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.

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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.

References

1. World Health Organization - Strategic Advisory Group of Experts on Immunization (SAGE). SAGE updates COVID-19 vaccination guidance 2023. Available from: https://www.who.int/news/item/28-03-2023-sage-updates-covid-19-vaccination-guidance (Accessed 20/04/2023).

2. Emergency Task Force European Medicines Agency. ETF statement on the use of the EMA approved bivalent original/Omicron BA.4-5 mRNA vaccines for primary series. 2022. Available from: https://www.ema.europa.eu/en/documents/other/etf-statement-use-ema-approved-bivalent-original/omicron-ba4-5-mrna-vaccines-primary-series_en.pd (Accessed 20/04/2023).
3. UK Health Security Agency. Immunisation against infectious disease. The Green Book: Chapter 14a- COVID-19 - SARS-CoV-2. 2023. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1141541/Greenbook-chapter-14a-9March2023.pdf (Accessed 20/04/2023).
4. Moderna Inc. Vaccines and Related Biological Products Advisory Committee Presentation January 26, 2023: Moderna COVID-19 Bivalent Vaccines Primary Series and Booster. 2023. Available from: https://www.fda.gov/media/164810/download (Accessed 17/04/2023).
5. Andersson NW, Thiesson EM, Hansen JV, Hviid A. Safety of bivalent omicron-containing mRNA-booster vaccines: a nationwide cohort study. medRxiv 2023:2023.01. 21.23284855.
6. Shimabukuro T. COVID-19 mRNA bivalent booster vaccine safety. ACIP meeting presentation 24/2/2023. 2023. Available from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-24/COVID-02-Shimabukuro-508.pdf (Accessed 17/04/2023).
7. Andersson NW, Thiesson EM, Baum U, et al. Comparative effectiveness of the bivalent BA. 4-5 and BA. 1 mRNA-booster vaccines in the Nordic countries. medRxiv 2023:2023.01. 19.23284764.
8. Lin D-Y, Xu Y, Gu Y, et al. Effectiveness of bivalent boosters against severe omicron infection. New England Journal of Medicine 2023;388:764-6.
9. Auvigne V, Tamandjou C, Schaeffer J, Vaux S, Parent du Chatelet I. Protection against symptomatic SARS-CoV-2 BA. 5 infection conferred by the Pfizer-BioNTech Original/BA. 4-5 bivalent vaccine compared to the mRNA Original (ancestral) monovalent vaccines–a matched cohort study in France. medRxiv 2023:2023.03. 17.23287411.
10. The Kirby Institute - University of New South Wales (UNSW) NCfIRaSN, Australian Red Cross Lifeblood , et al.,. Seroprevalence of SARS-CoV-2-specific antibodies among Australian blood donors: Round 4 update. 2022. Available from: https://kirby.unsw.edu.au/sites/default/files/COVID19-Blood-Donor-Report-Round4-Nov-Dec-2022.pdf (Accessed 20/04/2023).
11. International Vaccine Access Center JHBSoPH, World Health Organization, Coalition for Epidemic Preparedness Innovations,. Results of COVID-19 Vaccine Effectiveness Studies: An Ongoing Systematic Review. Forest Plots: Vaccine Effectiveness of Bivalent Ancestral Strain/Omicron-based Vaccines. 2023. Available from: https://viewhub.org/sites/default/files/2023-03/COVID19%20VE%20Studies_Bivalent%20VE%20Plots.pdf (Accessed 18/05/2023).
12. International Vaccine Access Center JHBSoPH, World Health Organization, Coalition for Epidemic Preparedness Innovations. Results of Studies Evaluating the Impact of SARS-CoV-2 Variants of Concern on COVID-19 Vaccines: An Ongoing Systematic Review. Overview of neutralizing antibody responses in recipients of variantcontaining vs. ancestral virus-based vaccines. . 2023. Available from: https://viewhub.org/sites/default/files/2023-03/Laboratory%20Evidence%20Bivalent%20Vaccines.pdf (Accessed 18/05/2023).
13. Zou J, Kurhade C, Patel S, et al. Neutralization of ba. 4–ba. 5, ba. 4.6, ba. 2.75. 2, bq. 1.1, and xbb. 1 with bivalent vaccine. New England Journal of Medicine 2023;388:854-7.
14. Arashiro T, Arima Y, Kuramochi J, et al. Effectiveness of BA. 1-and BA. 4/BA. 5-containing bivalent COVID-19 mRNA vaccines against symptomatic SARS-CoV-2 infection during the BA. 5-dominant period in Japan. Open forum infectious diseases: Oxford University Press; 2023.

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