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ATAGI statement on defining 'up-to-date' status for COVID-19 vaccination

This guidance summarises 'up-to-date' vaccination status, as defined by the Australian Technical Advisory Group on Immunisation (ATAGI) in their clinical guidance for the use of COVID-19 vaccines.

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Summary

- This guidance summarises 'up-to-date' vaccination status, as defined by the Australian Technical Advisory Group on Immunisation (ATAGI) in their clinical guidance for the use of COVID-19 vaccines.
- This 'up-to-date' guidance serves as the basis for policies for the public health management of the COVID-19 pandemic in a domestic context. It forms the basis of the due and overdue rules for the Australian Immunisation Register (AIR). Advice may change as the pandemic evolves.
- The application of this advice across various settings is a matter for governments and/or private entities as appropriate taking into account factors such as risk, proportionality, as well as local variables and priorities.

- All individuals aged 16 years and over are recommended to receive a COVID-19 vaccine booster dose to maintain an "up-to-date" status. This booster dose is now recommended from 3 months after the last primary dose. This is called the 'due date'.
- Initial protection is reduced and increased waning is evident following primary COVID-19 vaccination (usually 2 doses) against the Omicron variant. This warrants the inclusion of booster doses in a person's up-to-date status:
    - **Individuals aged 16 years and over** have previously been considered up-to-date with COVID-19 vaccination after completing an appropriate primary course of a Therapeutic Goods Administration (TGA) approved or recognised vaccine. To optimise protection from the Omicron SARS-CoV-2 variant, individuals should receive a booster dose 3 months after completion of their primary schedule. A person will be considered 'overdue' if a booster has not been received within 6 months of completing their primary schedule.
    - **Children and adolescents aged 5-15 years** are up-to-date after completion of a primary course of vaccination. A booster dose is not currently recommended for this age group.
    - **Severely immunocompromised individuals aged 5 years and over** require a 3rd primary dose of a COVID-19 vaccine from 2 months (and no later than 6 months) after dose 2 to remain up-to-date. Those who are aged 16 years and over are recommended a booster (4th) dose, 3 months after dose 3 of their primary vaccination course. However, for the purpose of being up-to-date in the AIR (which does not contain any information on medical conditions) only a total of 3 doses will be counted as being up-to-date in this subgroup.
    - **Individuals who have had prior COVID-19**, including asymptomatic SARS-CoV-2 infection, still require completion of the above vaccination schedule, but can defer receipt of the next dose for up to 4 months following their infection. This recommendation has changed from the previous 6-month interval. Some people may choose to be vaccinated prior to 4 months. Refer to ATAGI clinical guidance on people with a past SARS-CoV-2 infection.
- Vaccine schedules using mixed or the same brand of COVID-19 vaccine are acceptable for being considered up-to-date. The TGA is currently considering which vaccines, not already approved for use in Australia as a booster, will be recognised as valid by the Australia Immunisation Register, as a booster dose (e.g., if received overseas).

Table 1: COVID-19 vaccination schedules to be considered up-to-date

Age Group		**Primary dose 1 and 2[1], second dose recommended interval is vaccine brand dependent**	**Primary dose 3[2], usually given from 2 months after second dose**	**Booster dose[3] recommended from 3 months after last primary dose**
General Population	5–11 years	✓	not recommended	✗
	12–15 years	✓		✗
	16 years and over	✓		✓[4]
Severely Immuno-compromised	5–11 years	✓	✓	✗
	12–15 years	✓	✓	✗
	16 years and over	✓	✓[2]	✓[2][4]

People with evidence of previous SARS-CoV-2 infection[5]	5 years and over	Completion of vaccination according to above. The next dose can be deferred for up to 4 months from the date of diagnosis of the latest infection. For some people, prioritising vaccination sooner than 4 months after infection may be warranted.

✓: required ✗: not required

To be considered up to date with COVID-19 vaccination, an individual must have received all the required doses at the correct dose interval according to the recommendations above.

1 The recommended interval between the first two doses varies by vaccine and age group. 14 days is a minimum valid time frame for the first two doses to be considered 'up-to-date'. The primary course can be completed with any of the TGA-approved or TGA-recognised COVID-19 vaccines (only 1 dose is required if the Janssen COVID-19 vaccine was used for primary vaccination).

2 Severely immunocompromised individuals aged 5 years and older are recommended to have a 3rd COVID-19 vaccine dose as part of their primary course. This dose is usually recommended from 2 months but can be reduced to a minimum of 4 weeks in some instances. Severely Immunocompromised individuals aged 16 years and over are recommended 3 primary doses and a booster dose to be considered up-to-date from a clinical perspective. However, because the AIR does not contain any record of medical conditions, such individuals will only be assessed under the AIR as up-to-date based on receipt and timing of 3 vaccine doses (or 2 if received Janssen initially) as for people who are not immunocompromised.

3 Booster dose is a subsequent dose after an appropriate primary schedule based on choice of vaccine and immunocompromise status. Eligibility is from 3 months after last primary dose. The minimum time frame for a booster dose to be considered valid is 2 months. Although a booster dose at any time after 3 months is safe and effective, people who have not received a booster within 6 months of completing their primary series will be considered overdue.

4 Choice of vaccine is as per current ATAGI recommendations on booster doses, which may be updated as new data emerges and/or if additional vaccines are recommended. Currently, ATAGI recommends that either the Pfizer or Moderna vaccine is preferred over the AstraZeneca vaccine for use as a booster for age 18 years and over, and Pfizer is the only vaccine approved for use as a booster for age 16–17 years. Inadvertent use of a vaccine not recommended as a booster or for a specific age group may still be considered valid; providers should consult their state immunisation specialist service.

5 As specified per state/territory public health guidelines. Refer to the current Coronavirus Disease 2019 (COVID-19) Coronavirus Disease 2019 (COVID-19) CDNA National Guidelines for Public Health Units.

Introduction

ATAGI recognises the importance of providing guidance on a person's 'up-to-date' vaccination status from the clinical benefit perspective. This advice may serve as the basis for policies for the public health management of the COVID-19 pandemic in a domestic context.

This ATAGI advice considers a number of factors and scientific evidence, including but not limited to: the current widespread community transmission of SARS-CoV-2 in some jurisdictions, dominated by the Omicron variant; the recent shortening of the recommended booster vaccination interval and subsequent accelerated delivery of booster doses for all individuals aged 16 years and over; and the recommendation for receiving 3 primary doses in all individuals aged 5 years and over with severe immunocompromise.

Up-to-date vaccination status is defined by the number and timing of appropriate COVID-19 vaccine doses recommended for and received by an individual, according to their age and other factors. These recommendations aim to provide the optimal individual and/or population protective vaccination benefits (over risks) and take into account other factors, such as vaccine access. COVID-19 vaccine up-to-date status will likely need to be modified over time, with the ATAGI recommendations based on future changes in disease epidemiology and as new evidence becomes available regarding booster doses, including those that may be specifically targeting variants of concern (VOC).

ATAGI notes that the concept of being up-to-date with vaccination may be different to what has been required to be 'fully vaccinated', which is a term that has been used in the context of public health orders or mandates in various settings, including border control, quarantine, workplaces (e.g. aged care, health care), and in other select settings. These applications may involve legal and policy implications and are not within the remit of ATAGI but should be considered in the implementation of this advice. Appropriate vaccination requirements relating to international border settings are outside the remit of ATAGI and are a matter for other government policies.

The ATAGI COVID-19 up-to-date vaccination status recommendations will be utilised by the Australian Immunisation Register to assist in determining whether an individual has had the recommended vaccine doses, as outlined in Table 1.

Recommendations

ATAGI acknowledges that this change in definition of up-to-date status for COVID-19 vaccines may impact the status of an individual's COVID-19 immunisation certificate, and sufficient time should be provided to support implementation. It is recommended they be made effective by the end of March 2022.

Table 1 summarises the requirements for an individual to be considered up-to-date with COVID-19 vaccination according to age, medical conditions and time since vaccination.

Up-to-date COVID-19 vaccination status requires:

For individuals aged 16 years and over

- Receipt of a homologous (same brand) or heterologous (different brand) primary schedule of 2 doses of any TGA approved or TGA recognised COVID-19 vaccine at least 14 days apart, except for Janssen COVID-19 Vaccine where only 1 dose is required; and

Receipt of a booster dose of a TGA approved vaccine (Pfizer, Moderna, or AstraZeneca) at a recommended interval of 3 months after receipt of the last dose of a primary schedule, and not later than 6 months (i.e. within 3 months of becoming eligible). That is, an individual is considered not up-to-date at 6 months after the last dose of their primary course, unless they have received a booster dose with a TGA approved vaccine.

A booster can be given safely and effectively at any time after six months to become 'up-to-date' in the event that the booster had not been received earlier.

The TGA is currently considering which vaccines, not already approved for use in Australia as a booster, will be recognised as valid (e.g., if Novavax was given as a booster or a COVID-19 vaccine not available in Australia was received overseas).

For individuals aged 5 to 15 years

- Receipt of a homologous or heterologous primary schedule of two doses of any TGA approved or TGA recognised COVID-19 vaccine at least 14 days apart. A booster dose is currently not required. ATAGI will update advice on up-to-date status if and when boosters are recommended for children and adolescents in these age groups.

For individuals who are severely immunocompromised aged 5 years and over
(refer to detailed ATAGI advice)

- Receipt of an additional dose of a TGA approved vaccine or TGA recognised vaccine, due from 2 months after the 2nd primary dose, to complete the initial primary schedule (dose 3)*. This 3rd dose should usually be received within 6 months of dose 2.
- Of note, the AIR does not contain any record of medical conditions. Individuals who are severely immunocompromised will be considered up-to-date on the AIR if they meet dose number and interval requirements for people who are not immunocompromised.
- Those aged 16 years and over are recommended a booster (4th) dose, 3 months after dose 3 of their primary vaccination course. *People who are severely immunocompromised who received the Janssen COVID-19 vaccine require only 2 primary doses and an additional booster dose of a TGA approved vaccine.

For individuals with prior COVID-19

ATAGI recommends that individuals who have prior COVID-19 still go on to receive all of the recommended vaccine doses. For individuals with SARS-CoV-2 infection prior to commencing vaccination, or during the vaccination schedule, the next dose can be deferred for up to 4 months. This dose should be received by 4 months to remain up-to-date.

- However, some people may choose to be vaccinated prior to 4 months after infection. Refer to ATAGI clinical guidance on people with a past SARS-CoV-2 infection.

Additional considerations

ATAGI emphasises the importance of being up to date with immunisation particularly for those who are at higher risk of severe disease, such as older people and/or those with underlying special risk medical conditions, and for those who work in settings where limiting disease transmission is critical, e.g. health care and aged care settings. The risk of severe disease if infected by SARS-CoV-2 varies considerably with age, underlying medical conditions or treatment. While evidence shows that boosters increase direct protection against Omicron infection, and some indirect protection through reduced transmission is expected, the magnitude of this effect, its duration, and the overall indirect protection from boosters, is still unclear.

ATAGI continues to monitor this emerging evidence, both locally and internationally, and advice will be updated as indicated.

Rationale for including requirement of a booster dose in adults to be considered up-to-date for COVID-19 vaccination

ATAGI has previously provided advice on the SARS-CoV-2 Omicron variant and booster doses which outlined increased transmissibility and potential for reduced effectiveness of primary vaccination, as compared to previous variants. There has been rapid replacement of the previous Delta variant by Omicron (≥90% of cases) as the cause of infection in Australia as well as numerous other countries.[1]

Data have also steadily accumulated indicating that the numerous mutations[2] within the spike protein receptor binding domain of the Omicron variant facilitate immune escape and increase the likelihood of re-infection in individuals previously infected with earlier variants, and breakthrough infection of vaccinated individuals. Laboratory studies have shown up to a 122-fold reduction in neutralising antibody titres against Omicron in comparison to the ancestral strain.[3-6]

Early estimates of vaccine effectiveness against infection have similarly indicated lower initial vaccine effectiveness from two doses of Pfizer or AstraZeneca vaccine (36-88%)[7,8] against the Omicron variant which then wanes rapidly to 0-34% from about 4 months after the 2nd dose. A Pfizer booster dose appears to restore moderate levels of effectiveness against symptomatic Omicron infection (71-76%).[7] Vaccine effectiveness against hospitalisation with Omicron shows a similar pattern of waning, falling to 52% after a two-dose primary series. A booster dose increases vaccine effectiveness against hospitalisation to 88% (95% CI 78-93%)[9] . There have been no safety signals of concern for an earlier booster dose given from 3 months after the primary series where this is used overseas (e.g. United Kingdom).

Receipt of a primary schedule and a booster dose will provide individual protection from infection and hospitalisation with the Omicron variant, although these effects will wane. It is known that protection against onward transmission also wanes over several months after completing the primary series for the Delta variant.[10] This may be similar with the Omicron variant. It is expected that a booster will increase protection against symptomatic infection and this should lead to a parallel increase in protection against transmission, therefore providing some indirect protection to the wider population. However, evidence to confirm this, and the duration of protection, is awaited.

Individuals with previous COVID-19 are still recommended to complete their vaccination schedule. Early preprint evidence indicates that prior infection with the Delta or earlier variants is not completely protective against re-infection with the Omicron variant. South African data showed an increased risk of re-infection during the Omicron wave that was not present with previous Beta and Delta waves[11]. The data on Omicron infection and its protection against repeat Omicron infection are not yet available. As any infection occurring after the 26 November 2021 has the possibility of being due to either Omicron or Delta variant, to ensure a harmonised approach, ATAGI recommends boosting for all individuals with previous COVID-19. ATAGI has decreased the optional deferral period of vaccination after SARS-CoV-2 infection from 6 months to 4 months, due to the increased risk of re-infection with the Omicron variant, particularly for those who had a Delta variant infection in 2021.

At present, there are no booster recommendations for children aged 5-15 years of age. Should booster recommendations be adopted for these populations, this up-to-date advice will be reviewed accordingly.

Table 2: TGA approved and recognised vaccines

TGA approved vaccines	TGA recognised vaccines
Comirnaty (Pfizer Australia Pty Ltd)	Coronavac (Sinovac)
Vaxzevria (AstraZeneca Pty Ltd)	Covishield (AstraZeneca/Serum Institute of India)
COVID-19 Vaccine Janssen (Janssen-Cilag Pty Ltd)	Covaxin (manufactured by Bharat Biotech, India)
Spikevax (Moderna Australia Pty Ltd)	BBIBP-CorV (manufactured by Sinopharm, China) for individuals aged <60 years
Nuvaxovid (Biocelect Pty Ltd on behalf of Novavax Inc)	Sputnik V (Gamaleya Research Institute)

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