

# COVID-19 Vaccination and Child and Adolescent Health

*This brief was prepared with input from members of the MCRI COVID-19 Governance Group which draws on experts in paediatrics, mental health, epidemiology, public health, infectious diseases, immunology, child development, vaccinology and vaccine communication.*

## Key Updates

- The United States Food and Drug Administration (FDA) has given Emergency Use Authorisation to the use of the Pfizer vaccine (using one third of the dose used in older age groups) in those aged between five and 11 years.
- A real-world study has demonstrated that two doses of the Pfizer vaccine reduces the risk of hospitalisation for COVID-19 by 93% in those aged 12-18 years, and found that no vaccinated teenagers were admitted to intensive care for treatment of COVID-19.
- Australian Technical Advisory Group on Immunisation (ATAGI) have recommended a third dose of COVID-19 vaccines, for people over 12 years of age who are immunocompromised, as part of their primary course.

## Executive Summary

### Why is this issue important?

- Decisions to recommend the vaccination of children and adolescents against COVID-19 are based on scientific information about the burden of disease, and vaccine safety and efficacy. Ongoing clinical trials and real-world observations following vaccination of children and adolescents across the globe are useful to inform policies and public health safety.
- The Pfizer-BioNTech COVID-19 vaccine (Pfizer vaccine), and the Moderna COVID-19 vaccine (SPIKEVAC) are licensed for use in those aged 12 years and older.
- Policy considerations regarding vaccination of children and adolescents have centred around the direct effects of reducing transmission and preventing illness from COVID-19.
- The indirect impacts, such as recurrent lockdowns, school closures and school outbreak management, have significant effects on the mental health, wellbeing and educational outcomes of children and adolescents, and were also taken into account in the decision by ATAGI to approve the vaccines for use in Australian adolescents.

### What does the research tell us?

- Since the Delta variant, children and adolescents make up an increasing proportion of COVID-19 cases.
- COVID-19 can cause infection in children and adolescents that requires care in hospital, although this is uncommon, and rarely causes death. The impacts of long-COVID are yet unknown but based on 18 months of experience, most children have no persisting symptoms.

## Executive Summary cont

- 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. Current school outbreak management is disruptive to face to face learning.

### For those 12 years and older:

- The Pfizer vaccine is safe and protects from symptomatic infection and severe disease. Moderna also protects from symptomatic infection in adolescents and severe disease in adults. Both vaccines are routinely used in many countries.
- A real-world study of 464 adolescents aged 12-18 years from the United States demonstrated that two doses of Pfizer reduced hospitalisation for COVID-19 by 93%. The study included 179 adolescents with COVID-19 and 285 non-infected controls with a mean age of 15 years. Of the 179 COVID-19 cases, 97% were unvaccinated, and the 77 adolescents admitted to hospital and 2 subsequent deaths were all unvaccinated. The study was conducted during the predominance of the Delta variant, and reiterates the importance of vaccination to reduce severe disease in adolescents.<sup>2</sup>

### For children between five and 11 years of age:

- A clinical trial of 2,268 children using a smaller dose of the Pfizer vaccine administered three weeks apart found that immune responses were at least similar to the higher dose used in adolescents and young adults. The vaccine had 91% efficacy against symptomatic infection.<sup>1</sup>
- The United States has given Emergency Use Authorisation for the use of the smaller dose in children aged between five and 11 years of age.

### For children six months to five years of age:

- Pfizer and Moderna trials involving those from six months to five years of age are ongoing.

### For newborns and young infants:

- Vaccination of pregnant women builds antibodies against COVID-19 that might protect their infant. Antibodies made after a pregnant woman received an mRNA COVID-19 vaccine were found in umbilical cord blood. More data are needed to determine how these antibodies, similar to those produced with other vaccines, may provide protection to the baby.<sup>3</sup>
- Antibodies against COVID-19 are also detected in human milk after vaccination in pregnancy, which may further help protect breastfed newborns.<sup>4,5</sup>

## Considerations for policy

- To protect children under 12 years of age, continued efforts to vaccinate educational staff, early educators, and pregnant and breastfeeding mothers, should remain a priority.
- Parents and adults of all ages should be encouraged to be vaccinated now to protect children and schools from outbreaks.
- Continue to vaccinate children and adolescents aged 12 years and older – while preparing for a rollout to children from five to 11 years of age, pending demonstration of safety and efficacy, and Therapeutic Goods Administration (TGA) and ATAGI recommendations.
- If vaccination of five to 11-year-old children is approved in Australia it will be imperative to monitor the risk of adverse events over a longer period.
- Continue to encourage eligible adolescents 12 years and older to be vaccinated by investing in innovative age-appropriate interventions and resources that will increase vaccine confidence and uptake.
- The indirect effects of the pandemic on children and adolescents should remain centre when considering mandatory vaccinations of adults that pose a risk to children
- 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 vaccines.

## COVID-19 Vaccination for Children & Adolescents

This brief 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 broad 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, and it is highly dependent on the control of infection through vaccination and other public health and social measures more broadly in the community. Data from the US has found that vaccinated teenagers infected with COVID-19 are protected against hospitalisation compared with teenagers who are unvaccinated.<sup>2,6</sup> As public health restrictions are relaxed, unvaccinated children and adolescents will remain vulnerable to infection and disease.

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

Vaccinating 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 globally. We have two safe and efficacious COVID-19 vaccines for children and adolescents aged 12 years and older - the Pfizer and Moderna vaccines, which were approved by the TGA on 23 July and 16 September 2021.<sup>7,8</sup>

The potential benefits of vaccinating children and adolescents include:

- Protecting them from illness and death
- Minimising the need for school closures, and subsequent negative indirect impacts
- Reducing transmission within the household, community, and schools.

### 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.**<sup>2,9,10</sup> There are specific groups for whom the risk is greater, including those with some pre-existing medical conditions. Multisystem inflammatory syndrome in children (MIS-C) can also occur, which is a very rare, 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 extremely low..

**Long-COVID in children and adolescents is not well understood but seems to be relatively rare.** A review of 14 international studies found that long-COVID symptoms rarely persist beyond 12 weeks, however many studies have major limitations which limits an accurate determination of how common long-COVID is in children.<sup>10</sup> Further research is required to accurately determine how common long-COVID is in this age group, as this will be an important factor in assessing the risk and benefits of vaccination in younger children.

**In countries with high vaccine coverage in adults, unvaccinated people, including children and adolescents, carry the burden of COVID-19 infections.**<sup>11</sup> Importantly, even though the number of infections is high among children and adolescents in this situation, the burden of hospitalisations and deaths still occurs overwhelmingly in unvaccinated older age groups.<sup>12</sup> More recently, however, infections and hospitalisations are declining in all age groups in the US, including in unvaccinated children < 12 years old.

There are significant indirect effects of the pandemic on the mental health, learning and wellbeing of children and adolescents.<sup>13</sup>

**Prolonged school closures, lockdowns and outbreak management exacerbate these impacts**, differentially affecting those living with disadvantage, diminishing social mobility and impacting economic productivity.<sup>14-16</sup>

There have been increases in admissions to paediatric hospitals for mental health, eating disorders, substance use and suicide attempts.<sup>17</sup>

Studies are continually emerging that highlight the negative effects of the pandemic on the mental health of children and adolescents, particularly in those that were already experiencing adversity.<sup>18-20</sup>

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

The Pfizer and Moderna vaccines are safe and efficacious for those 12 years and older.

The Pfizer and Moderna mRNA vaccines are currently TGA approved for those 12 years and older.<sup>7, 21</sup>

The data from clinical trials of Pfizer and Moderna suggest these vaccines are safe and efficacious.<sup>2, 22, 23</sup>

Canada, the United States, Germany, France, Italy, the Netherlands, Spain, Israel and Singapore, among others, are offering a 2-dose regime to all those aged 12 years and older. The United Kingdom is offering 1 dose to those between 12 to 15 years of age.<sup>24</sup>

There have been very rare reports of myocarditis (inflammation of heart muscle) and pericarditis (inflammation of heart lining) after receipt of mRNA vaccines (Pfizer and Moderna),<sup>25-28</sup> and nearly all cases have responded quickly to treatment. Surveillance for this rare condition is ongoing.

Immunocompromised people, including children and adolescents above 12 years, are recommended to receive a third dose of COVID-19 vaccine as part of their primary regimen, two months after their second dose.<sup>29</sup> This third dose is intended to generate an immune response, in the immunocompromised, equivalent to the two-dose regimen of the general population.

Data on the safety or efficacy of vaccines in children younger than 12 years.

Children's immune systems differ to adults. This can be seen in how COVID-19 affects children differently to adults. Balancing the benefits and risks of vaccinating all healthy young children is more complex than in adults. Weighing up the risks and benefits is likely to differ between infants, young children, and adolescents.

Key reasons for vaccination in children younger than 12 years include reducing acute illness, reducing rare complications such as long-COVID and MIMS-TS (MIS-C), reducing community transmission, and keeping children in school and care settings. However, COVID-19 is generally asymptomatic or mild in children. The risk of rare adverse effects following vaccination in five to 11-year-olds will commence now that the US has approved vaccine in this age group. Whether vaccination impacts transmission in those under 12 years is also yet to be determined.<sup>30</sup>

It's important that the benefits and risks of vaccination in otherwise healthy children for under five years old, five to 11 years of age and adolescents be considered separately.

The United States has provided Emergency Use Authorisation for this vaccine in the five to 11-year age group. Additional safety data is likely to be available over the next months, after millions of children are vaccinated, which will provide more detailed information to be able to calculate a more accurate risk benefit ratio for this age group for the Australian context.

It is likely that children with underlying conditions will be prioritised for vaccination sooner.

The United States FDA has supported the use of a smaller dose of the Pfizer vaccine in children aged five to 11 years. The trial found that 2,268 children aged between five to 11 years vaccinated with two doses of 10 micrograms three weeks apart was well tolerated and had at least similar immune responses as adolescents and young adults receiving two doses of 30 micrograms.<sup>1</sup> The vaccine efficacy against symptomatic infection was 91% based on 16 events in the placebo group and three events in the vaccinated group. There were no hospitalisations due to COVID-19 in either group so vaccine efficacy against hospitalisation was not able to be calculated. There were no cases of peri/myocarditis in either group, although calculation of risk of rare side effects are not able to be determined in a study this size.

Moderna and Novavax are also studying its vaccine in children, and Pfizer has additional studies underway in those younger than five.

**When 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.<sup>31</sup>

**Vaccination of children and adolescents must consider several practical considerations, including:**

- Priority adult groups in Australia that are still unvaccinated. There are still 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 demographic and geographical areas.
- Vaccination of high-risk groups, especially older adults, remains very low in many low- and middle-income countries. Global vaccine equity is critical to reducing global transmission and reducing the risk of emergence of new variants of concern.<sup>32</sup> The global context therefore remains highly relevant to national policy.

## Where are the research gaps?

**There is increasing 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.<sup>32</sup> A more detailed review of the role of the Delta variant in children can be found in [MCRI COVID-19 Research Briefs](#).

**Long-COVID in children and adolescents is not well understood but seems to be relatively rare.** 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, or whether this effect will persist.

**Rare side effects and efficacy of vaccines in children younger than 12 years against Long-Covid and MIS-C, and transmission are not known.**

## 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.

**Eligible children and adolescents should be vaccinated now**

### All people aged 12 years and older:

- The Pfizer and Moderna vaccines are TGA approved, safe and efficacious for this population.
- Continue efforts to vaccinate everyone 12 years and above, including pregnant women.
- Continue efforts to encourage a third dose in the immunocompromised in all people >12 years old, and boosters for 18+years, when eligible.

## 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.

- Continue prioritisation of 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, including pregnant women, should be encouraged to be vaccinated now to protect their children, and schools, from outbreaks.
- Continue efforts to vaccinate everyone 12 years and above, including pregnant women.

### 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 TGA and ATAGI's recommendations based on disease burden, and vaccine safety and efficacy, before we consider vaccinating this population, including at-risk children in this age group. It is anticipated that this will be available before the end of 2021.
- The role of vaccinating children aged between five to 11 years to prevent school outbreaks should be explored.

### 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.
- Prioritise keeping schools and early childhood education and care centres open.
- Encourage all parents and adults to be vaccinated to protect children and adolescents.
- The risks and benefits of vaccination for those less than 12 years need continual re-evaluation with emerging research.
- Encourage Australia's contribution to global vaccine equity.



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