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.

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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.

References

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3. Chalkias S, McGhee N, Whatley JL, et al. Safety and Immunogenicity of XBB.1.5-Containing mRNA Vaccines. medRxiv. Published online 2023:2023-09. Available from: https://www.medrxiv.org/content/10.1101/2023.08.22.23293434v2 (Accessed 1/11/2023)
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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.

Tags:

Australian Technical Advisory Group on Immunisation (ATAGI) | COVID-19 | COVID-19 vaccines | Coronavirus (COVID-19)