limited, a fourth dose of mRNA COVID-19 vaccine has been demonstrated to be safe and well tolerated[22,23], with most adverse events being similar to previous doses and short-lived. Myocarditis and pericarditis are rare adverse events associated with mRNA COVID-19 vaccines which are known to occur more commonly among younger people aged 16-40 and among males. The incidence of myocarditis in males aged 16-29 years is approximately 1 person for every 30,000 given a first booster dose of the Pfizer COVID-19 vaccine.[4] Definitive myocarditis and pericarditis risks after second booster doses are not yet available. Data on the rate of myocarditis or pericarditis after a 4th dose are very limited; early data from Israel are imprecise due to low case numbers.[24]

More information

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

Emergency health management | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI recommendations on first booster dose in adolescents aged 12-15 years

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of a first booster dose in adolescents aged 12-15 years.

Date published: 9 June 2022

Audience: General public

Recommendations

- ATAGI recommends that a first booster dose of the Comirnaty (Pfizer) COVID-19 vaccine may be given to the following adolescents aged 12-15 years who have completed a primary course of vaccination 3 or more months ago:
    - those who are severely immunocompromised
    - those who have a disability with significant or complex health needs
    - those who have complex and/or multiple health conditions that increase the risk of severe COVID-19
- Currently, Spikevax (Moderna) and Nuvaxovid (Novavax) are not licensed for use as a first booster dose in this age group.
- ATAGI continues to recommend a 3-month interval between a recent confirmed SARS CoV-2 infection and a scheduled dose of COVID-19 vaccine.
- ATAGI does not recommend that a first booster dose of COVID-19 vaccine be given to all adolescents aged 12-15 years. There is insufficient evidence of severe disease in otherwise healthy adolescents in this age group who have already received two primary doses of a COVID-19 vaccine. ATAGI continues to recommend that all adolescents aged 12-15 years complete a primary vaccine course of 2 doses of COVID-19 vaccine, 8 weeks apart. A third primary dose from 2 months after dose 2 is recommended for those who are severely immunocompromised.
- ATAGI also recommends that all Australians, including adolescents aged 12-15 years, receive a dose of influenza vaccine as soon as practical. All COVID-19 vaccines can be co-administered (given on the same day) with an influenza vaccine.

Rationale

The current primary aim of the Australian COVID-19 vaccination program is to prevent severe disease, including hospitalisation and death. Early Australian and international data suggest that adolescents aged 12-15 years have a very low risk of severe disease or death from the Omicron variant of SARS-CoV-2, especially if they have completed

a primary series of vaccination.[1-3] There is currently insufficient evidence that a first booster dose provides additional protection against severe disease for most children and adolescents in this age group.

Adolescents aged 12-15 years who are at an increased risk of severe disease may receive a first booster dose

From first principles, ATAGI have identified three groups of adolescents aged 12-15 years who may be at greater risk of severe disease from COVID-19 compared to their peers:

- those who are severely immunocompromised
- those who have a disability with significant or complex health needs
- those who have complex and/or or multiple health conditions

A first booster dose of COVID-19 vaccine may offer additional protection against severe disease, noting the overall risk of admission to an intensive care unit and death in this age group remains very low.[1-3] There have been no confirmed deaths from COVID-19 in Australian adolescents aged 12-15 years during the period of Omicron predominance.[1,2] Most European and North American countries have also recorded no deaths except for England (1), Denmark (5), and the United States (17).[3] These data reflect deaths in adolescents aged 12-15 years with concurrent SARS-CoV-2 since February 1, 2022, and do not necessarily attribute cause of death to COVID-19.

Myocarditis following vaccination remains rare. Data from the United States and Israel suggest the risk of myocarditis following a third dose of the Pfizer COVID-19 vaccine in male adolescents aged 12-15 years ranges from 1 in 11 000-58 000 doses. This is probably lower than the rate after dose 2 and higher than the rate after dose 1.[4-5] There have currently been no reports of myocarditis following a first booster dose in female adolescents aged 12-15 years. Although female adolescents aged 12-15 years appear to have a lower risk of developing vaccine-associated myocarditis after any dose of the Pfizer COVID-19 vaccine compared to males, cases have been reported after doses 1 and 2. [4] See the ATAGI clinical guidance on myocarditis and pericarditis for details.

A third primary dose from 2 months after dose 2 is recommended for adolescents 12-15 years who are severely immunocompromised. The first booster dose for this cohort will be their 4th dose of a COVID-19 vaccine. The effectiveness and safety of a 4th dose in this age group is unknown, but the benefits are likely to outweigh the risks. There have been no safety concerns in severely immunocompromised people in older age groups.

A first booster dose is not recommended for all adolescents aged 12-15 years

At the current time, there is insufficient evidence that a first booster dose of a COVID-19 vaccine provides additional protection against severe disease for the majority of adolescents aged 12-15 years.

Adolescents aged 12-15 years who are not severely immunocompromised should receive 2 doses of an approved COVID-19 vaccine, 8 weeks apart, as a primary series.

Early evidence suggests two doses protects against severe disease, including admission to an intensive care unit and development of multisystem inflammatory syndrome in children, and this protection persists for at least several months after a primary course of vaccination in adolescents aged 12-18 years.[6-8] This is supported by Australian data that shows unvaccinated adolescents aged 12-15 years are more likely to be admitted to an intensive care unit compared to those who have received a primary series of COVID-19 vaccination.[1-2]

Advice may change as evidence emerges

This advice may change as new evidence or vaccines emerge or the aims of the vaccination program respond to local epidemiology (e.g. a new variant of SARS-CoV-2 becomes predominant). ATAGI will continue to regularly review the role of first booster doses in all adolescents aged 12-15 years.

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

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COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI updated recommendations for a winter dose of COVID-19 vaccine

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the COVID-19 vaccine winter dose.

Date published: 7 July 2022

Audience: General public

Summary

ATAGI has updated its recommendations for a winter dose of COVID-19 vaccine to help reduce severe disease from the emerging surge of Omicron BA.4 and BA.5 subvariant infections, and to reduce the burden on Australian hospitals and the healthcare system in coming months.

The updated recommendations are:

- Adults aged 50 to 64 years are now recommended to receive a winter booster dose of a COVID-19 vaccine.
- Adults aged 30 to 49 years can receive a winter booster dose of a COVID-19 vaccine, however the benefit for people in this age group is less certain.
- The interval recommended between a recent SARS-CoV-2 infection or the first booster dose and a winter booster dose is now 3 months.

ATAGI emphasises that people previously eligible for a winter booster dose remain at higher risk of severe disease and death from COVID-19 and should receive a winter booster dose as soon as possible. They include:

- all adults aged 65 years or older
- residents of aged care or disability care facilities
- Aboriginal and Torres Strait Islander people aged 50 years or older
- people who are severely immunocompromised (this will be their fifth dose)
- people aged 16 years or older with a medical condition that increases the risk of severe COVID-19 illness
- people aged 16 years or older with disability, significant or complex health needs, or multiple comorbidities which increase the risk of a poor outcome.

ATAGI emphasises that individuals who have previously been infected with SARS-CoV-2, irrespective of which variant it may have been, should continue to receive recommended vaccine doses, after an interval of 3 months, as prior infection alone will not provide sufficient protection against severe disease.

Rationale

The number of people ill from respiratory virus infections, including from COVID-19, has increased over the past few months, placing an increased strain on the Australian healthcare system, particularly hospitals. A surge in cases of COVID-19 from the SARS-CoV-2 Omicron BA.4 and BA.5 subvariants is a contributing factor and is expected to worsen in the coming months. Increasing the uptake of winter booster doses of COVID-19 vaccine in populations most at risk during this time is anticipated to play a limited, but important role in reducing the risk from COVID-19 to individuals and pressure on the healthcare system.

ATAGI notes with concern that coverage with first booster and winter booster doses of COVID-19 vaccine at this time are suboptimal , 70.6% and 59.5% of the respective eligible populations who have completed prior doses.[1] ATAGI emphasises the importance of vaccination in preventing severe disease and death during this time, particularly in older adults and people aged 16 years and older with a medical condition or disability.

Protection against Omicron BA.4 and BA.5

The Omicron BA.4 and BA.5 subvariants can partly escape the immune response generated by both prior vaccination and infection. [2,3] A first booster dose of COVID-19 vaccine has been shown to increase the immune response to these new subvariants, but wanes over several weeks. [2] A winter dose (the second booster dose) is anticipated to boost this immune response.

Reducing the interval between a first booster dose and a winter dose from 4 months to 3 months will also help provide earlier protection as infection rates rise. ATAGI re-emphasises that those individuals who have previously been infected with SARS-CoV-2, irrespective of which variant it may have been, should complete their vaccination course. Vaccination in addition to infection, as compared with prior infection alone, offers the best available protection against reinfection.

Based on first principles and currently available evidence, reaching a higher level of coverage of the COVID-19 winter booster dose in older adults, including those aged 50 to 64 years, is likely to reduce the number of COVID-19 related hospitalisations over the coming months. However, the impact of this expanded vaccine booster

recommendation alone is expected to be limited. ATAGI advises that other public health and social measures, in addition to vaccination, will have the greatest impact against the Omicron BA.4 and BA.5 surge in infections. This includes increased use of masks and increasing the use of antiviral treatment in people diagnosed with COVID-19, including in people aged 50 years and above.

Rates of hospitalisation, severe disease, and death from COVID-19 are lower in adults aged 50-64 years when compared with older adults, especially in people that have received a first booster dose.

ATAGI recognises that some people aged 30 to 49 years would also like to reduce their risk of infection from COVID-19 and therefore may consider a winter booster dose. While rates of hospitalisation, severe disease, and death from COVID-19 are low in this age group, other factors such as time off work and the risk of long COVID may influence an individual's personal decision to have a winter booster dose. The impact of vaccination on transmission and maintenance of healthcare capacity in this age group is uncertain but likely to be limited.

At this moment, ATAGI does not support making the winter booster dose available to healthy adults aged less than 30 years as it is unclear whether the benefits outweigh the risks in this population. However, a winter booster dose remains recommended for individuals aged 16 years or more who have a higher risk of severe outcomes from COVID-19 (i.e. they are immunocompromised or have a complex medical condition or disability) as they are most likely to benefit. Although very rare, myocarditis associated with the mRNA vaccines can occur, particularly in adolescent and young adult males. For more information see the ATAGI clinical guidance on myocarditis and pericarditis.

This Advice May Change

This advice may change if and as new COVID-19 vaccines or SARS-CoV-2 variants emerge or disease epidemiology changes. ATAGI will continue to regularly review the role of winter and all doses in the COVID-19 vaccination program.

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Tags: Immunisation | Communicable diseases | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI recommendations on COVID-19 vaccine use in children aged 6 months to <5 years

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) COVID-19 vaccine use in children.

Date published: 3 August 2022

Audience: General public

Summary of recommendations

- ATAGI recommends COVID-19 vaccination for **children aged 6 months to <5 years** with severe immunocompromise, disability, and those who have complex and/or multiple health conditions which increase the risk of severe COVID-19. These include children with the following or similar conditions:
    - Severe primary or secondary immunodeficiency, including those undergoing treatment for cancer, or on immunosuppressive treatments as listed in the ATAGI advice on 3rd primary doses of COVID-19 vaccine in individuals who are severely immunocompromised;
    - Bone marrow or stem cell transplant, or chimeric antigen T-cell (CAR-T) therapy;
    - Complex congenital cardiac disease;
    - Structural airway anomalies or chronic lung disease;
    - Type 1 diabetes mellitus;
    - Chronic neurological or neuromuscular conditions; or
    - A disability that requires frequent assistance with activities of daily living, such as severe cerebral palsy or Down Syndrome (Trisomy 21).
- The recommendation is for 2 primary doses, except for those with severe immunocompromise who require 3 primary doses. The recommended interval between each dose is 8 weeks.
- A paediatric formulation of the Moderna COVID-19 vaccine (Spikevax) was provisionally approved by the Therapeutic Goods Administration (TGA) on 19 July 2022 for use in children aged 6 months to 5 years and can be used for children aged 6 months to <5 years in the above categories.
- ATAGI reiterate the previous recommendation that all children aged 5 years or older are recommended to receive a two-dose course of COVID-19 vaccine.
- ATAGI does not currently recommend vaccination for children aged 6 months to <5 years who are **not** in the above risk categories for severe COVID-19. These children have a very low likelihood of severe illness from COVID-19. However, this is under ongoing consideration based on data on the disease burden and epidemiology, vaccine supply, emerging data on vaccine use in

this age group, and availability of new COVID-19 vaccines for this age group.

- Parents of eligible children aged 6 months to <5 years recommended for vaccination should seek COVID-19 vaccination as soon as they are able to secure a vaccination clinic appointment.

ATAGI's guidance takes into account:

- The very low risk of severe COVID-19 (e.g. hospitalisation due to COVID-19) in healthy children aged 6 months to <5 years. This age group is one of the least likely age groups to require hospitalisation due to COVID-19. Among the small number who are hospitalised or who die due to COVID-19, underlying medical conditions or immunocompromise are frequently present.
- A relatively low rate of paediatric inflammatory multisystem syndrome (PIMS-TS) following COVID-19 in children aged 6 months to <5 years compared to other older children, which has further declined with the Omicron variant compared to ancestral SARS CoV-2 strains.
- A clinical trial which included approximately 5500 children aged 6 months to 5 years and showed that the Moderna COVID-19 vaccine provided modest protection against infection (vaccine efficacy 35-52%) with the Omicron variant after two doses (25 mcg per dose). Safety data from the trial reported patterns of vaccine-related adverse events commonly seen in other age groups after mRNA vaccination, although fever was more common in this age group compared to older children and adults. Most side effects were mild to moderate and lasted approximately 1-2 days. Children in this trial who had evidence of a previous SARS-CoV-2 infection were more likely to have side effects after vaccination.
- The vaccine efficacy data were against infection with early Omicron variants and there may be differences in efficacy against the currently circulating SARS-CoV-2 subvariants BA.4 and BA.5. Modest efficacy against infection also suggests protection will predominantly be against severe illness rather than infection, although there were insufficient episodes of severe illness in this clinical trial to assess this specific outcome.
- Data on benefits in children with complex medical issues or severe immunocompromise are currently limited, but vaccination

is recommended based on first principles and evidence of benefit in other age groups.

- Up to one in four children in this age group had a fever following vaccination with Moderna vaccine, with higher rates seen in those with a history of previous COVID-19. As fever in this age group can sometimes result in medical review and/or investigations, and occasionally trigger a febrile convulsion, the side effect profile for this vaccination needs to be considered in the risk-benefit discussion.
- There is insufficient evidence to suggest that vaccination of infants and children would impact community transmission.
- ATAGI notes that there are currently constraints on the global availability and domestic supply of the Moderna vaccine for children aged 6 months to <5 years, which may persist until an alternative brand, variant-based or bivalent vaccines become available for this age group. Vaccine supply was one, among many, considerations in the ATAGI advice for this age group.

ATAGI will continue to monitor evolving evidence in areas of current uncertainty including vaccine effectiveness, duration of protection, and vaccine safety in this age group including data on febrile convulsions, safety of co-administration with other vaccines, and rare adverse events such as myocarditis/pericarditis (noting there have been very few cases of vaccine associated pericarditis or myocarditis in the 5-11 year old age group). ATAGI's recommendations may be updated as alternative brands of COVID-19 vaccine for this age group or variant vaccines become available and as COVID-19 epidemiology changes including the appearance of any new variants of concern.

Dosing and schedule

The recommended schedule for vaccination in this age group is 2 doses, 8 weeks apart with a minimum interval of 4 weeks for Moderna vaccine in special circumstances. See the COVID-19 Clinical guidance for variations on vaccination schedule.

The recommended dose of Moderna for this age group is 25 mcg, compared with 50 mcg dose for children aged 6 to 11 years, and 100 mcg dose for people aged 12 years and over.

The Moderna vaccine for children aged 6 months to 5 years is a new formulation (blue cap vial) consisting of a new concentration of 100 mcg/mL in multi-dose vials containing 10 doses, each 0.25 mL. ATAGI reminds immunisation providers to be vigilant for the potential for dosing errors with the Moderna vaccine in all children, and to ensure that the correct formulation is selected for the child to be vaccinated.

Children with severe immunocompromise should receive a 3rd primary dose, 8 weeks after the 2nd dose (minimum 4 weeks in exceptional circumstances, e.g. when there is anticipated intensification of immunosuppression). This advice is based on first principles of decreased immune responses seen in other age groups with these conditions after only 2 doses. See the ATAGI advice on a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Coadministration with other vaccines in children aged 6 months to <5 years

Moderna paediatric COVID-19 vaccine can be co-administered with other vaccines if separation of vaccines would be logistically challenging, such as with outreach programs to remote areas, or children receiving complicated catch-up schedules. Parents and guardians should be made aware that co-administration may increase the likelihood of mild to moderate adverse events including fever.

Where possible, it is preferable to separate administration of Moderna paediatric COVID-19 vaccine and other vaccines by 7-14 days, depending on what vaccine has most recently been administered, to minimise the risk of adverse events such as fever. Measles-Mumps-Rubella live vaccine causes fever 7-10 days after vaccination, while with most inactivated vaccines, fever occurs within 3 days after vaccination. Receipt of routine vaccines was generally excluded in clinical trials from 14 days before the first dose to 14 days after the second dose, except for influenza vaccine which was separated from any Moderna COVID-19 vaccine by at least 14 days. This recommendation may change once more co-administration data are available.

Antipyretics

Prophylactic paracetamol to reduce the risk of fever is not routinely recommended prior to or immediately after vaccination. However, paracetamol or ibuprofen can be given as required after vaccination for any discomfort or fever.

Timing following SARS-CoV-2 infection

ATAGI currently recommends COVID-19 vaccination be deferred for 3 months after a confirmed SARS-CoV-2 infection. Vaccination after this interval is likely to provide a better immunological boost and optimise the duration of protection.

Children aged 5 years of age

All **children aged 5 years and above are already recommended for COVID-19 vaccination** as per ATAGI's advice for children 5 – 11 years. Previously, only the Pfizer vaccine was registered for use in 5 year olds and Moderna was registered from 6 years of age. However, 5 year old children may now receive either Moderna 25 mcg or Pfizer 10 mcg COVID-19 vaccine. It is preferred to complete a primary vaccination schedule in children aged 5 years or older with the same brand of vaccine for both doses.

Children who turn 6 years old between doses should receive the dose that is applicable to them on the day of vaccination. Providers should note carefully that the dose of Pfizer COVID-19 vaccine is the same for children aged 5 years and those aged 6 to 11 years, while the Moderna dose increases from 25 mcg in 5 year old children (0.25mL of 100 mcg/mL blue cap vial) to 50 mcg for those aged 6 to 11 years (0.25mL of 200mcg/mL red cap vial).

Rationale

Burden of COVID-19 in children aged 6 months to <5 years

Disease epidemiology

Since late November 2021, the Omicron variant has become established as the dominant strain of SARS-CoV-2. Initial waves of BA.1 and BA.2 have resulted in substantial numbers of Australian children who have been infected with SARS-CoV-2. Australian serosurvey data in June 2022 estimates that 46.2% of adults have contracted SARS-CoV-2 infection.[1] The proportion of children aged 6 months to <5 years with prior infection is likely to be higher due to the absence of an available COVID-19 vaccine in this age group. Emergence of subvariants BA.4 and BA.5 has led to a further significant escalation in case numbers over the winter period of 2022. Data from the National Interoperable Notifiable Diseases Surveillance System (NINDSS) has shown more than 350,000 COVID-19 notifications, and 8 COVID-19 deaths in children aged 0-5 years between 1 December 2021 and 17 June 2022.

Risk of severe disease

Despite large numbers of infections occurring in children in Australia and internationally, studies reveal that very low numbers of children aged 6 months to <5 years of age have severe COVID-19 infections (that is, those who require hospitalisation, intensive care admission or result in death). In NSW, a study which followed almost 12,000 children aged ≤16 years with SARS-CoV-2 infection during the Delta period, found that children aged 6 -23 months and 2 to 4 years had a low rates of hospitalisation (including some of the least likely to be hospitalised in terms of absolute numbers) from COVID-19, and that these were often precautionary due to reduced oral intake.[2] A study in Iceland revealed that over 95% of SARS-CoV-2 infected children aged 6 months to 7 years during March 2020 to August 2021 had no or mild symptoms[3]; while a comprehensive review of all children who died due to COVID-19 between March 2020 to December 2021 in the United Kingdom revealed a very low rate of mortality in children (infection fatality rate of 0.61 per 100,000 infections in all children; and an even lower rate of 0.3 per 100,000 infections in children aged 1 to 4 years).

Of those children who died due to COVID-19, three-quarters of deaths occurred in children with an underlying condition: especially severe neurodisability or significant immunocompromise.[4]

Overall, severe COVID-19 in children is extremely rare, even among children with underlying conditions.[3,5-8] During the Omicron period, there has been a low burden of severe disease in children as shown by unpublished hospitalisation data reviewed by ATAGI from tertiary paediatric hospitals, and the Paediatric Active Enhanced Disease Surveillance (PAEDS) network.

While studies have shown vaccination may reduce the risk of paediatric inflammatory multisystem syndrome (PIMS-TS) in children[9], children aged 6 months to <5 years are at lower risk of PIMS-TS than older children (160 per million for 0-4 years vs 280 per million for 5-11 years during period of ancestral SARS-CoV-2 circulation). Furthermore, rates of PIMS-TS are 86-95% lower in the context of the currently circulating variant (Omicron), and episodes appear milder compared to the period of the ancestral strain.[10,11]

Immunogenicity of the COVID-19 vaccine in children aged 6 months to <5 years:

The evidence regarding the immunogenicity of Moderna vaccine in infants and children 6 months to 5 years derives primarily from the phase 2-3 P204 clinical trial run by Moderna. The presumed protective efficacy was determined through immunobridging, i.e. the demonstration of an equivalent or better immune response in infants and children 6 months to 5 years compared with the immune response in young adults 18 to 25 years, where efficacy has previously been shown against the ancestral strain. The neutralising antibody responses were measured in a small subset of 230 infants/toddlers aged 6 to 23 months and 264 children aged 2 to 5 years, and were compared to the neutralising antibody responses of 295 young adults aged 18 to 25 years. These neutralising antibody titres were 1.28 times higher in children aged 6 to 23 months, and equivalent in those aged 2 to 5 years to those seen in 18 to 25 year old adults. These neutralising antibody responses were against an ancestral SARS-CoV-2 strain (D614G), not the Omicron variant.

A sub-analysis investigating the difference in neutralising antibody responses between participants who had a prior SARS-CoV-2 infection and those who did not have evidence of prior infection, showed that infants and children with prior SARS-CoV-2 infection had a higher neutralising antibody response to vaccination. The neutralising antibody response was 3.8 times higher in infants/toddlers aged 6 to 23 months, 3.4 times higher in children 2 to 5 years, and 2.8-2.9 times higher in adults 18 to 25 years with prior infection compared to those with no evidence of prior infection in each respective age group.

This trial excluded infants who were premature and/or of low birth weight and excluded many children with serious underlying health conditions, and children with a history of febrile convulsions. Additionally, neither co-administration with other childhood vaccines nor vaccination with other vaccines within 14 days of each Moderna dose were permitted in the study. Therefore, the immune response generated in children with underlying medical conditions or when co-administering other infant and childhood vaccinations has not been studied, although no concerns have been raised about the use and benefits of COVID-19 vaccines in these groups in other age groups.

Vaccine efficacy of the COVID-19 vaccine in children aged 6 months to <5 years

There is limited evidence on the efficacy of Moderna in infants and children 6 months to <5 years, with most evidence coming from the phase 2-3 P204 clinical trial conducted by Moderna during October 2021 to February 2022.[12-15] All cases of COVID-19 which occurred in the P204 clinical trial were found to be due to the Omicron variant. It is important to note that efficacy demonstrated in these trials was likely to be against the BA.1 Omicron variant with an expected reduction in protection against infection with current BA.4 and BA.5 sub-variants which demonstrate a greater degree of immune escape.[16]

Vaccine efficacy against symptomatic COVID-19 from 14 or more days after dose 2 in infants/toddlers 6 to 23 months (N=2024 participants) and children 2 to 5 years (N=3452) without evidence of prior SARS-CoV-2 infection was:

- 50.6% (95% confidence interval [CI] 21.4 to 68.6) in infants/toddlers 6 to 23 months
- 36.8% (95% CI 12.5 to 54.0) in children 2 to 5 years

When participants with prior SARS-CoV-2 infection were included, vaccine efficacy against symptomatic COVID-19 from 14 or more days after dose 2 was:

- 52.1% (95% CI 24.3 to 69.3) in infants/toddlers aged 6 to 23 months
- 34.5% (95% CI 9.8 to 52.0) in children aged 2 to 5 years

There were no cases of severe COVID-19 reported as of the data cut off of the P204 trial, which had a median 71 days of follow-up post-dose 2. While efficacy is modest, ATAGI expects vaccination to offer greater protection against severe disease compared to infection with Omicron as has been shown in other age groups.[17]

As infants and children with chronic medical conditions, including severe immunocompromise were excluded from the P204 trial, the efficacy of the Moderna vaccine in these groups is not known. However, it is anticipated that these high-risk groups and severely immunocompromised children aged 6 months to <5 years are likely to have greater relative benefit from vaccination than the healthy population in the P204 trial due to their greater risk of severe disease. Likewise, severely immunocompromised children are also likely to benefit from a 3rd primary dose to improve immune responses to vaccination, similar to older people.

Risks of vaccination against COVID-19 in children aged 6 months – <5 years

Safety data from clinical trials[12–15]

The P204 Moderna trial demonstrates that local reactions were more frequently reported post-dose 2 among the entire 6 month to 5 year cohort, and were more common (particularly lymphadenopathy) in children who had previously had SARS-CoV-2 infection.

Lymphadenopathy was more frequently reported after Moderna vaccination than placebo, and more frequently reported in the cohort aged 6 to 23 months (1.5% Moderna vs. 0.2% placebo) than the cohort aged 2 to 5 years (0.9% Moderna vs. <0.1% placebo).

The safety profile of the Moderna vaccine in children aged 6 months to 5 years was similar to that of the Moderna vaccine in other age groups, with systemic events more frequently reported after dose 2. Fever rates after dose 2 were high for most age groups, but relative to other ages, infants and young children aged 6 months to 5 years had higher rates of fever after both dose 1 and dose 2 than many of the other groups.

Fever rates (≥38^{O}C) after Moderna COVID-19 vaccine by age.[13,18]

Age-group	Dose 1 Moderna	Dose 2 Moderna	Any dose
6 to 23 months	11.0%	14.6%	21.8%
24 to 36 months	11.3%	18.9%	26.1%
37 months to 5 years	7.7%	16.0%	20.9%
6 to 11 years	3.3%	23.9%	25.7%
12 to 17 years	2.5%	12.2%	14.7%
18 to 64 years	0.9%	17.4%	18.0%
≥65 years	0.3%	10.0%	10.2%
≥18 years overall	0.8%	15.5%	15.8%

Most fevers in children occurred within 2 days of vaccination and were of short duration (median 1 day for fever), with 1 in 3 vaccine recipients requiring anti-pyretic medication. Additionally, children who had previously had SARS-CoV-2 infection were more likely to have a fever than those without a history of past infection. As the P204 trial had only approximately 6-8% of trial participants with evidence of previous infection, which is lower than currently seen in Australia, post-vaccination fever may be seen more frequently after vaccination with Moderna in the Australian context than was seen in the study. ATAGI supports the use of antipyretic medication such as paracetamol to manage fevers in vaccinated infants and young children. Routine paracetamol prior to immunisation or in afebrile children to reduce the risk of fever is not currently recommended.

Young children may be prone to febrile convulsions, as these commonly occur in around 2-5% of children between the ages of 6-months to 5-years, with a peak incidence between 12 and 18 months of age.[19] These occur most frequently due to viral infections but can be precipitated by fever after vaccination. One vaccine-related febrile convulsion was reported during the P204 trial. This occurred in a 17 month old child, 2 days after dose 1. Another 3 febrile convulsions were reported in the 6 to 23 month age group but were considered not related to vaccination. Importantly, ATAGI notes that children with a history of febrile convulsion were excluded from this study, and that there may be an increased risk of recurrence of febrile convulsions in children who have had a previous febrile convulsion. A child with a previous febrile convulsion from vaccination (including with a COVID-19 vaccine) is not contraindicated to receive a subsequent dose; parents should discuss the risks and benefits of future doses with their child's GP.

ATAGI notes that the P204 trial was not powered to detect rare cardiac adverse events and uncertainties around the rates of potential vaccine-related myocarditis/pericarditis in this infant and young child age-cohort remain. No cardiac events reported during the P204 trial met the USA Centers for Disease Control and Prevention (CDC) criteria for probable or confirmed myocarditis or pericarditis in the 6 month to 5 year cohort. ATAGI is continuing to monitor rates of rare adverse events including myocarditis as vaccination in this age group becomes more widespread internationally.

There were more medically attended adverse events (including any reported cases of COVID-19) considered related to vaccination compared to the placebo group in both the infant/toddler cohort aged 6 to 23 months (1.5% vs 0.8%) and in children 2 to 5 years (1.0% vs 0.3%). Data on adverse events specific to high-risk groups for Moderna vaccine are not yet available. Additionally, the safety of the Moderna vaccine when co-administered (or closely administered) with other infant and childhood vaccinations has not yet been studied.

Initial data on the use of the Moderna vaccine in this age group are reassuring. It has been approved in the USA for infants and children aged 6 months to 5 years at the 25mcg dose. For the period 18 June 2022 to 20 July 2022, just over 544,000 children under 5 years of age have received at least one dose of Moderna (25mcg) in the USA.[20]

Currently, no serious safety signals have been reported in the USA by the CDC or FDA. Second dose data may be expected from mid August 2022.

Conclusion

The recommendation of COVID-19 vaccination in children aged 6 months to <5 years has been made after consideration of potential benefits and risks in this age group. Modest efficacy against Omicron infection, but a lack of evidence so far on vaccine effectiveness in the wider population, or against more recent sub-variants, has been weighed against the very low risk of severe disease. There also needs to be careful assessment of the greater potential for adverse events due to vaccination in this age group; these include fever, febrile convulsion and medically attended adverse events. Data are awaited regarding some aspects of vaccine safety including co-administration with other vaccines and rarer adverse events such as myocarditis, noting there have been very few cases of vaccine associated pericarditis or myocarditis in the 5-11 year old age group. Greater clarity on both benefits and risk is expected with accumulating use of COVID-19 vaccines in this age group globally, as it is already being administered in both the United States and Canada. At this stage, ATAGI is recommending vaccination in children likely to have a higher risk of severe COVID-19 and in whom the benefits are likely to clearly outweigh any risk from vaccination. ATAGI notes that there are currently constraints on the global availability and domestic supply of the Moderna vaccine for children aged 6 months to <5 years, which may persist until such time as alternative brand, variant-based or bivalent vaccines are available. Vaccine supply was one, among many, considerations in the ATAGI advice for this age group. Parents and providers should have a clear understanding of risk and benefits for their child prior to vaccination. ATAGI will continue to monitor evidence from vaccination in children aged 6 months to <5 years internationally and update its recommendations as indicated.

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases | COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

Novavax vaccine for adolescents aged 12–17 years

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of the Novavax vaccine for adolescents aged 12-17 years.

Date published: 25 August 2022

Audience: General public

On 28 July 2022 the Therapeutic Goods Administration (TGA) provisionally approved Nuvaxovid (Novavax) COVID-19 vaccine (Biocelect Pty Ltd/Novavax Inc) for use in adolescents aged 12-17 years.

The Australian Technical Advisory Group on Immunisation (ATAGI) has evaluated data on immunogenicity, efficacy, safety, and international recommendations to make recommendations on the use of Novavax COVID-19 vaccine in this age group.

The Australian Government has accepted advice from ATAGI that adolescents aged 12-17 years can receive the Novavax COVID-19 vaccine for their primary course of COVID-19 vaccination.

Adolescents aged 12-17 years will be able to book in to receive Novavax COVID-19 vaccine from 5 September 2022.

ATAGI Recommendations

Novavax primary course

- ATAGI recommends COVID-19 vaccination in all adolescents aged 12-17 years.
- Pfizer, Moderna or Novavax can be used for the primary course of COVID-19 vaccination in this age group.
- Compared with the mRNA vaccines (Pfizer and Moderna), there is less information on safety and immunogenicity of the Novavax COVID-19 vaccine.
- The recommended primary course dosing schedule for Novavax COVID-19 vaccine is 2 doses, 8 weeks apart. The manufacturer's dosing schedule is 2 doses, at least 3 weeks apart.
    - While there is no evidence on extended dosing intervals for Novavax, the extended interval of 8 weeks is consistent with other COVID-19 vaccines and evidence from other COVID-19 vaccines has suggested a longer dose interval may improve vaccine effectiveness.
    - The longer dose interval may also reduce the risk of myocarditis and pericarditis, particularly for those most at risk of these side effects (males aged 12-39 years).
- People with severe immunocompromise are recommended to receive 3 doses of COVID-19 vaccine, for more details see the Provider Guide to COVID-19 vaccination of people with immunocompromise.

Novavax boosters

Novavax is not registered by the TGA for use as a booster dose in adolescents aged 12-17 years, however ATAGI have advised that Novavax can be used as a booster in this age group if no other COVID-19 vaccine brand is suitable for that person.

Background information

Novavax COVID-19 vaccine is a spike protein-based vaccine. Each 0.5mL dose contains 5 micrograms of the of SARS-CoV-2 spike protein and 50 micrograms of Matrix-M as an adjuvant.

The ATAGI Clinical Guidance for COVID-19 vaccine providers and associated documents will be updated shortly.

ATAGI will continue to evaluate further data on the safety and efficacy of Novavax COVID-19 vaccine as it emerges, including in special populations and as a booster vaccine. ATAGI will provide updated recommendations as required.

Tags: Immunisation | Young people's health | Communicable diseases | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI statement on use of the Moderna bivalent Original/Omicron vaccine

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding COVID-19 Moderna Spikevax Bivalent Original/Omicron BA.1 vaccine.

Date published: 12 September 2022

Audience: General public

On 29 August 2022 the Therapeutic Goods Administration of Australia granted provisional registration for the Moderna Spikevax Bivalent Original/Omicron BA.1 (subsequently referred to as Moderna bivalent) vaccine for use as a booster dose in people aged 18 years and older.

Recommendations

- The Moderna bivalent vaccine can be used as an alternative vaccine for any booster dose in people aged 18 years or older, according to the current ATAGI recommendations for booster doses.
- ATAGI have made no changes to the current booster recommendations and is not advising any extra booster doses beyond the second booster dose (fourth dose) in selected populations.
- Booster doses of COVID-19 vaccine should be given at least 3 months after the most recent COVID-19 vaccine dose or previous SARS-CoV-2 infection.
- Eligible individuals can receive Moderna bivalent or the original vaccines (various brands) whichever is available to them. Both bivalent and original vaccines result in an improvement in the immune response against BA.1 and BA.4/BA.5 Omicron subvariants, with the Moderna bivalent vaccine showing a small incremental benefit over the original vaccine for Omicron neutralisation.
- Coadministration of Moderna bivalent vaccine with other non-COVID vaccines is acceptable, as per current ATAGI clinical guidance.
- The Moderna bivalent vaccine is not recommended for the primary course of vaccination (first two doses in most people or first three doses in severely immunocompromised people).
- ATAGI does not currently recommend use of the Moderna bivalent vaccine as a booster in anyone under 18 years as it is not registered for this age group.

Considerations

- As of 28 August 2022, 71.7% of the eligible population have received a 3rd dose (first booster for most people) and 54.4% of eligible people aged 50 years or older have received a second booster dose (fourth dose for most people) which suggests that many people are overdue for a booster dose.[1]
- ATAGI considers receiving all recommended doses to be a more important factor in obtaining optimal protection against severe COVID-19 than which variant is contained within the dose.[2]
- While booster vaccination with a variant-containing vaccine may not necessarily 'match' the circulating variant, it is anticipated to induce a broad immune response to current SARS-CoV- 2 variants.[3-5]
- The Moderna bivalent vaccine is only registered for use as a booster vaccine and contains 50mcg of mRNA, comprising equal quantities encoding the spike protein from the original SARS-CoV-2 virus and Omicron BA.1 variant. The Moderna primary course requires 100mcg doses and therefore the Moderna bivalent vaccine is not considered suitable for primary vaccination. There are no data as yet on the immunogenicity of this bivalent vaccine in a primary series.
- COVID-19 case numbers due to BA.4 and BA.5 Omicron subvariants have now peaked in Australia and are expected to reduce and plateau. There is uncertainty about the timing of any future increase in cases due to the current or new variants and the characteristics of these variants (transmissibility/virulence).
- An assessment of potential benefits, risks and timing of second booster doses, in light of current epidemiology, should be considered in those adults in whom the benefits appear less certain, such as adults aged 30-49 years without other risk factors for severe COVID-19.

Vaccine presentation

- The Moderna bivalent vaccine is presented as a blue-capped multi-dose vial (100 mcg/mL) containing either five 0.5mL doses, or ten 0.5mL doses. The vaccine does not require dilution.

- Each dose should be administered intramuscularly, preferably in the deltoid.
- To minimise the risk of administration errors, providers should preferably prepare and store doses of the Moderna bivalent vaccine separately from other vaccines due to the use of similar coloured vaccine vial caps (such as the Moderna paediatric vaccine 6 months to 5 years formulation). Doses withdrawn in advance of administration should be clearly labelled.

This advice may change

ATAGI continues to monitor evidence on vaccine effectiveness, the epidemiology of SARS-CoV-2 (including its seasonality and emerging subvariants), and on other candidate bivalent COVID-19 vaccines (including BA.4/BA.5 subvariant vaccines). ATAGI will add to its recommendation as further evidence on the bivalent vaccine(s) and knowledge about other uncertainties accumulates.

Rationale

The Moderna bivalent vaccine generates a modestly higher level of antibody response against multiple SARS-CoV-2 Omicron subvariants (approximately 1.6-1.9 times) including BA.1 and BA.4/BA.5, and a similar antibody response against the original virus, compared with the Moderna original booster vaccine. There remains uncertainty however regarding how this translates to clinical protection. Modelling data suggests that there may be a small increment in protection over an original booster, particularly in those with lower levels of pre-existing immunity, such as people who have only had 2 COVID-19 vaccine doses or who are a longer period from previous infection or vaccination.[2] The safety profile of the bivalent vaccine as a booster in adults appears similar to the original vaccine. There are no data on the immunogenicity or safety of the Moderna bivalent vaccine in people under 18 years of age.

Studies monitoring the effectiveness of the vaccine once it is deployed both in Australia and in other countries will provide more data in relation to the protection provided by the bivalent vaccine against

infection and severe disease, and the cross-protection it provides against variants/subvariants, including those which differ from those in the vaccine.

Vaccine immunogenicity

Evidence supporting use of the Moderna bivalent vaccine is limited to immunogenicity and safety data from the Moderna P205 study at 4 weeks after a second booster (fourth dose).[4,5] Participants aged ≥18 years received Moderna bivalent vaccine as their second booster dose, at least 3 months following a Moderna original primary course (100 mcg doses) and Moderna original first booster dose (50mcg).

Immunogenicity data are available from non-contemporaneous cohorts: 437 people who received the Moderna bivalent vaccine and 377 people who received the Moderna original vaccine as 2nd boosters. There were modestly higher neutralising antibody titres against the Omicron BA.1 variant with the Moderna bivalent vaccine, in people with no previous SARS-CoV-2 infection (1.7 times higher in the bivalent group than the original vaccine group [95% CI 1.5 – 2.0]). In people with prior infection, neutralising titres against BA.1 were 1.9 times higher with the bivalent vaccine (95% CI 1.5- 2.4).

Neutralising antibody titres against the original virus were similar following the Moderna bivalent booster compared with the Moderna original booster in both those with and without previous SARS- CoV-2 infection (1.3 times higher [95% CI 1.1-1.5] and 1.2 times higher [95%CI 1.1 – 1.4], respectively, in the bivalent group).[4,5]

Cross-protection against variants/subvariants

Evidence suggests the Moderna bivalent vaccine can provide cross-protection against variants and subvariants not included in the vaccine. Neutralisation titres against the BA.4 and BA.5 subvariants were 1.7 times (95% CI 1.5-1.9) higher with the Moderna bivalent vaccine compared with the Moderna original vaccine, although absolute neutralisation titres were lower than those seen against the BA.1 variant.[5] Binding antibody levels against previous variants such as Alpha and Delta were also similar or slightly higher with the bivalent vaccine than the original vaccine.[4]

Duration of protection

While duration of protection is not known with the Moderna bivalent original/Omicron BA.1 vaccine, there is the potential for increased duration of protection as shown by a previous investigational Moderna bivalent vaccine encoding the original virus and the Beta variant, used as a first booster, 6 or more months after a primary Moderna course. This vaccine continued to show higher neutralisation titres than the Moderna original vaccine against multiple variants including Omicron at 180 days after the booster dose.[6] It is anticipated that the registered Moderna bivalent original/Omicron BA.1 vaccine may show a similar pattern.

Safety data from clinical trials

The P205 trial (bivalent original/Omicron BA.1)[4] and bivalent original/Beta trial[6] demonstrate that the safety profile of the Moderna bivalent vaccines was similar to the first or second booster of the Moderna original vaccine, and to the second dose of the primary series of the original vaccine.

The most commonly reported local adverse reactions following a second booster dose of the Moderna bivalent vaccine were injection site pain (77%), fatigue (55%), headache (44%) and myalgia (40%).[4] The risk of myocarditis or pericarditis (very rare adverse effects of COVID-19 vaccines) following the Moderna bivalent vaccine has not yet been characterised, as this vaccine has not been used extensively in large populations. However, there is no reason to believe the safety of the Moderna bivalent vaccine is any different to other Moderna mRNA vaccines.

Uncertainties

ATAGI will continue to monitor evidence in several areas listed below and update its advice as data accumulate:

- Evidence of clinical protection of the Moderna bivalent vaccine through population-based vaccine effectiveness studies including any incremental benefit of Moderna bivalent vaccine over the original vaccine
- Duration of protection of bivalent vaccines

- Disease epidemiology including emergence of any future variants of concern
- Cross-protection of bivalent vaccines against new variants
- Incremental benefit of BA.4/BA.5-specific vaccines
- Safety of bivalent booster vaccines including rare adverse events such as myocarditis/pericarditis.

Further reading

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases

COVID-19

COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI recommendations for a booster dose of the paediatric Pfizer COVID-19 vaccine in children aged 5 to 11 years

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on Pfizer booster doses for children aged 5 to 11 years.

Date published: 24 October 2022

Audience: General public

Recommendations

- ATAGI recommends that a booster dose of the Paediatric Pfizer COVID-19 vaccine (10mcg, ancestral strain) may be given to the following children aged 5 to 11 years who have completed a primary course of vaccination 3 or more months ago:
    - those who are severely immunocompromised
    - those who have a disability with significant or complex health needs
    - those who have complex and/or multiple health conditions that increase the risk of severe COVID-19
- Currently, Spikevax (Moderna) and the bivalent COVID-19 vaccines are not licensed for use as booster doses in this age group.
- ATAGI continues to recommend a 3-month interval between a recent confirmed SARS CoV-2 infection and a scheduled dose of COVID-19 vaccine.
- ATAGI does not recommend that a booster dose of COVID-19 vaccine be given to all children aged 5 to 11 years. There is insufficient evidence of severe disease in otherwise healthy children in this age group who have already received two primary doses of a COVID-19 vaccine. ATAGI continues to recommend that all children aged 5 to 11 years complete a primary vaccine course of 2 doses of COVID-19 vaccine, 8 weeks apart. A third primary dose from 2 months after dose 2 is recommended for those who are severely immunocompromised.

Rationale

> Children aged 5 to 11 years who are at an increased risk of severe disease may receive a booster dose.

The current primary aim of the Australian COVID-19 vaccination program is to prevent severe disease, including hospitalisation and death. From first principles, ATAGI have identified three groups of children aged 5 to 11 years who may be at greater risk of severe disease from COVID-19 compared to their peers:

- those who are severely immunocompromised
- those who have a disability with significant or complex health needs
- those who have complex and/or or multiple health conditions.

A booster dose of COVID-19 vaccine may offer additional protection against severe disease, noting the overall risk of admission to an intensive care unit and death in this age group remains very low.[1]

A third primary dose from 2 months after dose 2 is recommended for children aged 5 to 11 years who are severely immunocompromised. The first booster dose for this cohort will be their 4th dose of a COVID-19 vaccine. The effectiveness and safety of a 4th dose in this age group is unknown, but the benefits are likely to outweigh the risks. There have been no safety concerns in severely immunocompromised people aged 12 years and older.

Booster doses are not recommended for all children aged 5 to 11 years

At the current time, there is insufficient evidence that a booster dose of a COVID-19 vaccine provides additional protection against severe disease for the majority of children aged 5 to 11 years.

Early data suggest children aged 5 to 11 years have a very low risk of hospitalisation and death from COVID-19, especially if they have completed a primary series of vaccination.[1] There has been a reduction

in the number of cases of multi-system inflammatory in children (MIS-C) and no confirmed deaths from COVID-19 in Australian children aged 5 to 11 years during the Omicron wave.[1,2]

A substantial proportion of Australian children in this age group have been infected with the Omicron variant of SARS-CoV-2 over the last 9 months.[3] Although data are limited, past infection probably provides additional protection against severe disease, especially in those children with a completed primary series.

Children aged 5 to 11 years who are not severely immunocompromised should receive 2 doses of an approved COVID-19 vaccine, 8 weeks apart, as a primary series.

Advice may change as evidence emerges

This advice may change as new evidence or vaccines emerge or the aims of the vaccination program respond to local epidemiology (e.g. a new variant of SARS-CoV- 2 becomes predominant). ATAGI will continue to regularly review the role of booster doses in all children aged 5 to 11 years.

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Tags:

Immunisation

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Australian Government
Department of Health and Aged Care

ATAGI recommendations on use of the Pfizer bivalent (Original/Omicron BA.1) COVID-19 vaccine

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) the Pfizer bivalent (Original/Omicron BA.1) COVID-19 vaccine.

Date published: 14 November 2022

Audience: General public

On 27 October 2022, the Therapeutic Goods Administration of Australia provisionally approved the Pfizer (Comirnaty) Bivalent Original/Omicron BA.1 vaccine (subsequently referred to as Pfizer bivalent) for use as a booster COVID-19 vaccine in people aged 18 years and older. The Australian Technical Advisory Group on Immunisation (ATAGI) has evaluated the immunogenicity, efficacy, and safety data on this vaccine.

Recommendations

ATAGI updates its existing recommendations regarding use of bivalent Original/Omicron BA.1 vaccines with the following:

- The Pfizer bivalent vaccine can be used as an alternative vaccine to any of the available mRNA COVID-19 vaccines (Pfizer original vaccine, Moderna bivalent vaccine or Moderna original vaccine) for any booster dose in people aged 18 years or older who are currently recommended to receive a COVID-19 booster.
- In those who are eligible for a booster dose, ATAGI does not have a preference for bivalent mRNA vaccines over original mRNA vaccines.
- Booster doses of COVID-19 vaccine should be given at least 3 months after the most recent COVID-19 vaccine dose or confirmed SARS-CoV-2 infection.
- As with other mRNA COVID-19 vaccines, the Pfizer bivalent vaccine can be co-administered with other non-COVID-19 vaccines.

- The Pfizer bivalent vaccine is not recommended for the primary course of vaccination (the first two doses in most people or first three doses in severely immunocompromised people).
- ATAGI does not currently recommend use of the Pfizer bivalent vaccine as a booster in anyone aged **under** 18 years as it is not registered for use in this age group.

Read the summary of current ATAGI recommended doses and vaccines.

Vaccine presentation

The Pfizer bivalent vaccine is presented as a grey-capped multi-dose vial containing six 0.3mL doses of 30 mcg. The vaccine does not require dilution.

Each dose should be administered intramuscularly, preferably in the deltoid.

Rationale

The original Pfizer and Moderna COVID-19 vaccine used mRNA from the ancestral (original) strain of SARS-CoV-2. Newer combination formulations of COVID-19 booster vaccines have been developed using mRNA encoding for the spike protein the BA.1 sublineage of the Omicron variant together with the mRNA encoding ancestral strain spike.

All mRNA COVID-19 booster vaccine doses (bivalent and original) result in an improvement in the immune response against Omicron subvariants BA.1 and BA.4/BA.5. The inclusion of BA.1 in bivalent vaccines is expected to provide a greater breadth of protection compared with ancestral vaccines against current and future Omicron sub-variants such as BQ.1 and XBB, though there are no published data yet to demonstrate this.

A clinical trial among people aged over 55 years has demonstrated that the Pfizer bivalent vaccine induces a modestly higher level of antibody response against BA.1 and BA.4/5 Omicron subvariants compared to

the Pfizer COVID-19 original vaccine, when used as a second booster dose. There are no objective data to translate this directly to clinical protection.

Modelling suggests that differences in the additional protection against COVID-19 from a bivalent booster over an original booster are relatively small compared to the protection obtained from receiving any booster at all.[1]

The safety profile of the bivalent vaccine as a booster dose in adults aged over 55 years appears similar to the original vaccine.

There are no data yet on the immunogenicity or safety of the Pfizer bivalent vaccine in people under 55 years of age. Evidence from a monovalent Omicron BA.1 vaccine in people aged 18 to 55 years, showing improved immune response against BA.1, was used to infer protection. There are no data on the use of any Pfizer vaccine containing the Omicron variant in any population aged <18 years. There are no studies at present which compare the Pfizer bivalent vaccine head-to-head with the Moderna bivalent vaccine.

Vaccine immunogenicity

Evidence supporting use of the Pfizer bivalent vaccine is limited to immunogenicity and safety data from the C4591031 trial (substudy E) at 4 weeks after a second booster dose (fourth dose).[2] Participants aged >55 years received Pfizer bivalent vaccine as their second booster dose, 5 to 12 months following a Pfizer original primary course (30mcg) and Pfizer original first booster dose (30mcg).

The trial included 305 people who received the Pfizer bivalent vaccine and 305 people who received the Pfizer original vaccine as a second booster dose. Against the Omicron BA.1 variant, the Pfizer bivalent vaccine provided 1.6 times higher neutralising antibodies compared to the original vaccine, in people without prior infection (95% CI: 1.17, 2.08).[2] Against the original virus, neutralising antibody titres were similar for the Pfizer bivalent and Pfizer original vaccine (Geometric mean ratio 0.99 [95% CI: 0.82, 1.20]).[2]

While immunogenicity data are not available for people aged ≤55 years, the C4591031 trial (substudy D) included a cohort of participants aged 18 to 55 years who received the Pfizer monovalent Omicron BA.1 vaccine (30mcg) as a second booster. The trial included 263 people

receiving the Pfizer monovalent omicron vaccine and 280 people receiving the Pfizer original vaccine. Against the Omicron BA.1 variant, neutralising antibodies for the Pfizer monovalent vaccine were higher compared to the Pfizer original vaccine (unpublished company data) by a similar degree to that seen in the Pfizer bivalent study.

Cross-protection against variants/subvariants

Evidence from a small subgroup analysis of 20 participants in each group from the trial suggests that Pfizer bivalent vaccine may provide cross-protection against variants and subvariants not included in the vaccine. Neutralisation titres against BA.4 and BA.5 subvariants were higher for the bivalent vaccine (226.3 [95% CI: 120.7, 424.1) compared with the original vaccine (110.9 [95% CI: 67.9, 180.9]).[3] Pre-print studies, that have not yet been peer reviewed, have found that BA.4/5 bivalent vaccines induce an immune response against emerging sub-variants BQ.1.1 and XBB[4,5,6]. There are no published data on the immunogenicity of BA.1 bivalent vaccines against these newer sublineages.

Safety data from clinical trials[3]

The Pfizer bivalent trial and the Pfizer monovalent BA.1 trial suggest that the safety profile of these vaccines is similar to the Pfizer original vaccine.

The most commonly reported local and systemic adverse reactions following a second booster of the Pfizer bivalent vaccine in people aged over 55 years were injection site pain (58%), fatigue (49%), headache (34%) and myalgia (22%). The most commonly reported local and systemic adverse reactions following a second booster of the Pfizer monovalent vaccine in people aged 18 to 55 years were injection site pain (78%), fatigue (64%), headache (48%) and myalgia (34%). The risk of myocarditis or pericarditis (very rare adverse effects of COVID-19 vaccines) following the Pfizer bivalent vaccine has not yet been characterised as this vaccine has not been used extensively in large populations. However, evidence from booster doses with the original Pfizer mRNA vaccine, which has been used for longer and on more people, shows that the frequency of myocarditis is lower for booster doses compared with second doses, and this is not expected to be different with bivalent booster vaccines.

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Tags:

Australian Technical Advisory Group on Immunisation (ATAGI)

COVID-19 | COVID-19 vaccines

Coronavirus (COVID-19)

Australian Government
Department of Health and Aged Care

ATAGI recommendations on use of the Pfizer COVID-19 vaccine for children aged 6 months to 4 years

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of the Pfizer COVID-19 vaccine for children aged 6 months to 4 years (Pfizer 6 months to 4 years).

Date published: 14 November 2022

Audience: General public

On 29 September 2022 the Therapeutic Goods Administration (TGA) provisionally approved Comirnaty (Pfizer) COVID-19 vaccine for use in children aged 6 months to 4 years.

ATAGI has evaluated data on immunogenicity, efficacy, and safety to consider the use of the Pfizer 6 months to 4 years COVID-19 vaccine in this age group.

The COVID-19 Moderna <5 years vaccine has already been recommended by ATAGI on 3 August 2022 in this age group, for high-risk children (as identified below). There is no preference for either the Moderna <5 years or Pfizer 6 months to 4 years COVID-19 vaccine in high-risk children aged 6 months to <5 years; however completion of a primary schedule with the same brand of vaccine is recommended. Further advice will be included in the ATAGI clinical guidance in due course.

ATAGI does not currently recommend vaccination for children aged 6 months to <5 years who are **not** in the below risk categories for severe COVID-19. Further information regarding the low risk of severe COVID-19 in healthy children aged

6 months to <5 years is available in this statement.

ATAGI Recommendations

ATAGI recommends the Pfizer 6 month to 4 years COVID-19 vaccine as a primary course of vaccination against SARS-CoV-2 for children aged 6 months to 4 years with severe immunocompromise, complex or multiple health conditions, or disability with significant or complex health needs.

This includes children with the following or similar conditions:

- Severe primary or secondary immunodeficiency, including those undergoing treatment for cancer, or on immunosuppressive treatments as listed in the ATAGI advice on 3rd primary doses of COVID-19 vaccine in individuals who are severely immunocompromised;
- Bone marrow or stem cell transplant, or chimeric antigen T-cell (CAR-T) therapy recipients;
- Complex congenital cardiac disease;
- Structural airway anomalies or chronic lung disease;
- Type 1 diabetes mellitus;
- Chronic neurological or neuromuscular conditions; or
- A disability with significant or complex health needs, such as severe cerebral palsy or Down Syndrome (Trisomy 21).

The Pfizer 6 months to 4 years vaccine requires 3 primary doses, each containing 3mcg of mRNA. ATAGI recommends an interval of 8 weeks between each dose. Children with severe immunocompromise are also recommended to receive

3 primary doses. ATAGI will update this recommendation if future evidence demonstrates a need for additional doses.

ATAGI currently recommends the administration of COVID-19 vaccines be deferred for 3 months after a confirmed SARS-CoV-2 infection. Vaccination after this interval is likely to provide a better immunological response and optimise the duration of protection.

Background Information

The Pfizer vaccine for 6 months to 4 year old children (Pfizer 6 month to 4 years vaccine) is an mRNA vaccine. Each 0.2mL dose contains 3 micrograms of mRNA. Results of a recent clinical trial demonstrate the Pfizer 6 month to 4 years vaccine is effective at protecting against COVID-19 disease in children who have not yet been infected with SARS-CoV-2, and most side effects are short-term. However, there are little data available regarding the impact of COVID-19 vaccines on routine immunisations recommended in this age group. Furthermore, severe COVID-19 in this cohort is very rare.

The recommended primary course dosing schedule is 3 doses, 8 weeks apart. Whilst this differs from the interval used in the clinical trial conducted by Pfizer, research suggests a longer dose interval may improve vaccine effectiveness and reduce the risk of rare side effects, including myocarditis or pericarditis.

Recent safety data from the United States, indicates that the Pfizer 6 month to 4 years vaccine has a good safety profile. As at 1 September 2022, over 890,000 doses have been administered with only a small number of adverse events following immunisation reported.

ATAGI will continue to evaluate further data on the safety and efficacy of vaccinations against COVID-19 in this age group and provide updated recommendations as required.

Tags:

Australian Technical Advisory Group on Immunisation (ATAGI)

COVID-19 | COVID-19 vaccines

Coronavirus (COVID-19)

Australian Government
Department of Health and Aged Care

ATAGI 2023 booster advice

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding COVID-19 boosters in 2023. These recommendations replace previous ATAGI COVID-19 vaccine booster advice.

Date published: 8 February 2023

Audience: General public

The goal of the Australian COVID-19 vaccination program remains the prevention of severe illness from COVID-19. ATAGI has evaluated this risk in the context of high population levels of hybrid immunity (i.e., combined immunity from past infection and past vaccination), the

evidence regarding COVID-19 vaccine effectiveness, including for new bivalent vaccines, and the changing epidemiology of COVID-19 related to newly emerged subvariants of Omicron.

These recommendations replace previous ATAGI COVID-19 vaccine booster advice.

Overview

- ATAGI **recommends** a 2023 COVID-19 vaccine booster dose for adults in the following groups, if their last COVID-19 vaccine dose or confirmed infection (whichever is the most recent) was 6 months ago or longer, and regardless of the number of prior doses received:
    - All adults aged 65 years and over
    - Adults aged 18-64 years who have medical comorbidities that increase their risk of severe COVID-19, or disability with significant or complex health needs.
- ATAGI advises the following groups should **consider** a 2023 booster dose if their last COVID-19 vaccine dose or confirmed infection (whichever is the most recent) was 6 months ago or longer, and regardless of the number of prior doses received, based on an individual risk benefit assessment with their immunisation provider.
    - All Adults aged 18-64 years without risk factors for severe COVID-19
    - Children and adolescents aged 5-17 years who have medical comorbidities that increase their risk of severe COVID-19, or disability with significant or complex health needs.
- ATAGI advises that a booster dose is **not recommended** at this time for children and adolescents aged under the age of 18 who do not have any risk factors for severe COVID-19.
- Regarding vaccine choice, all currently available COVID-19 vaccines are anticipated to provide benefit as a booster dose, however bivalent mRNA booster vaccines are preferred over other vaccines. These include: Pfizer Original/Omicron BA.4/5, as well as Pfizer Original/Omicron BA.1 or Moderna Original/Omicron BA.1. Moderna Original/Omicron BA.4/5 is

currently under evaluation by the Therapeutic Goods Administration.

- COVID-19 vaccine can be co-administered with influenza and other vaccines.
- Administration of a 2023 COVID-19 booster dose should aim to occur prior to June 2023 and at a time of 6 months or greater following the most recent COVID-19 vaccine dose or confirmed infection.
- Ongoing surveillance of COVID-19 infection rates and clinical outcomes, new variants, and vaccine effectiveness will inform future recommendations for additional booster doses.

ATAGI 2023 Booster Advice*

Age	At risk**	No risk factors
<5 years	Not recommended	Not recommended
5-17 years	Consider	Not recommended
18-64 years	Recommended	Consider
≥ 65 years	Recommended	Recommended

*mRNA bivalent booster preferred; for ages in which a bivalent vaccine is not approved, use a vaccine approved for that age group. A 2023 booster dose should be given 6 months after a person's last dose or confirmed infection.

**Includes those with a medical condition that increases the risk of severe COVID-19 illness (refer to ATAGI clinical guidance) or those with disability with significant or complex health needs or multiple comorbidities which increase the risk of poor outcomes from COVID-19.

Rationale

Epidemiology of SARS-CoV-2 as of February 2023

Multiple new Omicron subvariants have emerged since the BA.4/5 wave in Australia during July and August 2022, displaying increased immune-escape properties (e.g. BQ.1 and XBB)[1,2]. These have co-circulated without any specific subvariant establishing clear dominance. Numerous immunological studies report reduced neutralisation of new Omicron subvariants by both vaccine-induced and naturally derived

antibodies[3,4]. COVID-19 vaccines may have a reduced and/or shorter duration of protection against infection from these subvariants compared with older variants, however vaccines (together with hybrid immunity from natural infection) continue to provide strong protection against severe COVID-19. Of note, early evidence suggests that the newer Omicron subvariants do not cause more severe disease compared with the original Omicron subvariant (BA.1)[5].

Anticipated benefits of a 2023 COVID-19 vaccine booster dose

An additional COVID-19 booster dose is anticipated to address waning of protection against severe COVID-19 prior to winter. This will provide an increase in protection against severe illness and protect the healthcare system during a time of high demand.

It is recommended to defer vaccination for 6 months following a confirmed SARS-CoV-2 infection, as this, together with prior vaccine doses received, will boost protection against COVID-19. ATAGI notes that testing rates have decreased and there are likely to have been many people with undetected SARS-CoV-2 infection within recent months. There are no safety concerns for individuals receiving a COVID-19 vaccine who may have had undetected SARS-CoV-2 infection within the past 6 months.

The increase in protection against severe illness from COVID-19 following a booster dose is most beneficial for people at higher risk of severe illness, i.e., older adults and those with relevant medical risk factors[6,7]. Studies conducted throughout the pandemic, including during Omicron epidemic waves have identified a higher risk of hospitalisation among older adults and adults with immunosuppression or other chronic medical conditions, compared with younger or healthy adults[8,9].

ATAGI considers a booster dose beneficial for all adults aged 65 years and older. The risk of severe disease increases with each decade of age. With similar levels of hybrid immunity to the Australian population, UK modelling during the Omicron era found that 800 people aged 70 years and above would need to be given a booster to prevent one hospitalisation from COVID-19, compared with 8000 people aged 50 to 59 years and 92,500 people aged 40-49 years[10]. However, a booster

dose may still be beneficial for people aged 5-64 years based on individual circumstances such as underlying conditions that increase their risk of severe disease.

For children and adolescents aged 5-17 years with risk factors for severe illness, a booster dose may be beneficial; decision-making around booster vaccination should be based on an individual risk-benefit assessment with their immunisation provider. The risk of severe disease with current high population levels of hybrid immunity in children and adolescents aged 5-17 years without risk factors is now considered to be lower than when previous ATAGI booster advice was issued. At present, most at-risk children aged 6 months to <5 years who have received a primary course have done so within recent months and a booster dose is not recommended at present.

ATAGI continues to recommend a primary course of vaccination against COVID-19, followed by a booster dose for those eligible, even in individuals who have had past infection. Adults who have already been infected with an Omicron subvariant and vaccinated with 3 doses of COVID-19 vaccine are at lower risk of reinfection and hospitalisation compared to those who have been infected but not vaccinated[11].

Potential risks of a COVID-19 booster dose

For people aged under 65 years, the decision to have a 2023 COVID-19 booster dose in the coming months should take into account an individual's age, risk factors for severe COVID-19, number and timing of previous doses or previous infection, and risk factors (predominantly age) for myocarditis and pericarditis following vaccination.

Adolescents and younger adults have a lower age-related risk of severe COVID-19, and a comparatively higher risk of myocarditis following vaccination. The risk of myocarditis is highest in people aged 16-30 years (peak 16-18 years), and is higher in males than females[12–14]. The risk of myocarditis appears to be lower after COVID-19 booster doses in comparison with dose 2 of the primary course and is lower following Pfizer COVID-19 vaccine as compared with Moderna COVID-19 vaccine in some contexts[14,15]. See COVID-19 vaccination – Guidance on myocarditis and pericarditis after COVID-19 vaccines for more information.

Vaccine choice

Any age-appropriate COVID-19 vaccine, including original (ancestral virus-based) vaccines, are expected to boost neutralising antibodies and thereby provide additional protection against any infection and longer lasting protection against severe disease.

However, most immunogenicity studies have shown a trend towards BA.4/5-based vaccines inducing higher neutralising activity against Omicron subvariants (including BQ.1 and XBB) than original vaccines or BA.1-containing vaccines[4,16–18], although a few studies reported similar neutralising antibody titres when comparing the responses to different vaccines[19]. Early published and preprint data on whether these increases in neutralisation activity translate into measurable differences in clinical protection suggest a small advantage in vaccine effectiveness with bivalent vaccines over original vaccines in preventing hospitalisation and death[20,21]. However, further confirmatory studies are awaited. Early data suggest that the vaccine effectiveness of BA.1-based bivalent booster vaccines is similar to ancestral-based booster doses, but potentially with slower waning of protection[6,22].

For more information on which vaccines are available for each age group refer to the COVID-19 vaccine doses and administration webpage. Bivalent Original/Omicron BA.1 vaccines are only registered for use in people aged 18 years and over. The Pfizer bivalent Original/Omicron BA.4/5 vaccine is registered for use from 12 years of age.

There are currently insufficient data to determine the timing of any additional future COVID-19 booster doses. However it is likely, as with influenza vaccine, that regular doses of COVID-19 vaccine will be needed to maintain immunity against SARS-CoV-2 over years to come, particularly for those at highest risk of severe disease. ATAGI will continue to monitor data on the duration of protection from booster doses, as well as on new circulating virus variants or subvariants, and will provide updated vaccine advice as required.

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Tags:

Australian Technical Advisory Group on Immunisation (ATAGI)

COVID-19 | COVID-19 vaccines

Coronavirus (COVID-19)

Australian Government
Department of Health and Aged Care

ATAGI recommendations on use of the Pfizer bivalent (Original/Omicron BA.4/5) COVID-19 vaccine

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of the Pfizer bivalent (Original/Omicron BA.4/5) COVID-19 vaccine.

Date published: 8 February 2023

Audience: General public

On 20 January 2023, the Therapeutic Goods Administration of Australia provisionally approved the Pfizer (Comirnaty) Bivalent Original/Omicron BA.4/5 vaccine (subsequently referred to as Pfizer bivalent BA.4/5) for use as a booster COVID-19 vaccine in people aged 12 years and older. The Australian Technical Advisory Group on Immunisation (ATAGI) has evaluated the immunogenicity, efficacy, and safety data on this vaccine.

Recommendations

ATAGI advises that the Pfizer bivalent BA.4/5 vaccine can be used as a booster dose by adolescents and adults aged ≥12 years who are recommended to receive a COVID-19 booster according to the ATAGI 2023 booster advice.

The Pfizer bivalent BA.4/5 vaccine is not currently registered for use in children aged <12 years or as a primary series . An approved alternative COVID-19 vaccine, e.g. Pfizer Original COVID-19 vaccine, should be used in children aged 5-11 years who require a booster dose.

Vaccine presentation

The Pfizer bivalent vaccine is presented as a grey-capped multi-dose vial containing six 0.3mL doses of 30 mcg. The vaccine does not require dilution.

Each dose should be administered intramuscularly, preferably in the deltoid.

Rationale

Pfizer has updated its bivalent formulation of the COVID-19 vaccine to include 15mcg of mRNA encoding the BA.4/5 Omicron subvariant spike protein replacing the previous BA.1 Omicron subvariant in the Pfizer bivalent Original/Omicron BA.1 vaccine. 15mcg of the ancestral strain spike protein mRNA remains unchanged.

Two Pfizer immunogenicity studies in adolescents and adults aged ≥12 years who had received a primary series and first booster of Pfizer original vaccine provide a comparison between neutralising antibody levels after a second booster of 30 mcg of the Pfizer bivalent BA.4/5 vaccine and a second booster of the Pfizer original vaccine. Adults aged >55 years who received the Pfizer bivalent BA.4/5 vaccine developed higher neutralising antibody titres to the BA.4/5 Omicron subvariant (geometric mean ratio 2.91, 95%CI 2.45-3.44) than those who received the Pfizer original vaccine. Neutralisation of newer BQ.1.1 and XBB.1 subvariants was also higher than with the original vaccine. The bivalent vaccine had non-inferior and modestly higher titres for ancestral strain neutralisation (GMR 1.38, 95%CI 1.22-1.56).[1] Similar trends were seen in 12-17 year and 18-55 year age groups.

An additional four studies report higher neutralisation titres following a booster dose of Pfizer bivalent BA.4/5 vaccine for BA.4/5 and other sub-variants (e.g. BQ.1, XBB) compared to the Pfizer original vaccine.[2-5] Two studies have found the neutralisation response to be similar between bivalent BA.4/5 and original vaccines.[6,7] Early published and preprint data on whether these increases in neutralisation activity translate into measurable differences in clinical protection suggest a small advantage in vaccine effectiveness with bivalent vaccines over original vaccines in preventing hospitalisation and death.[8,9] A US study showed vaccine effectiveness (VE) against hospitalisation or death with a bivalent BA.4/5 booster (either Pfizer or Moderna) was 61.8% (95% CI 48.2 to 71.8%) compared with an original booster VE of 24.9% (95%CI 1.4 to 42.8%).[9] A nationwide cohort study conducted in Nordic countries during July to December 2022 found VE against hospitalisation for a second booster of bivalent BA.4/5 vaccine of

80.5% (95%CI 69.5% to 91.5%) and for an original vaccine second booster of 64.9% (95%CI 57.7% to 72.2%), both relative to not receiving a second booster.[8]

The short term safety of the Pfizer bivalent BA.4/5 vaccine was shown to be similar to the previous Pfizer bivalent BA.1 and original vaccines when used as a booster. Adverse reactions following Pfizer bivalent BA.4/5 as a second booster dose included pain at the injection site (68.5%), fatigue (56.4%), headache (41.4%), muscle pain (25.8%), chills (16.9%), joint pain (13.4%), fever (7.3%), injection site swelling (5.4%), injection site redness (4.8%), and lymphadenopathy (0.3%). No new adverse reactions were identified.[1,10] The suggestion of an increased risk of ischaemic stroke in adults aged 65 years or older following receipt of Pfizer bivalent BA.4/5 vaccine has emerged from a single US surveillance system. Currently, this is not considered to be a true safety signal.Additional US surveillance systems and those in other countries have not detected an association despite widespread use of the Pfizer bivalent BA.4/5 vaccine.[11]

ATAGI will continue to monitor the emerging evidence related to bivalent vaccines and the changing COVID-19 epidemiology.

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Tags:

Immunisation

Australian Technical Advisory Group on Immunisation (ATAGI)

Communicable diseases | COVID-19

COVID-19 vaccines

Coronavirus (COVID-19)

Australian Government
Department of Health and Aged Care

ATAGI recommendations on use of the Moderna bivalent (Original/Omicron BA.4/5) COVID-19 vaccine

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of the Moderna bivalent (Original/Omicron BA.4/5) COVID-19 vaccine.

Date published: 28 February 2023

Audience: General public

Recommendations

ATAGI advises that the Moderna bivalent BA.4/5 vaccine can be used in eligible adolescents and adults aged 12 years or older who are recommended (or advised to consider) a COVID-19 booster dose according to the ATAGI 2023 booster advice.

All currently available COVID-19 vaccines are anticipated to provide benefit as a booster dose, however bivalent booster vaccines, including the Moderna bivalent BA.4/5 vaccine and Pfizer bivalent BA.4/5 vaccine, are preferred over other vaccines.

The Moderna bivalent BA.4/5 vaccine is not registered for use in children aged under 12 years or as a primary series. Currently, the Pfizer original COVID-19 vaccine (orange cap) is the only formulation recommended for use in this age group. Providers can refer to the ATAGI COVID-19 vaccine doses and administration webpage to check which vaccines are recommended by age group.

The Moderna bivalent BA.4/5 vaccine contains 25mcg of the SARS-CoV-2 BA.4/5 Omicron subvariant spike protein mRNA and 25mcg of the ancestral strain spike protein mRNA.

Rationale

Immunogenicity data from the Moderna clinical trial demonstrate a trend towards the BA.4/5 vaccine inducing higher neutralising activity against Omicron subvariants (including BQ.1 and XBB) than original vaccines or BA.1-containing vaccines.[1] This study reported 5.1-6.3 times greater neutralising antibody levels against the BA.4/5 Omicron subvariants at 1 month after a booster dose of Moderna bivalent BA.4/5 vaccine compared to Moderna original vaccine in adults aged 18 years and older who had previously received a primary series and booster dose of Moderna original vaccine.[1]

Early evidence suggests a booster dose of Moderna bivalent BA.4/5 vaccine provides greater protection against hospitalisation and death from severe Omicron disease compared to a booster dose of Moderna original vaccine at 1-3 months in adults (63.8% vs 38.6%, respectively).[2] Very few cases of hospitalisation or death from severe Omicron disease have occurred in children aged less than 12 years.[3]

The very small risk of myocarditis or pericarditis following Moderna bivalent BA.4/5 vaccine does not appear to be greater than the risk after a first booster dose of Moderna original vaccine or a booster dose of Pfizer bivalent BA.4/5 vaccine in adolescents and adults aged 12 years and above at this time.[4,5] There has been no association between Modern bivalent BA.4/5 vaccine and thrombotic stroke.[4,5]

ATAGI will continue to monitor the emerging evidence related to bivalent vaccines and the changing COVID-19 epidemiology.

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Tags: Immunisation | Communicable diseases | COVID-19 | COVID-19 vaccines | Coronavirus (COVID-19)

Australian Government
Department of Health and Aged Care

ATAGI advice on the preferential use of bivalent COVID-19 vaccines for primary vaccination of people aged 12 years or older

ATAGI has made recommendations on the use of bivalent COVID-19 vaccines as a primary course.

Date published: 30 May 2023

Audience: General public

ATAGI has reviewed the available evidence and advises that for people aged 12 years or older, a bivalent COVID-19 vaccine is now preferred over original (ancestral) vaccines for primary vaccination.

ATAGI further advises that:

- People aged 12-17 years are recommended to receive a BA.4/5-containing bivalent vaccine for both the primary course and booster doses.
- People aged ≥18 years are recommended to receive either a BA.1-containing bivalent vaccine or a BA.4/5-containing bivalent vaccine for both the primary course and booster doses.
- People aged ≥12 who have commenced their primary course with an original (ancestral) vaccine are recommended to complete the course with a bivalent vaccine.

- ATAGI considers there to be no additional safety concerns when using bivalent vaccines for the primary course, compared with the original vaccines.
- When using a bivalent vaccine for primary vaccination, the number of doses and the interval between the doses are the same as for the original (ancestral) vaccine formulations.
- Original (ancestral) vaccines continue to be available for individuals aged ≥12 years who either prefer to not to receive a bivalent primary course; or who cannot or choose not to have an mRNA vaccine..
- There is currently no bivalent vaccine available for children aged 6 months – 11 years, and existing original vaccines should continue to be used for this age group.
- The ATAGI COVID-19 2023 Booster Advice provides guidance on which individuals are recommended, or can consider, a COVID-19 vaccine booster dose for additional protection against severe COVID-19.

Rationale

Currently available vaccines in Australia include monovalent original vaccines which contain the ancestral strain of SARS-CoV-2 and bivalent vaccines which contain both the ancestral strain and an Omicron subvariant (either BA.1 or BA.4/5). Bivalent mRNA vaccines are authorised by the Therapeutics Goods Administration (TGA) for use as booster doses after a primary course in either those aged ≥12 years [Pfizer (Comirnaty) bivalent Original/Omicron BA.4/5 vaccine and Moderna (Spikevax) bivalent Original/Omicron BA.4/5] or ≥ 18 years [Pfizer (Comirnaty) bivalent Original/Omicron BA.1 vaccine and Moderna (Spikevax) bivalent Original/Omicron BA.1].

Bivalent vaccines are designed to broaden cross-protection from vaccination against Omicron and its subvariants by including an Omicron strain in the vaccine. Circulating strains since 2022 have all evolved as subvariants from the first Omicron variant. Pre-Omicron variants no longer circulate, and reversion to a pre-Omicron variant by a future strain is considered unlikely.

ATAGI therefore considers the bivalent vaccines (which protect against either Omicron subvariants BA.1 or BA.4/5) preferable for use in a primary series. ATAGI notes that use of bivalent vaccines for primary vaccination is consistent with evolving advice from the World Health Organization's Strategic Advisory Group of Experts on Immunization (SAGE)[1] and the European Medicines Agency's Emergency Task Force[2], and that off-label use has been permitted in the United Kingdom.[3]

Early immunogenicity and safety data on bivalent vaccines used as primary vaccination are limited.[4] The safety of bivalent vaccines is similar to monovalent original vaccines when used as a booster dose.[5,6] ATAGI has no additional concerns regarding the safety or effectiveness of bivalent vaccines compared with monovalent vaccines when used for a primary course.

While there are currently no efficacy or effectiveness studies of bivalent vaccines when used for the primary vaccination course, early effectiveness studies of bivalent vaccines used as a booster dose suggest equivalent or better protection than original vaccines.[7-9] There

is no reason to expect that using bivalent vaccines for a primary vaccination course would differ, particularly in the context of widespread community transmission in Australia which suggests that most previously unvaccinated recipients will have some pre-existing immunity from prior infection.[10]

ATAGI has reviewed the available data comparing the immunogenicity and effectiveness of BA.1 vaccines to BA.4/5 vaccines.[11-14] This evidence suggests that both vaccines provide similarly high levels of protection against serious illness and death from Omicron subvariants. ATAGI recommends that for both primary and booster vaccination, BA.1 bivalent vaccines and BA.4/5 bivalent vaccines are both suitable for people aged ≥ 18 years, and BA.4/5 bivalent vaccines can be used for people aged 12 - 17 years.

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Tags: Immunisation | Young people's health | Australian Technical Advisory Group on Immunisation (ATAGI) | COVID-19 | COVID-19 vaccines

Australian Government
Department of Health and Aged Care

ATAGI Update on the COVID-19 Vaccination Program

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding an additional COVID-19 dose for highest risk people in 2023. These recommendations are in addition to the previous ATAGI COVID-19 vaccine booster advice published in February 2023.

Date published: 1 September 2023

Audience: General public

1 September 2023

The primary aim of COVID-19 vaccination continues to be to reduce the risk of serious illness and death. This is particularly important for older adults and those with risk factors for severe disease. ATAGI last issued recommendations regarding a 2023 dose of COVID-19 vaccine in February 2023.

This advice provides guidance on who should consider receiving an additional dose of a COVID-19 vaccine in 2023, recognising that older age remains the strongest risk factor for severe COVID-19 disease.

This updated advice also reflects that much of the population, particularly younger individuals with no other medical conditions, are currently well-protected against severe disease from COVID-19 from a combination of their previous vaccinations (including those who have already received a 2023 dose) and additional immunity gained from a previous infection.

Recommendations

ATAGI **recommends** that all adults aged ≥ 75 years **should receive** an additional 2023 COVID-19 vaccine dose if 6 months have passed since their last dose.

ATAGI advises the following groups should **consider** an additional 2023 COVID-19 vaccine dose if 6 months have passed since their last dose, after discussion with their healthcare provider:

- All adults aged 65 to 74 years, and/or
- Adults aged 18 to 64 years with severe immunocompromise.
- Within the above groups, an additional 2023 COVID-19 vaccine is likely to be of most benefit for people who:
    - Have no known history of SARS-CoV-2 infection (and therefore are unlikely to have protection from hybrid immunity),
    - Have medical comorbidities that increase their risk of severe COVID-19, or disability with significant or complex health needs, or
    - Reside in a residential aged care facility.

ATAGI continues to encourage all adults who were recommended to have a COVID-19 vaccine dose in February 2023, and who have not yet had one, to receive a vaccine dose as soon as possible (refer to Table below).

For younger people or older adults without severe immunocompromise who have already had a dose in 2023, no further doses are currently recommended. Their baseline risk of severe illness is low if they have already been vaccinated, and particularly if they have also had prior infection.[1] Therefore a further 2023 dose will offer little additional benefit even if it has been more than 6 months since their last dose.

ATAGI continues to note that while there is minimal benefit from having a COVID-19 vaccine dose too soon after infection, current SARS-CoV-2 testing rates have dropped significantly, so from a practical perspective it is challenging for many individuals to know if or when they last had an infection. Where previous infection details are unknown, it is appropriate to proceed with a first 2023 dose, and an additional dose for eligible people outlined in this update.

A person may be vaccinated earlier than the recommended 6-month interval where considered appropriate, such as before starting an immunosuppressant, before overseas travel or if someone cannot reschedule vaccination easily (such as in an outreach or inreach vaccination program).

There are no additional safety concerns relating to the use of additional doses in older adults and people at high risk of severe SARS CoV-2.

ATAGI 2023 COVID-19 Booster Advice – first and additional dose*

	2023 COVID-19 booster dose (February 2023 guidance)		**Additional 2023 COVID-19 booster dose (September 2023 guidance)**	
Age	**At risk#**	**No risk factors**	**At risk#**	**No risk factors**
<5 years	Not recommended	Not recommended	Not recommended	Not recommended
5-17 years	Consider	Not recommended	Not recommended	Not recommended

18-64 years	Recommended	Consider	Consider **if severe immunocompromise**^	Not recommended
65-74 years	Recommended	Recommended	Consider	Consider
≥ 75 years	Recommended	Recommended	Recommended	Recommended

- *mRNA bivalent vaccine preferred; for ages in which a bivalent vaccine is not approved, use a vaccine approved for that age group. Timing: 2023 vaccine doses should be given from 6 months after a person's last dose.
- #Includes those with a medical condition that increases the risk of severe COVID-19 illness (refer to ATAGI clinical guidance) or those with disability with significant or complex health needs or multiple comorbidities which increase the risk of poor outcomes from COVID-19.
- ^ For details, refer to the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

Rationale

Nationally there was a gradual increase in COVID-19 case notifications from March to June 2023 across all age groups[2]. While the number of cases has declined substantially in recent weeks, virus transmission will continue to occur. COVID-19 cases also continue to be reported in residential aged care facilities.[2] Most cases of severe illness (e.g., requiring hospitalisation) continue to be in older adults, particularly those aged ≥ 75 years.[3] Among cases reported to the National Notifiable Diseases Surveillance System (NNDSS) during the 4th Omicron wave (October 2022 – April 2023), around 2% of Australians aged 65-74 were hospitalised with COVID-19, compared with 7.2% of people aged ≥ 75 years.[3]

COVID-19 vaccine doses provide good protection against severe illness and death for several months. However, protection wanes over time. In an Australian study conducted from November 2022 – March 2023, absolute vaccine effectiveness (VE) of a booster COVID-19 vaccine dose against mortality in adults aged ≥ 65 years was 74.7% (95% CI 64.9 – 81.7) within 3 months of the dose but declined to 52.9% (95% CI 43.5 – 60.8) after 9 months following that dose.[4] In adults aged ≥ 75 years, VE

fell from 78.3% (95% CI 69.4 – 84.7) within 3 months of a dose to 60.5% (95% CI 52 – 67.5) after 9 months.[4] In adults aged ≥ 75 years, the difference in the rate of COVID-19 mortality in those whose most recent dose was > 9 months earlier compared with those vaccinated within the previous 3 months was 11 out of 10,000 persons a year. In adults aged 65-74 years the difference was only 1 out of 10,000, emphasising that the benefit of a recent vaccine dose is higher with increasing age.

Multiple factors contribute to the relatively lower rates of severe illness in younger compared with older age groups. SARS-CoV-2 has consistently caused more severe illness, hospitalisation and deaths in older adults, particularly those with major medical comorbidities and/or frailty. An analysis of NNDSS data from the 4th Omicron wave, about 1% of people aged 18-49 with reported SARS-CoV-2 infection were hospitalised.[3] Furthermore, much of the population now has 'hybrid immunity', a combination of protection from previous vaccination and prior infection. This is supported by serosurveillance conducted at the end of 2022, which indicates that about 70% of the adult population and 64% of children had evidence of infection with SARS-CoV-2.[1,5]

Globally, vaccine advisory groups recognise that severe COVID-19 disproportionally affects older adults and people with high-risk medical conditions. [6-8] These people will benefit most from additional vaccine doses.

2023 booster doses delivered

Since 1 January 2023, approximately 3.8 million COVID-19 booster doses have been administered to Australians aged over 18 years.[2] Among eligible aged care residents (i.e., who had not had a dose or known infection within the prior 6 months), around 66% had received a booster dose as of 16 August 2023.[9] Only 53% of people aged 65 years and older have received a booster dose in the last 6 months.[9] These data reflect that a significant proportion of adults ≥ 65 years of age, and particularly aged care residents, should be strongly encouraged to receive a COVID vaccine now.

Additional information and timing of future advice

Bivalent Omicron-based mRNA COVID-19 vaccines continue to be preferred for all doses in people aged ≥ 12 years.

ATAGI notes that XBB.1.5-based vaccines have been developed, but these are not yet approved for use by any country and updates will be provided as information is available.

Ongoing surveillance of COVID-19 infection rates and clinical outcomes, new variants, and vaccine availability and effectiveness will inform future recommendations for additional COVID-19 vaccine doses from ATAGI.

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Tags:

Australian Technical Advisory Group on Immunisation (ATAGI)

COVID-19 | COVID-19 vaccines

Coronavirus (COVID-19)

Australian Government
Department of Health and Aged Care

ATAGI recommendations on use of the Moderna and Pfizer monovalent Omicron XBB.1.5 COVID-19 vaccines

Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of XBB 1.5 COVID-19 vaccines.

Date published: 20 November 2023

Audience: General public

20 November 2023

The Therapeutic Goods Administration of Australia has approved the following XBB 1.5 vaccines for use as primary and additional doses:

- Pfizer monovalent Omicron XBB.1.5 vaccine 5 - <12 years formulation (light blue cap)
- Pfizer monovalent Omicron XBB.1.5 vaccine ≥12 years formulation (dark grey cap)
- Moderna monovalent Omicron XBB.1.5 vaccine, registered for use in people aged 12 years and older.

Recommendations

Monovalent Omicron XBB.1.5 vaccines are now available in Australia. ATAGI advises the following:

- All currently available COVID-19 vaccines are anticipated to provide benefit to eligible people, however the monovalent Omicron XBB.1.5 vaccines are preferred over other vaccines for use in children aged 5 years or older and adults who are currently recommended primary or additional doses of COVID-19 vaccine according to the Australian Immunisation Handbook
- For those who have had the recommended 2023 dose/s of COVID-19 vaccine, ATAGI is not recommending further doses or re-vaccination with an XBB.1.5-containing vaccine at this time
- ATAGI notes the recent increase in COVID-19 cases across Australia since November 2023. ATAGI encourages all people who have not yet had their recommended 2023 dose/s to receive them as soon as possible (see Appendix).

There are no monovalent XBB.1.5-containing vaccines registered for use in children aged 6 months to 4 years. Currently, Pfizer original (maroon cap) is the only formulation available for use in this age group. Providers can refer to the Australian Immunisation Handbook to check which vaccines are recommended by age group.

Formulations

- The Moderna monovalent XBB.1.5 ≥ 12 years pre-filled syringe contains 50mcg of the SARS-CoV-2 XBB.1.5 Omicron subvariant

spike protein mRNA.

- The Pfizer monovalent XBB.1.5 ≥12 years formulation (dark grey cap) contains 30mcg of the SARS-CoV-2 XBB.1.5 Omicron subvariant spike protein mRNA.
- The Pfizer monovalent XBB.1.5 5-<12 years formulation (light blue cap) contains 10mcg of the SARS-CoV-2 XBB.1.5 Omicron subvariant spike protein mRNA.

Each formulation should be administered intramuscularly, preferably in the deltoid.

Novavax XBB.1.5 vaccine is not currently available. Novavax Original vaccine can be given to people aged 12 years and older, but XBB.1.5-based vaccines are preferred.

Rationale

Most Omicron subvariants currently circulating in Australia are sub-lineages of XBB.1 with BA.2.8 representing a small but growing proportion.[1] The World Health Organisation (WHO) has recommended COVID-19 vaccine formulations target the XBB.1 subvariant and move away from inclusion of the original (ancestral) strain.[2]

Vaccine effectiveness and safety of XBB.1.5-containing vaccines have been largely inferred from earlier COVID-19 vaccine formulations. Limited direct data are available.

Early human immunogenicity data demonstrate an 8.7-10.4 times increase in neutralising antibodies against the Omicron XBB.1.5 subvariant and other recently circulating subvariants at 29 days after receiving a dose of the Moderna monovalent XBB.1.5 vaccine in people who completed at least a primary course of vaccination.[3] Local and systemic reactions following the Moderna monovalent XBB.1.5 vaccine occurred at similar or lower rates compared to the original and bivalent (original/BA.4/5) Moderna formulations.[3] The most frequent adverse events reported after a non-primary dose were injection site pain (in 68%), fatigue (44%), muscle pain (38%), and headache (34%).[3]

While there are no direct comparisons between monovalent Pfizer XBB.1.5 and Pfizer bivalent boosters in humans, immunogenicity data in mice demonstrated a rise in neutralising antibodies against the

Omicron XBB.1.5 subvariant that was approximately 5 times higher compared to an additional dose with Pfizer bivalent (original/BA.4/5) vaccine.[4]

ATAGI has no additional safety concerns regarding the use of XBB.1.5-containing vaccines compared to older vaccine formulations.

Older vaccine formulations continue to provide strong protection against severe disease.[2] Available data suggests monovalent XBB vaccines provide modestly enhanced protection from severe disease compared to older vaccines.[5]

ATAGI encourages people to follow the recommended public health measures (e.g., mask wearing in high-risk settings, staying home when unwell) during the current COVID-19 wave.

ATAGI will continue to monitor the emerging data on vaccine effectiveness and safety of Moderna and Pfizer monovalent XBB.1.5 and the changing COVID-19 epidemiology. ATAGI will provide updated advice in early 2024. Until that time, the existing advice for further doses remains and is summarised in the Appendix below.

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Appendix

ATAGI updated the recommendations for doses of COVID-19 in February and September 2023. These recommendations have not changed at this time. As published in the September statement, the current recommendations for further doses are summarised below:

Table 1. Current recommendations for further COVID-19 vaccine doses (unchanged from September 2023)

	first 2023 dose (February 2023 guidance)*		**second 2023 dose (September 2023 guidance)***	
Age	**At risk#**	**No risk factors**	**At risk#**	**No risk factors**
<5 years	Not recommended	Not recommended	Not recommended	Not recommended
5-17 years	Consider	Not recommended	Not recommended	Not recommended
18-64 years	Recommended	Consider	Consider **if severe immunocompromise^**	Not recommended
65-74 years	Recommended	Recommended	Consider	Consider
≥ 75 years	Recommended	Recommended	Recommended	Recommended

- *XBB.1.5-containing vaccine preferred for all doses. For eligible children aged 6 months to 4 years, use Pfizer Original 6 month - <5 year formulation (maroon cap) as the only available formulation for this age group. Timing: 2023 vaccine doses should be given from 6 months after a person's last dose and can be given in early 2024, pending updated advice from ATAGI.
- #Includes those with a medical condition that increases the risk of severe COVID-19 illness (refer to the Australian Immunisation Handbook) or those with disability with significant or complex health needs or multiple comorbidities which increase the risk of poor outcomes from COVID-19.
- ^ For details, refer to the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

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