Memo

The use of booster vaccinations in 12–17-year-olds: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	21 February 2022
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	Astrid Koornneef, Director, National Immunisation Programme Allison Bennett, Manager, System Enablers, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Consideration

Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the use of COVID-19 booster vaccinations in 12–17-year-olds.

Background and context

2. The adult formulation (30 µg) of the Pfizer COVID-19 vaccine (Comirnaty) has been granted provisional approval for a primary course schedule from Medsafe (New Zealand) for use in those aged 12 years and older, given as 2 doses at least 3 weeks apart.[1]

3. On 28 October 2021, Medsafe updated the provisional approval for the Pfizer vaccine to state: "*a booster dose of Comirnaty may be administered intramuscularly at least 6 months after completion of the primary course in individuals aged 18 years of age and older.*"[1]

4. In November 2021, CV TAG recommended the use of boosters in those aged over 18 years, providing a list of priority groups. The most recent recommendation about booster doses was provided by CV TAG on 1 February 2022, stating "*a booster dose of the COVID-19 vaccine should be given from 3 months after the primary course to all eligible people aged 18 years and over, including immunocompromised individuals and pregnant persons.*" A list of priority groups was again provided with this recommendation.

5. The Ministry of Health sought clinical and scientific advice from CV TAG on the need for and use of the adult formulation of the Pfizer vaccine as a booster dose in those aged 12-17-years-old, including advice on timing after a primary course, and whether any subgroups require prioritisation.

Clinical trial evidence

6. Pfizer conducted a randomised blinded placebo-controlled trial of approximately 10,000 participants aged ≥16 years, including 78 people that were 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-boosted group.[2] Preliminary findings therefore suggest an increase of vaccine effectiveness against documented SARS-CoV-2 infection in adolescents in this age group who received a booster compared to adolescents who have recently completed the primary vaccination course. Data are still accumulating about waning of protective vaccination effects in periods of Omicron-dominance.

Advice from other jurisdictions

7. Recommendations have been made by several advisory bodies in other countries about booster vaccinations for 12–17-year-olds. Some countries have broken this age group down further into 12–15-year-olds and 16–17-year-olds and made differential recommendations. These recommendations are summarised here:

   a. ***Australian Technical Advisory Group on Immunisation (ATAGI)***

      i. *16–17-year-olds:* On 3 February 2022, ATAGI recommended a booster vaccination with Pfizer for all 16–17-year-olds who have previously received any Australian Therapeutic Goods Administration (TGA) approved or recognised vaccines for their primary vaccine schedule, from 3 months after receiving their last primary dose.[3] This includes those who were aged under 16 years when they received their last primary dose and are now aged 16 years.

         - Those who are severely immunocompromised and have received a third primary dose of COVID-19 vaccine 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.
         - Those who have recently had a 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.
         - Those who have previously developed myocarditis or pericarditis after a primary dose should discuss the benefits and risks of a COVID-19 vaccine booster dose with their cardiologist/treating doctor.
         - People with previous anaphylaxis to an mRNA vaccine should not receive a Pfizer COVID-19 vaccine booster dose, and no other vaccines have yet been approved as boosters.

      ii. *12–15-year-olds:* No advice to date.

   b. ***Joint Committee on Vaccination and Immunisation (JCVI), United Kingdom***

      i. *16–17-year-olds:* JCVI advises that booster vaccinations with the adult formulation of the Pfizer vaccine should be offered to all persons aged 16–17 years, given at

least 3 months after completion of the primary course.[4] No advice has been given on timing after infection.

ii. *12–15-year-olds:* JCVI advises that booster vaccinations with the adult formulation of the Pfizer vaccine should be offered to 12–15-year-olds who are in a clinical risk group or who are a household contact of someone (of any age) who is immunosuppressed.[4] Booster vaccinations with the adult formulation of the Pfizer vaccine should also be offered to 12–15-year-olds who are severely immunocompromised and who have had a third primary dose.[4] No advice has been given about the timing after infection.

c. ***Advisory Committee on Immunization Practices (ACIP), USA.***[1]

i. *12–15-year-olds and 16–17-year-olds:* all 12–17-year-olds should receive a booster dose 5 months after their initial Pfizer vaccination series.[5] No advice has been given on timing after infection.

d. ***National Advisory Committee on Immunization (NACI), Canada***

i. *12–15-year-olds and 16–17-year-olds:* A booster dose of an mRNA COVID-19 vaccine (Pfizer adult formulation preferred) may be offered ≥6 months after completion of a primary COVID-19 vaccine series to adolescents 12–17 years of age:[6]

- with an underlying medical condition at high risk of severe illness (specific conditions listed [6]) due to COVID-19, including those who are immunocompromised and who received a three-dose primary series,
- who are residents of congregate living settings (e.g., shelters, group homes, quarters for migrant workers, correctional facilities),
- who belong to racialised and/or marginalised communities disproportionately affected by COVID-19.

ii. No recommendations for booster doses for the wider general adolescent population 12–17 years of age have been made to date.

iii. NACI recommends waiting 3 months after COVID-19 infection before administering a booster for all vaccinated people aged 12 and over, provided it is at least 6 months after completing a primary series.[7]

8. ATAGI and NACI cite substantial evidence supporting these decisions:[3, 6]

a. Epidemiology (e.g., a rise in the proportion of COVID-19 cases observed in younger age groups with Omicron compared to previous variants),

b. Disease severity (e.g., in indigenous 12–17-year-olds, and those with 2 or more chronic conditions),

c. Decreased effectiveness of the vaccine against Omicron,

d. Waning efficacy after a primary course in adolescents,[8]

e. Efficacy of booster in those aged 16–17 years old included in the Pfizer booster trial (no data available in 12–15-year-olds),[9]

[1] Note: official statement by ACIP not yet published, and statements here are based on Centers of Disease Control and Prevention (CDC) statements.

f. Potential reductions in transmission in 16–17-year-olds (based on results for Alpha and Delta variants after primary vaccination), and

g. Safety data (e.g., preliminary evidence from Israel, where rates 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).[8]

Recommendations

9. CV TAG met on Tuesday 8 February, Tuesday 15 February, and Friday 18 February 2022 to consider guidance on booster doses for 12–17-year-olds.

10. **CV TAG noted that:**

a. **Overall, there is very limited data on which to base any recommendations about boosters in this age group.**

b. The goal of offering booster doses in New Zealand is to prevent severe disease caused by SARS-CoV-2, and to reduce burden on hospitals and other healthcare providers.

c. Young New Zealanders are well protected against severe disease with a primary vaccination course. Healthy 12-17-year-olds who do not suffer from chronic or underlying conditions and who are not on immunosuppressant medication are unlikely to have significant additional health benefit from a third (booster) vaccination at this stage.

d. Māori and Pacific peoples are at an increased risk of severe disease and hospitalisation,[10] and therefore require prioritisation and targeted, community-led campaigns. Increasing the vaccination coverage of first and second doses, particularly for Māori and Pacific peoples over the age of 5 years, should remain the priority of the COVID-19 vaccination programme in New Zealand.

e. Some 16–17-year-olds have finished school and may be in the workforce, tertiary study, or communal accommodation settings, which places them at greater risk of exposure to SARS-CoV-2.

f. While the AstraZeneca vaccine has been used as a booster in the adult population, it is not currently indicated for use in those aged under 18 years of age. Other COVID-19 vaccines (e.g. Janssen, Novavax) also are not approved for use in this age group at this time.

g. Many peak bodies internationally (including ATAGI, JCVI and ACIP) have recommended all 16–17-year-olds receive a booster dose. NACI in Canada only recommend its use in those at-risk and at a ≥6 months interval. Advice for 12–15-year-olds varies from only recommending boosters for at-risk adolescents (Canada, UK), recommending all 12–15-year-olds receive a booster (US), and some have yet to provide advice (Australia).

h. Recommendations from the Australian, UK, USA and Canadian peak bodies about the interval between primary and booster doses for adolescents range from 3 to 6 months.

i. **Pfizer are yet to submit an application (and data) to Medsafe for the use of the booster in this age group. As a result, Medsafe have not assessed the use of the booster in this age group.** Data on the quality, safety, reactogenicity and efficacy of use of the Pfizer vaccine as a booster in 12–17-year-olds are likely to be submitted to Medsafe by Pfizer for consideration in late February or early March. The timeframe for a decision depends on the extent of the data and if expert advice is required from the Medicines Assessment Advisory Committee. Therefore, CV TAG recommendations would be for off-label use in the meantime.

11. **CV TAG recommends that:**

a. **For 16-17-year-olds:**

i. A single Pfizer booster dose be made available to all 16–17-year-olds who wish to receive it.

ii. Further to this, a Pfizer booster dose is **recommended** in 16–17-year-olds who are at higher risk of COVID-19 severe disease and hospitalisation. At-risk groups include:

- Adolescents with an underlying health condition or immunocompromise that increases the risk of severe disease (See Appendix 1), including those in 11.a.iii below
- Māori and Pacific adolescents, due to the greater risk of severe disease and hospitalisation
- Adolescents who are household contacts of persons (of any age) who are severely immunocompromised (as defined in the Ministry of Health Immunisation Handbook, these individuals are eligible for a three-dose primary course), noting that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunocompromised.

iii. Those who have received a third primary dose of COVID-19 vaccine (because of severe immunocompromise) should also receive a booster dose (4th dose).

iv. 16–17-year-olds who have recently had a SARS-CoV-2 infection and are now eligible for a booster based on the recommendations above are recommended to defer their booster dose for 3 months after infection.

b. **For 12-15-year-olds:**

i. **Use of a booster dose in 12-15-year-olds is not currently recommended**.

ii. Clinicians may consider giving a booster dose to 12-15-year-olds who are clinically at-risk (as defined in Appendix 1), including those who received a three-dose primary course due to severe immunocompromise. Advice for clinicians is available from IMAC.

iii. Any wider recommendations will be deferred until after Medsafe has received and assessed an application from Pfizer in this age group.

c. **With regard to timing**, a booster dose in all eligible populations described here should be administered at least 3 months after the second dose, or in line with the timing for the general population.

d. **People with previous anaphylaxis** to an mRNA vaccine or other contraindications may not be advised to receive a Pfizer COVID-19 vaccine booster dose. Those who have previously developed myocarditis or pericarditis after a primary dose should discuss the benefits and risks of receiving a Pfizer booster dose with their cardiologist/treating doctor. Use of other vaccines as boosters in these groups can be considered on an individual basis. Support for clinicians on this decision-making is available from IMAC.

e. Consideration should be given to equity and whānau-based approaches and ensuring that other immunisation programmes are not compromised, e.g., measles and HPV vaccination.

12. **Ongoing concern was noted around formal and informal vaccine mandates requiring booster doses in this age group, and the associated implications for access to work, educational facilities, and recreational facilities.**

13. CV TAG will continue to monitor all relevant information and will update their recommendations on boosters in 12–17-year-olds as further evidence becomes available.

Dr Ian Town
Chief Science Advisor and
Chair of the COVID-19 Vaccine Technical Advisory Group

Appendix 1: Underlying health condition or conditions of immunocompromise [11]

Note: This list is not exhaustive, clinicians may use their judgement for conditions that are not listed here that are associated with severe outcomes from COVID-19 infection.

- Chronic lung disease including bronchiectasis, cystic fibrosis, BiPAP for OSA
- Non-repaired congenital heart disease, acquired heart disease or congestive heart failure
- Poorly controlled asthma (regular symptoms occurring in a usual week that affect the patient's quality of life and includes anyone with an admission in the last 2 years or anyone with 2 or more courses of steroids in the last two years)
- Obesity (BMI ≥95th centile for age)
- Diabetes (insulin-dependent)
- Chronic kidney disease (GFR <15 ml/min/1.73m2)
- Severe cerebral palsy (or neurodevelopmental disorder)
- Complex genetic, metabolic disease or multiple congenital anomalies
- Trisomy 21/Downs Syndrome
- Primary or acquired immunodeficiency
- Haematologic malignancy and post-transplant (solid organ or HSCT in last 24 months)
- On immunosuppressive treatment including chemotherapy, high-dose corticosteroids, biologics or DMARDS

References

1. Medsafe - New Zealand Medicines and Medical Devices Safety Authority. *New Zealand Data Sheet, Comirnaty Covid-19 Vaccine*. 2021; Available from: https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.
2. Food and Drug Administration (FDA). *Pfizer-Biontech COVID-19 Vaccine Review Memorandum - December 8, 2021*. 2021 [cited 2022 16 February]; Available from: https://www.fda.gov/media/154869/download.
3. Australian Technical Advisory Group on Immunisation (ATAGI). *ATAGI recommendations for use of Pfizer COVID-19 vaccine as a booster dose in adolescents aged 16-17 years*. 03 February 2022; Available from: https://www.health.gov.au/news/atagi-recommendations-for-use-of-pfizer-covid-19-vaccine-as-a-booster-dose-in-adolescents-aged-16-17-years.
4. Joint Committee on Vaccination and Immunisation (JCVI). *JCVI issues new vaccination advice for children and young people*. 22 December 2021; Available from: https://www.gov.uk/government/news/jcvi-issues-new-vaccination-advice-for-children-and-young-people.
5. Centers for Disease Control and Prevention (CDC). *CDC Expands Booster Shot Eligibility and Strengthens Recommendations for 12-17 Year Olds*. 05 January 2022; Available from: https://www.cdc.gov/media/releases/2022/s0105-Booster-Shot.html#:~:text=Today%2C%20CDC%20is%20endorsing%20the,initial%20Pfizer%2DBioNTech%20vaccination%20series.
6. National Advisory Committee on Immunization (NACI). *An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI) Rapid response: Guidance on the use of booster COVID-19 vaccine doses in adolescents 12-17 years of age*. 28 January 2022; Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/guidance-use-booster-covid-19-vaccines-adolescents-12-17-years-age.pdf.
7. National Advisory Committee on Immunization (NACI). *Summary Of National Advisory Committee On Immunization (NACI) Rapid Response Of February 4, 2022. Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2*. 4 Feb 2022; Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/naci-summary-rapid-response-updated-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.pdf.
8. Oliver, S. and Centers for Disease Control and Prevention (CDC). *Recommendation Framework: Pfizer-BioNTech vaccine booster doses in 12–15 year olds. ACIP Meeting January 5, 2022*. 5 Jan, 2022; Available from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/06_COVID_Oliver_2022-01-05.pdf.
9. Food and Drug Administration (FDA). *CBER assessment of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) administered to individuals 16 to 17 years of age after completion of a primary vaccination series with the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY*. 8 Dec 2021; Available from: https://www.fda.gov/media/154869/download.
10. Steyn, N., Binny, R. N., Hannah, K., Hendy, S. C., James, A., Lustig, A., Ridings, K., Plank, M. J., Sporle, A., *Māori and Pacific people in New Zealand have a higher risk of hospitalisation for COVID-19.* New Zealand Medical Journal, 2021. **134**(1538).

11. Starship Child Health. *COVID-19 disease in children*. Clinical guidelines 2022 [cited 2022 18 February]; Available from: https://starship.org.nz/guidelines/covid-19-disease-in-children/.