ATAGI recommendations on use of Spikevax Moderna COVID-19 Bivalent Original / Omicron BA.1 Booster (Moderna Bivalent booster) for adults aged 18 years and over

Frequently Asked Questions

12 September2022

What is the Moderna bivalent booster vaccine, and how is it different to other COVID-19 boosters?

- The Moderna bivalent booster vaccine contains the mRNA sequences encoding the spike protein for two different SARS-COV-2 variants: the ancestral strain (as used in the original Moderna vaccine) and the Omicron BA.1 subvariant.
- Booster vaccination with a variant-containing vaccine is anticipated to induce a broad and more durable immune response to SARS-CoV-2, including future variants, and may not necessarily 'match' the most recent circulating variant.
- The Moderna bivalent booster generates:
    - a modestly higher level of antibody response against Omicron virus subvariants (approximately 1.6-1.9 times) including BA.1 and BA.4/BA.5, and
    - a similar antibody response against the ancestral virus, compared with the original Moderna ancestral vaccine.
- Although, there remains uncertainty regarding how this translates to clinical protection, it is expected to be at least as effective, if not modestly better, in preventing infection and severe disease from SARS-CoV-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 aged under 18 years.
- Vaccine companies are also working on new generation vaccines that cover the ancestral strain and the Omicron BA.4 and BA.5 subvariants, but these are still in the development and approval phases.

Who can have the Moderna bivalent booster?

- ATAGI recommends that the Moderna bivalent booster can be used in people aged 18 years and older for the first or second booster dose (i.e. the third or fourth dose for most people), according to the current ATAGI recommendations for booster doses.
    - The booster dose 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, whichever is later.
    - For more information on booster doses, visit https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-your-vaccination/booster-doses#booster-doses
- 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.
- Both Moderna bivalent booster and ancestral vaccines (various brands) will continue to be available in the near future.
    - Eligible individuals can receive whichever COVID-19 booster vaccine is available to them.
- ATAGI recommends that any person who has not yet received a first or recommended second COVID-19 booster dose, arrange to receive their booster soon, using either the Moderna bivalent booster or an alternative ancestral vaccine.
- As of 28 August 2022, 71.7% of the eligible population have received a first booster and 39.6% of eligible people aged 30 years and over have received a second booster, which suggests that many people are overdue for COVID-19 boosters.
- From 10 October 2022, patients will be able to access the Moderna bivalent booster as an option, along with the other registered COVID-19 vaccines.

Why will both the ancestral/original COVID-19 vaccine and the Moderna bivalent booster be available? Isn't the new vaccine better because it has Omicron in it?

- The Moderna bivalent booster contains the mRNA sequences for two different SARS-COV-2 variants: the ancestral strain (as used in the original Moderna vaccine) and the Omicron BA.1 subvariant.
- The Moderna bivalent vaccine generates a modestly higher level of antibody response against Omicron virus subvariants (approximately 1.6-1.9 times) including BA.1 and BA.4/BA.5, and a similar antibody response against the ancestral virus, compared with the Moderna ancestral booster vaccine.
- There remains uncertainty regarding how this translates to clinical protection, however it is expected to be at least as effective, if not modestly better, in preventing infection and severe disease from SARS-CoV-2.
- 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.
- Booster vaccination with a variant-containing vaccine is anticipated to induce a broad and more durable immune response to SARS-CoV-2, including future variants, and may not necessarily 'match' the most recent circulating variant.

What if my vaccine provider only has the ancestral/original COVID-19 vaccine? How many providers will have supply of the Moderna bivalent booster?

- 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.
- Both Moderna bivalent booster and ancestral vaccines (various brands) will continue to be available in the near future. Eligible people can receive whichever COVID-19 booster vaccine is available to them.
- ATAGI recommends that any person who is due to receive a first or second recommended COVID-19 booster dose but has not yet done so, arrange to receive their booster soon, using either the Moderna bivalent booster, or an alternative ancestral vaccine.

I have recently had Omicron COVID-19 infection, should I get the Moderna bivalent booster?

- ATAGI continue to emphasise the importance of receiving the COVID-19 vaccinations recommended for your age or individual health needs.
- If you have recently had COVID-19, your booster dose should be given at least 3 months after your previous infection.
- The booster doses provide additional protection against severe disease, hospitalisation and death as compared with the primary course.
- The Moderna bivalent booster contains the mRNA sequences encoding the spike protein for two different SARS-COV-2 variants: the ancestral strain (as used in the original Moderna vaccine) and the Omicron BA.1 subvariant.
- Booster vaccination with a variant-containing vaccine is anticipated to induce a broad and more durable immune response to SARS-CoV-2, including future variants, and may not necessarily 'match' the most recent circulating variant.
- For more information on booster doses, visit https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-your-vaccination/booster-doses#booster-doses

If Omicron BA.4 and BA.5 are the dominant circulating subvariants, why are you recommending a new vaccine that has Omicron BA.1?

- The Moderna bivalent booster contains the mRNA sequences for two different SARS-COV-2 variants: the ancestral strain (as used in the original Moderna vaccine) and the Omicron BA.1 subvariant.
- Booster vaccination with a variant-containing vaccine is anticipated to induce a broad and more durable immune response to SARS-CoV-2, including future variants, and may not necessarily 'match' the most recent circulating variant.
- The Moderna bivalent vaccine generates:
    - a modestly higher level of antibody response against Omicron virus subvariants (approximately 1.6-1.9 times) including BA.1 and BA.4/BA.5, and
    - a similar antibody response against the ancestral virus, compared with the Moderna ancestral booster vaccine.
- There remains uncertainty regarding how this translates to clinical protection, however it is expected to be at least as effective, if not modestly better, in preventing infection and severe disease from SARS-CoV-2.
- 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.

I am aged in my 30s or 40s and have recently had the Omicron infection, should I get the Moderna bivalent booster?

- On 7 July 2022 ATAGI recommended that adults aged 30 to 49 years can receive a second booster dose of a COVID-19 vaccine; however, the benefit for people in this age group is uncertain.
- 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 second booster dose.
- People in this age group should assess their personal benefits and risks of vaccination as well as current epidemiology to determine the best timing of second booster doses.
- 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 a person's 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.
- If you are aged 30 to 49 years you should have a discussion with your healthcare provider on benefits and risks of a second booster, including the Moderna Bivalent vaccine.

I have recently had my COVID-19 booster dose, should I get the Moderna bivalent booster?

- If you are eligible for a second booster dose of COVID-19 vaccine, you should have this at least 3 months after your first booster dose.
- For more information on booster doses, visit https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-your-vaccination/booster-doses#booster-doses

I've had my second booster (fourth dose). Can I have the Moderna bivalent booster?

- ATAGI does not recommend third booster doses of any COVID-19 vaccine at present.
- 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 and other uncertainties accumulates.

I haven't yet had a dose of COVID-19 vaccine. Can I have the new Moderna bivalent booster as my primary course?

- The TGA have granted provisional registration for the Moderna bivalent booster for use as a booster vaccine.
- ATAGI recommends that the Moderna bivalent booster can be used for the first or second booster dose, according to the current ATAGI recommendations for booster doses in people aged 18 years or older.
- The Moderna primary series requires a 100mcg dose of mRNA, whereas the Moderna bivalent booster contains 50mcg of mRNA (containing equal quantities from the ancestral and Omicron BA.1 variants), therefore the Moderna bivalent booster is not considered suitable for primary vaccination at present.
- There are currently no data on the immunogenicity of this bivalent vaccine in a primary series.

My child is due for their booster dose, can they have the Moderna bivalent booster?

- ATAGI does not recommend use of the Moderna bivalent booster as a booster in anyone aged under 18 years.
- The TGA registration for the Moderna bivalent booster is for use as a booster dose in people aged 18 years and over.
- For those aged 12 to 17 years, only the Pfizer vaccine is registered as a booster dose. While it is not TGA-registered as a booster dose in this age group, Novavax can be used as a booster dose in people aged 12 to 17 years if no other COVID-19 vaccine brand is suitable for that person.
- For more information on:
    - booster doses, visit https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-your-vaccination/booster-doses#booster-doses
    - the TGA announcement, see https://www.tga.gov.au/media-release/tga-provisionally-approves-moderna-bivalent-covid-19-vaccine-use-booster-dose-adults

When will other bivalent vaccines be available in Australia?

- The Australia Government is committed to procuring and rolling out improved vaccines as quickly as possible once they become available, however vaccine sponsors must first obtain TGA approval.
- Following TGA approval, ATAGI will also review the evidence and make recommendations on the use of these vaccines.

Is the Moderna bivalent booster recommended for people with severe immunocompromise?

- The Moderna bivalent booster is not recommended for the primary course of COVID-19 vaccination. For people with severe immunocompromise, this is the first three doses of the vaccine.
- The Moderna bivalent booster is expected to be at least as effective, if not modestly better, in preventing infection and severe disease from these SARS-CoV-2 variants.
- The safety profile of the bivalent vaccine as a booster in adults appears similar to the original vaccine.
- The Moderna bivalent booster is available to all individuals aged 18 years and older, including people with severe immunocompromise.

How many booster doses of COVID-19 vaccine do I need?

- ATAGI does not recommend third booster doses of any COVID-19 vaccine at present.
- The Moderna bivalent booster is not recommended for primary doses (first two doses in most people or first three doses in severely immunocompromised people).
- ATAGI does not recommend use of the Moderna bivalent booster in anyone aged under 18 years.
- A single COVID-19 vaccine booster dose is recommended for people aged 16 years and older who completed their primary course 3 or more months ago.

- Adolescents aged 12 to 15 years in the following groups who completed their primary course 3 or more months ago may receive a single COVID-19 vaccine booster:
    - 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.
    - For more information on boosters in adolescents aged 12 to 15 years see: ATAGI recommendations on first booster dose in adolescents aged 12-15 years.
- A second booster dose (a fourth dose) is recommended for people in the following groups, 3 months after the first booster dose:
    - people aged 50 years and older
    - residents aged 16 years and older of an aged care or disability care facility
    - people aged 16 years and older who have complex, chronic, or severe medical conditions that increase their risk of severe illness from COVID-19
    - people aged 16 years and older with disability with significant or complex health needs, or multiple comorbidities that increase the risk of poor outcome from COVID-19.
- ATAGI has advised people aged 30 to 49 years old can receive a fourth dose if they choose.
    - The benefit for people in this age group is less certain and ATAGI encourages people in this age group to have a discussion with their regular medical provider to review their individual health needs and the benefits and risks of a second booster dose.
- For more information on booster doses, visit https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-your-vaccination/booster-doses#booster-doses

How can I book in for a Moderna bivalent booster?

- Locations for vaccinations are currently being finalised and appointments will be updated on the Vaccine Clinic Finder shortly.
- Appointments for vaccinations will be available as soon as practicable.

How can I find extra information or help accessing a COVID-19 vaccination?

- Keep up to date with COVID-19 vaccinations by visiting www.health.gov.au and using the search terms "COVID-19 vaccination Moderna Bivalent booster" or online through your state or territory health department.
- If you have questions about COVID-19 and vaccinations, you can call the National Coronavirus Helpline 24 hours a day, 7 days a week on 1800 020 080.
- If you need assistance to book a vaccination, you can SMS EVA (Easy Vaccine Access) to arrange a call-back at a time that suits you. EVA offers information and advice about COVID-19 vaccines and can help with:
    - locating an appropriate vaccine appointment
    - completing the COVID-19 vaccine booking during the call
    - locating a drop-in vaccination clinic, where appointments are not required
    - accessing an interpreter.
- SMS 'Hey EVA' to 0481 611 382 to arrange for a specially trained National Coronavirus Helpline call handler to call you back. You will receive an SMS reply asking for your name, preferred language, state, preferred date and time and best number for a call back. EVA is available every day from 7am to 10 pm (AEST).

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General Booster FAQs [*if needed*]

What are the current booster dose recommendations?

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- Adolescents aged 12 to 15 years in the following groups who completed their primary course 3 or more months ago may receive a single COVID-19 vaccine booster:
    - 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.
    - For more information on boosters in adolescents aged 12 to 15 years see: ATAGI recommendations on first booster dose in adolescents aged 12-15 years.
- A second booster dose (a fourth dose) is recommended for people in the following groups, 3 months after the first booster dose:
    - people 50 years or older
    - residents aged 16 years and older of an aged care or disability care facility
    - people aged 16 years and older who have complex, chronic, or severe medical conditions that increase their risk of severe illness from COVID-19
    - people aged 16 years and older with disability with significant or complex health needs, or multiple comorbidities that increase the risk of poor outcome from COVID-19.
- ATAGI has advised people aged 30 to 49 years old can receive a fourth dose if they choose.
    - The benefit for people in this age group is less certain and ATAGI encourages people in this age group to have a discussion with their regular medical provider to review their individual health needs and the benefits and risks of a second booster dose.
- For more information on booster and 4th doses, visit https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-your-vaccination/booster-doses#booster-doses