Australian Government
Department of Health

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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

Type:
News

Intended 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 (4th 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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