

Research Brief

COVID-19 vaccination for children & adolescents

Executive Summary

Why is this issue important?

- Decisions on whether to vaccinate children and adolescents are based on scientific information about the burden of COVID-19 disease, and vaccine safety and efficacy. Information continues to evolve through clinical trials and real-world observations following vaccination of children and adolescents globally.
- Currently the Pfizer-BioNTech Covid-19 vaccine (Pfizer vaccine) is licensed for use in those aged 12 years and older (approved by the Therapeutic Goods Administration (TGA) on 23 July 2021).¹
- Policy considerations regarding vaccination of children and adolescents have centred around the direct effects of preventing illness and disease from COVID-19. The indirect impacts, such as recurrent lockdowns and school closures, also need to be considered. These have significant effects on the mental health, wellbeing and educational outcomes of children and adolescents.

What does the research tell us?

- COVID-19 can cause infection in children and adolescents that requires care in hospital, although this is uncommon, and can rarely cause death. The impacts of long-COVID are yet unknown.
- The Pfizer vaccine can safely protect those aged 12 years and older from infection, and is being used in many countries. Although clinical trials are underway, there are currently no data about the safety and efficacy of vaccines that will be in use in Australia among those younger than 12 years.
- We do not know how vaccinating children and adolescents impacts their ability to transmit to others, or the extent to which the Delta variant is changing the disease burden in children and adolescents. This will be important when considering vaccination for these groups.
- There are significant indirect effects of the pandemic on the mental health, learning and wellbeing of children and adolescents. These differentially impact those most disadvantaged. Prolonged school closures and lockdowns, in the absence of vaccination, can exacerbate these impacts.

Considerations for policy

- To protect children and adolescents in the community and keep schools open we should prioritise vaccination for teachers, early educators, and school staff.
- Parents and adults of all ages should be encouraged to be vaccinated now to protect children and schools from outbreaks.
- Continue to vaccinate at-risk children and adolescents aged 12 years and older. Those who are living with at-risk household members should be considered for vaccination.
- Everyone 16 years and older should be vaccinated.
- Consider vaccinating those aged 12-15 years as soon as possible, taking into account pragmatic considerations of the national vaccine roll-out.
- The indirect effects of the pandemic on children and adolescents should be considered when weighing up when and whether to vaccinate children and adolescents.
- Continue and encourage Australia's contribution to global vaccine equity.

This document outlines key considerations to inform policy on vaccinating children and adolescents in Australia with the COVID-19 vaccine.

COVID-19 vaccination for children & adolescents

Policy about vaccinating children and adolescents focuses on the burden of disease and death from COVID-19.

However, we know the indirect effects of the pandemic also contribute to the health and wellbeing of children and adolescents, and these should also be considered in vaccination policy.

Why is this issue important?

It is important to consider the widespread needs of children and adolescents when thinking about Australia's vaccination program.

Policy considerations regarding vaccination of children and adolescents have centred around preventing illness and disease from COVID-19. This is important as we know that severe illness and death from COVID-19, although rare, does occur in children and adolescents. Once the community is opened up and public health restrictions are relaxed, unvaccinated children and adolescents will remain vulnerable to infection and disease.

The indirect impacts of recurrent lockdowns and school closures also need to be included in policy considerations. These have significant effects on the mental health, wellbeing and educational outcomes of children and adolescents.

Whether to vaccinate children and adolescents with a COVID-19 vaccine is based on scientific information about safety and efficacy, and the burden of disease. This information continues to evolve through clinical trials and observations of vaccine rollout among children and adolescents globally. We have a safe and efficacious COVID-19 vaccine for children and adolescents aged 12 years and older - the Pfizer vaccine, which was approved by the TGA on 23 July 2021.¹

The main benefits of vaccinating children and adolescents include:

- Protecting them from illness and death,
- Minimising the need for school closures, and subsequent negative indirect impacts.

What does the research tell us?

Vaccination is important to prevent severe disease and death from COVID-19.

Severe disease, although uncommon, does occur in children and adolescents.² There are specific groups for whom the risk is greater, including those with medical conditions. Multisystem inflammatory syndrome in children (MIS-C) can also occur, which is a delayed, post-COVID-19 complication with varied symptoms that affect several organs and systems in the body. Risk of death from COVID-19, even in those with medical conditions, is very low. However, some deaths will occur in the absence of vaccination.

Long-COVID in children and adolescents is not well understood. There are insufficient data on its incidence in children and adolescents and how long it lasts, as well as its causes.³ Without a better understanding of long-COVID, it is difficult to factor this into the risk-benefit ratio of vaccination.

In countries with high vaccine coverage in adults, unvaccinated people, including children and adolescents, carry the burden of COVID-19 infections.⁴ Importantly, even though the number of infections is greatest among children and adolescents in this situation, the burden of hospitalisations and deaths still remains greatest in older age groups.⁵

There are significant indirect effects of the pandemic on the mental health, learning and wellbeing of children and adolescents.⁶

Prolonged school closures and lockdowns exacerbate these impacts, differentially affecting those living with disadvantage, diminishing social mobility and negatively impacting future economic productivity.⁷⁻⁹

There have been substantial increases in admissions to paediatric hospitals for mental health, substance use and suicide attempts.¹⁰

Studies are continually emerging that highlight the negative effects of the pandemic on the mental health of children and adolescents.¹¹⁻¹³

Prolonged school closures and lockdowns, in the absence of vaccination, exacerbate these impacts.

The Pfizer vaccine is safe and efficacious for those 12 years and older.

The Pfizer vaccine is currently TGA approved for those 12 years and older, while the Moderna mRNA vaccine is currently under review for use in Australia.^{1,14}

The data from clinical trials of Pfizer and Moderna suggest these vaccines are safe and efficacious.^{15,16}

Canada, the United States, Germany, France, Italy, the Netherlands, Spain, Singapore and Israel, among others, are vaccinating all those aged 12 years and older. The United Kingdom is vaccinating all those aged 16 years and older, those aged 12-15 years who are at-risk, and also have plans to vaccinate those living with at-risk family members.¹⁷

There have been very rare reports of myocarditis (inflammation of heart muscle) and pericarditis (inflammation of heart lining) among children, adolescents and adults after receipt of mRNA vaccines (Pfizer and Moderna) in the United States,^{18,19} Canada,²⁰ and Israel.²¹ Most cases have responded quickly to treatment.²² Surveillance for this rare condition is ongoing. Anyone receiving a mRNA COVID-19 vaccine should be counselled about the risk of myocarditis and pericarditis, and encouraged to attend for medical care if they develop relevant symptoms.

There are no data on the safety or efficacy of vaccines in children younger than 12 years.

Clinical trials of the Pfizer and Moderna vaccines in this group, including infants as young as 6 months, are ongoing. Preliminary data are not yet available. The United States Food and Drug Administration asked Pfizer and Moderna, in July 2021, to add more participants to these clinical trials, to assess the likelihood of developing myocarditis or pericarditis.²³

While the supply of vaccines is limited, it is likely that the best community outcomes will be achieved if adults are protected first.

Available data suggests that vaccinating adults first will do more to protect other adults and children in the community, compared to vaccinating children and adolescents first.²⁴

The recent Doherty modelling report found that vaccinating those 16 years and above will have most impact on reducing transmission, and the

incremental benefit of vaccinating those aged 12-15 years on preventing transmission was minimal.²⁴

This suggests that vaccination of those 16 years and older will be an important component in controlling the pandemic in Australia.

Vaccination of children and adolescents must take into account several practical considerations, including:

- **The current limited supply of mRNA vaccines in Australia.**
- **Priority adult groups in Australia that are still unvaccinated.** There are still large gaps in vaccination of adults in high-risk settings, adults at greater risk of severe illness or death from COVID-19, and adults in priority groups in distinct geographical areas.
- **Vaccination of high-risk groups, especially older adults, remains very low in many countries in the world.** Global vaccine equity is critical to reducing global transmission and reducing the risk of emergence of new variants of concern.²⁵ The global context therefore remains highly relevant to national policy.

Where are the research gaps?

There are insufficient data about the disease caused by the Delta variant in children and adolescents. The Delta variant is more transmissible than other variants, and makes the control of outbreaks difficult, even when public health measures are in place.²⁶ There is some evidence suggesting that the Delta variant could lead to more severe disease in all people, including children and adolescents, compared with other variants.²⁷ More evidence about the role of the Delta variant in COVID-19 disease in children and adolescents is needed.

Long-COVID in children and adolescents is not well understood. Without a better understanding, it is difficult to factor long term effects into decisions regarding vaccination.

We do not know if vaccinating children and adolescents will help to decrease the spread of COVID-19. There are insufficient data to know if vaccinating children and adolescents will prevent spread in the household, schools or community.

There are no data on the safety or efficacy of vaccines in children younger than 12 years. More information is needed before recommendations can be made.

Considerations for policy and practice

The following considerations highlight the health and wellbeing of children and adolescents as a priority for Australian vaccine policy and practice.

1. Some children and adolescents should be vaccinated now

At-risk children and adolescents 12 years and older:

- The Pfizer vaccine is TGA approved, safe and efficacious for this population. At-risk children and adolescents in this age group who are at a higher risk of severe COVID-19 outcomes have been approved as a priority for vaccination in Australia.²⁸
- Continue to vaccinate at-risk children and adolescents aged 12 years and older.
- Children and adolescents who are living with at-risk adult household members should be considered for vaccination.

Adolescents aged 16 to 18 years:

- The Pfizer vaccine is TGA approved, safe and efficacious for this population, and is projected to be available to them from 30 August 2021.²⁹
- The eligibility population in Doherty modelling included this group, indicating them to be an important group for vaccination.
- Consider everyone 16 years and above for vaccination now.

Children and adolescents 12-15 years:

- This age group should be vaccinated as soon as possible, taking into account pragmatic considerations.

2. Keeping schools and early childhood education and care centres open should be a national COVID-19 policy priority. This means we must consider the direct and indirect effects of the pandemic on children and adolescents.

Right now:

- Prioritise teachers, early educators, and school staff for vaccination. This will help protect children and adolescents in the community and help keep schools open.
- Parents and adults of all ages should be encouraged to be vaccinated now to protect their children, and schools, from outbreaks.

3. Some vaccination decisions require more research

Children younger than 12 years:

- There is no COVID-19 vaccine currently licensed in this age group in Australia.
- We need to wait for sufficient data on disease burden, and vaccine safety and efficacy, before we consider vaccinating this population, including at-risk children in this age group.

4. We must consider our role in helping to vaccinate populations around the world. We encourage Australia's contribution to global vaccine equity.

Summary

- Continue to vaccinate those 12 years and above who are at risk. Consider including those who are living with at-risk household members.
 - Vaccinate those 16 years and above now.
 - When appropriate, vaccinate those 12-15 years more broadly.
 - Prioritise teachers, early educators and school staff for vaccination.
- Encourage all parents and adults to be vaccinated to protect children and adolescents.

This report was prepared by members of the **MCRI COVID-19 Governance Group** which draws on experts in paediatrics, mental health, epidemiology, public health, infectious disease, immunity, child development, and vaccine development and communication.

MCRI COVID-19 Governance Group co-chairs:



Prof Sharon Goldfeld Prof Andrew Steer

Technical enquiries: belle.overmars@mcri.edu.au
Media enquiries: media@mcri.edu.au

Murdoch Children's Research Institute
50 Flemington Road Parkville, Victoria, 3052 Australia
www.mcri.edu.au/covid-19

References

1. Therapeutic Goods Administration (TGA). TGA Provisional Approval of Pfizer-BioNTech COVID-19 vaccine to include 12-15 years age group Canberra: Australian Government Department of Health; 2021 [updated Jul 23; cited 2021 Aug 11]. Available from: <https://www.tga.gov.au/tga-provisional-approval-pfizer-biontech-covid-19-vaccine-include-12-15-years-age-group>.
2. Zimmermann P, Curtis N. Why is COVID-19 less severe in children? A review of the proposed mechanisms underlying the age-related difference in severity of SARS-CoV-2 infections. *Archives of Disease in Childhood*. 2021;106(5):429-39.
3. Munblit D, Sigfrid L, Warner JO. Setting Priorities to Address Research Gaps in Long-term COVID-19 Outcomes in Children. *JAMA Pediatrics*. 2021.
4. Mallapaty S. Will COVID become a disease of the young? : *Nature*; 2021 [updated Jul 8; cited 2021 Aug 11]. Available from: <https://www.nature.com/articles/d41586-021-01862-7>.
5. Our World In Data. Case fatality rate of COVID-19 by age: Our World In Data; 2021 [cited 2021 Aug 11]. Available from: <https://ourworldindata.org/mortality-risk-covid#case-fatality-rate-of-covid-19-by-age>.
6. Chanchlani N, Buchanan F, Gill PJ. Addressing the indirect effects of COVID-19 on the health of children and young people. *CMAJ*. 2020;192(32):E921-e7.
7. Brown N, Te Riele K, Shelley B, Woodroffe J. Learning at home during COVID-19: effects on vulnerable young Australians. Tasmania, Australia: Peter Underwood Centre for Educational Attainment, University of Tasmania; 2020.
8. Yoshikawa H, Wuermler AJ, Britto PR, Dreyer B, Leckman JF, Lye SJ, et al. Effects of the Global Coronavirus Disease-2019 Pandemic on Early Childhood Development: Short- and Long-Term Risks and Mitigating Program and Policy Actions. *The Journal of pediatrics*. 2020;223:188-93.
9. Roubinov D, Bush NR, Boyce WT. How a Pandemic Could Advance the Science of Early Adversity. *JAMA Pediatrics*. 2020;174(12):1131-2.
10. Children First Canada. Kids are in Crisis - Canada's Top Advocates and Experts Unite to Declare #codePINK Canada: Children First Canada; 2021 [updated May 19; cited 2021 Aug 11]. Available from: <https://childrenfirstcanada.org/code-pink/kids-are-in-crisis-canadas-top-advocates-and-experts-unite-to-declare-codepink/>.
11. The Royal Children's Hospital Child Health Poll. COVID-19 pandemic: Effects on the lives of Australian children and families. The Royal Children's Hospital Melbourne, Parkville, Victoria 2020 July 2020. 8 p.
12. Australian Institute of Health and Welfare. COVID-19 and the impact on young people Canberra: Australian Government; 2021 [updated Jun 25; cited 2021 Aug 11]. Available from: <https://www.aihw.gov.au/reports/children-youth/covid-19-and-young-people>.
13. Children's Health Queensland Hospital and Health Service. Mental health of one in five Australian children impacted by pandemic Queensland: Queensland Government; 2020 [updated Oct 13; cited 2021 Aug 11]. Available from: <https://www.childrens.health.qld.gov.au/media-release-children-mental-health-impacted-by-pandemic/>.
14. Therapeutic Goods Administration (TGA). TGA grants provisional determination for the Moderna COVID-19 vaccine, Elasmomeran Canberra: Australian Government Department of Health; 2021 [updated Jun 24; cited 2021 Aug 11]. Available from: <https://www.tga.gov.au/media-release/tga-grants-provisional-determination-moderna-covid-19-vaccine-elasmomeran>.
15. Moderna. Moderna Announces TeenCOVE Study of its COVID-19 Vaccine in Adolescents Meets Primary Endpoint and Plans to Submit Data to Regulators in Early June: Moderna; 2021 [updated May 25; cited 2021 Aug 11]. Available from: <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-teencove-study-its-covid-19-vaccine>.
16. Business Wire. Pfizer-BioNTech Announce Positive Topline Results of Pivotal COVID-19 Vaccine Study in Adolescents: Business Wire; 2021 [updated Mar 31; cited 2021 Aug 11]. Available from: <https://www.businesswire.com/news/home/20210331005503/en/>.
17. Morton B, Faulkner D. Covid: First 16 and 17-year-olds begin to get vaccine invites: BBC; 2021 [updated Aug 7; cited 2021 Aug 11]. Available from: <https://www.bbc.com/news/uk-58112765>.
18. Centers for Disease Control and Prevention (CDC). Myocarditis and Pericarditis U.S.: U.S. Department of Health and Human Services; 2021 [updated Jun 23; cited 2021 Aug 11]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>.
19. Centers for Disease Control and Prevention (CDC). COVID-19 Vaccine Safety Updates U.S.: CDC; 2021 [updated Jun 10; cited 2021 Aug 11]. Available from: <https://www.fda.gov/media/150054/download>.
20. Government of Canada. Health Canada updates Pfizer-BioNTech and Moderna COVID-19 vaccine labels to include information on myocarditis and pericarditis Canada: Government of Canada; 2021 [updated Jun 30; cited 2021 Aug 11]. Available from: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75959a-eng.php>.
21. European Medicines Agency. COVID-19 vaccine safety update: European Medicines Agency; 2021 [updated Jun 18; cited 2021 Aug 11]. Available from: https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-18-june-2021_en.pdf.
22. National Advisory Committee on Immunization (NACI). An Advisory Committee Statement (ACS): Recommendations on the use of COVID-19 Vaccines Canada: Public Health Agency of Canada; 2021 [updated Jul 22; cited 2021 Aug 15]. Available from: <https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/recommendations-use-covid-19-vaccines-en.pdf>
23. VOA News. FDA Asks Moderna, Pfizer to Add More Children to COVID-19 Vaccine Efficacy Studies U.S.: VOA News; 2021 [updated Jul 27; cited 2021 Aug 11]. Available from: <https://www.voanews.com/covid-19-pandemic/fda-asks-moderna-pfizer-add-more-children-covid-19-vaccine-efficacy-studies>.
24. McVernon J, Price D, Campbell T, Golding N, Baker C, Walker J, et al. Doherty Institute Modelling Report for National Cabinet. Melbourne: Peter Doherty Institute; 2021.
25. Bullen C. Calls for global strategy of 'maximum suppression' of COVID-19 Australia: Royal Australian College of General Practitioners (RACGP); 2021 [updated Apr 6; cited 2021 Aug 11]. Available from: <https://www1.racgp.org.au/newsgp/clinical/experts-call-for-global-strategy-of-maximum-suppre>.
26. Kupferschmidt K, Wadman M. Delta variant triggers new phase in the pandemic. *Science*. 2021;372(6549):1375-6.
27. Australian Government Department of Health. ATAGI statement regarding COVID-19 vaccines in the setting of transmission of the Delta variant of concern Canberra: Australian Government Department of Health; 2021 [updated Aug 2; cited 2021 Aug 11]. Available from: <https://www.health.gov.au/news/atagi-statement-regarding-covid-19-vaccines-in-the-setting-of-transmission-of-the-delta-variant-of-concern>.
28. State Government of Victoria. Vaccination information for children and teenagers Victoria: State Government of Victoria; 2021 [updated 2021 Aug 8; cited 2021 Aug 11]. Available from: <https://www.coronavirus.vic.gov.au/vaccination-information-children-and-teenagers>.
29. Australian Government Department of Health. When will I get a COVID-19 vaccine?. Canberra: Australian Government Department of Health; 2021 [updated Aug 19; cited 2021 Aug 20]. Available from: <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-vaccinated-for-covid-19/when-will-i-get-a-covid-19-vaccine>