Australian Government
National Health and Medical Research Council

NHMRC

National COVID-19 Health and Research Advisory Committee*

Date of report: 19 November 2021

Ethics of vaccination in children under twelve years of age (5-11)

Focus

The majority of young children infected with SARS-CoV-2 present with mild symptoms or are asymptomatic. While some children experience severe illness and require medical intervention and management due to COVID-19, the majority of children still experience lower incidences of severe illness and death due to COVID-19 than adults.[1]

Furthermore, while children infected with the original and alpha strains of SARS-CoV-2 transmitted it at a lower rate than that of adults, increased transmission due to the Delta strain cannot yet be ruled out.[2,3,4] If that proves to be the case, and with more children back at school, consideration is being given to the need to vaccinate children between the ages of 5 and 11.

The drug company Pfizer recently announced that it had conducted a study on more than 2,200 children aged between five and 11 with a lower dose of its COVID-19 vaccine which, in its regular dosage, is already available to adults and children aged 12-18. On 29 October, the FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age.[5]

This paper explores two main ethical considerations associated with vaccinating children between the ages of 5 and 11, namely:

- best interests of the child, and
- community interests and supporting the common good.

These ethical considerations are discussed in the current Australian context where:

- there are no wide-scale or independent studies to determine the safety of administering mRNA or other COVID-19 the vaccines to this younger age group
- there are already high vaccination rates of adults and older children in the Australian community
- children 5-11 who are infected don't experience high rates of severe illness and hospitalisation from COVID-19 disease
- children 5-11 who are infected may not transmit the virus as readily as adults (noting that the impact of the Delta variant on transmission in this age group is not yet fully understood)
- many adults in some parts of the world are still unable to access vaccines at all.

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* NHMRC is providing secretariat and project support for the Committee, which was established to provide advice to the Commonwealth Chief Medical Officer on Australia's health response to the COVID-19 pandemic. The Committee is not established under the NHMRC Act and does not advise the NHMRC CEO.

Out-of-scope issues

The following issues are out of scope for this paper:

1. Vaccination of neonates and children under 5 years of age
2. Consent issues (as children between the ages of 5 and 11 are unable to provide valid consent, parental consent would be required)
3. Mandatory vaccination policies
4. Resource allocation issues and issues of cost
5. Policy recommendations.

Notes

This report was developed by NCHRAC members Professor Angus Dawson and Professor Michael Good, with the assistance of NHMRC staff.

Ethical analysis

Vaccination of children under 12 for SAR-CoV-2 presents unique ethical issues, as the balance of risk and benefit is different than in older age groups. This is because of the low rate of severe illness in this demographic and the lack of large scale trials which include this age group.[6] Figure 1 was developed by Zimmerman et al and summarises the arguments for and against vaccinating children against COVID-19 and presents different factors that relate to the individual child and the community.

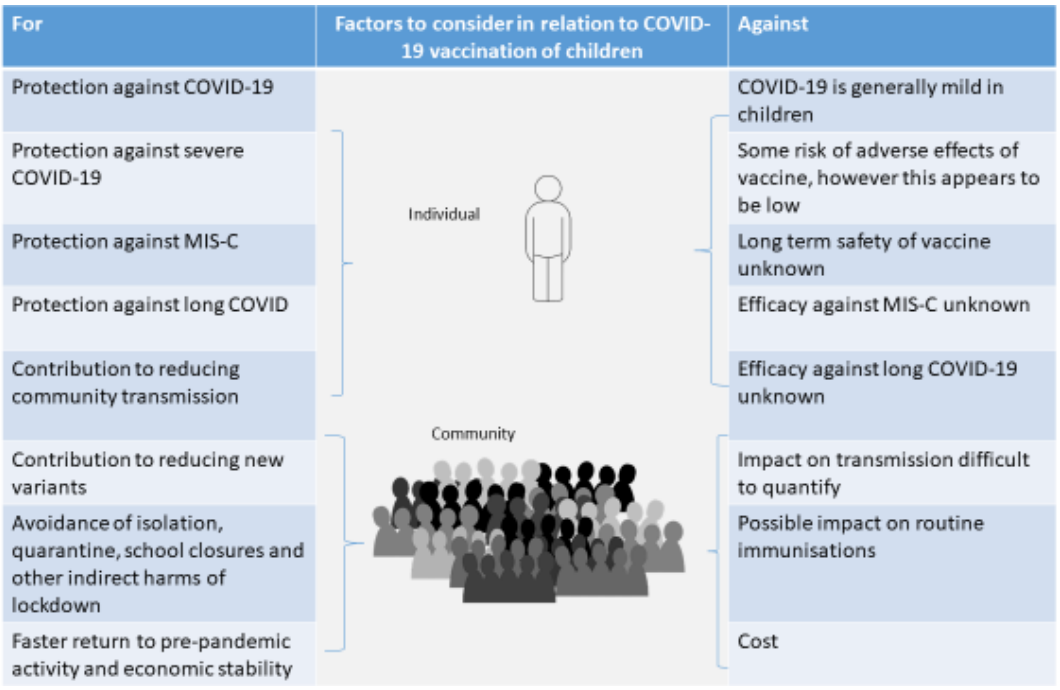

Figure 1 Summary of the arguments for and against vaccinating children against COVID-19 (reproduced from Zimmerman P, et al.)

Arguments for and against vaccination of young children often focus on a risk-benefit analysis.[7] This analysis weighs the risks of vaccination to the child against the benefits to the child and the broader community. This paper focuses on two ethical considerations that should be taken into account when developing policy for vaccinating young children against SARS-CoV-2. These considerations are:

- best interests of the child
- community interests and supporting the common good.

Best interests of the child

When young children lack their own decision-making capacity, it is common to appeal to the key ethical consideration of what is in a child's best interests. The best interest principle can be understood as an overall judgment as to what a rational person would decide taking into account all relevant circumstances in order to maximise the child's well-being.

To make a decision based on best interest, it is necessary to balance the potential harms and benefits of possible actions and inactions. With respect to vaccination, the key variables, at the individual level, are: the availability and quality of evidence of the risk of harm resulting from vaccination, the likelihood of that harm occurring and how significant the potential consequences are, the likelihood of contracting the infection and the potential harm caused by the illness itself.[8]

The likelihood of contracting the infection

The likelihood of infection (and possible harm) from COVID-19 disease is dependent on the incidence of COVID-19 in the community as well as future projections and is key in calculating the medical risk-benefit ratio for individual children. Further detail regarding how this was considered by the FDA in their recent decision is included in the discussion on the safety information of COVID-19 vaccines for children under 12 later in this advice.[9]

In terms of cases in this age group in Australia, it is of note that in 2021, since mid-October, national case numbers in children aged 5 to 11 years have steadily increased, while the case numbers in other paediatric age groups has declined.[10]

The number of paediatric COVID-19 cases by age group (as at 31 October 2021) are included in Table 1. In 2021, up to 31 October, children aged 5-11 represent 40.3% of paediatric cases (ages 0-17), 53.9% of school aged children and 11.0% of the total locally acquired COVID-19 cases in Australia. Primary school aged children (which approximates the 5-11 age group) represent 57% of the total number of enrolled school aged children.[11]

Table 1: Locally acquired cases of COVID-19 reported in Australia in children (1 January to 31 October 2021)

Age Group	Cases	% (all ages)
0-5	9,730	6.9
5-11	15,531	11.0
12-15	8,728	6.2
16-17	4,556	3.2
TOTAL (children)	38,545	27.4
TOTAL (all ages)	140,644	100

DATA SOURCE: National Interoperable Notifiable Diseases Surveillance System, extracted 2 November 2021 for cases notified up to 31 October 2021[13]

Evidence of the risk of harm resulting from vaccination

Studies to determine the safety and efficacy of vaccines for young children are currently underway. Given the safety profile of the vaccine in adults and children from 12-18, and the recent FDA authorisation of the emergency use of the Pfizer Vaccine to include children 5 to 11 years of age, it is reasonable to assume in the short term, that the vaccines are safe for the 5-11 age cohort. The single Pfizer trial raises no safety concerns, based on the use of a 1/3 adult dose of that specific vaccine. This study also appears to show no incidence of myocarditis, the only major concern associated with use of the vaccines in 16-18 year old males.[12] It is important to note that the incidence of myocarditis in the 12-15 year old age group is estimated to be 180 cases per million for fully vaccinated 12-15 year old males. The current phase 2/3 trial has enrolled approximately 4700 5-11 year olds, and therefore it is likely that very rare adverse events will not be reported. Longer term post market surveillance in the USA will be necessary to fully understand the risk of clinical (and sub-clinical) myocarditis in 5-11 year olds.[9]

It is likely that more data on the safety and efficacy of vaccinating the under 12 cohort will be available in the coming months, as a number of other countries have begun vaccinating children under 12 years of age. As of early November 2021, COVID-19 vaccination of children under the age of 12 is occurring in the Middle East, the Americas and the Asia-Pacific region. A summary table of the countries administering vaccines in young children is included at Appendix 1.

Benefits of vaccinating the 5-11 cohort

There are physiological and psycho-social benefits of vaccinating the 5-11 cohort (as summarised in Figure 1).[a] The physiological benefits of vaccination include protection against infection and protection against serious illness and hospitalisation. Based on current evidence, the physiological benefits from vaccination appear to be minimal for the majority of children, as infected children are commonly asymptomatic and serious illness, hospitalisation or death from COVID-19 amongst this age group is rare (see Table 2).

[a] This paper does not characterise benefits as 'direct' and 'indirect,' principally because the conventional definition of 'direct benefit' as being purely a physiological benefit is not considered valid. In contrast, we argue that the physiological benefit and psycho-social benefits of vaccination to children are both direct benefits.

A summary of COVID-19 disease severity by age group from 1 January 2021 to 17 October 2021 is included in Table 2. In the 5-11 year age group, almost 1 in 40 cases of COVID-19 required hospitalisation in 2021 with less than half a percent requiring ICU admission (up to 17 October). Paediatric hospitalisation rates should be interpreted with caution as admission can be required for reasons other than clinical care related to COVID-19.[10]

Table 2: Australian COVID-19 cases and disease severity by age group (1 January 2021 – 17 October 2021)

Age group	Total cases	Not severe		Hospitalised (excluding ICU and death)		ICU (excluding death)		Died	
		Cases	%	Cases	%	Cases	%	Cases	%
0-4	8257	7843	95.0	408	4.9	6	0.1	0	0.0
5-11	12,282	11,979	97.5	297	2.4	6	<0.05	0	0.0
12-15	7368	7113	96.5	244	3.3	9	0.1	2	<0.05
16-17	3975	3822	96.2	143	3.6	10	0.3	0	0.0
18-29	30,241	28,062	92.8	2013	6.7	159	0.5	7	<0.05
30-39	21,564	19,187	89.0	2120	9.8	245	1.1	12	0.1
40-49	15,038	12,811	85.2	1893	12.6	307	2.0	27	0.2
50-59	11,203	9,069	81.0	1655	14.8	400	3.6	79	0.7
60-69	6217	4470	71.9	1293	20.8	325	5.2	129	2.1
70-79	2960	1713	57.9	888	30.0	155	5.2	204	6.9
80-89	1506	640	42.5	593	39.4	32	2.1	241	16.0
90+	385	160	41.6	133	34.5	0	0.0	92	23.9
Un-known	2	2	100.0	0	0	0	0.0	0	0.0
TOTAL	120,998	106,871	88.3	11,680	9.7	1,654	1.4	793	0.7

DATA SOURCE: National Interoperable Notifiable Diseases Surveillance System, extracted 26 October 2021[13]

Australia has been successful in containing COVID-19 outbreaks when compared with many countries such as the United States and the United Kingdom. However, there is evidence from high transmission settings that demonstrates that children who do become infected with COVID-19 may require hospitalisation for severe acute COVID-19 disease and/or may be affected by Multisystem Inflammatory Syndrome in Children (MIS-C) and/or long-term effects of COVID-19.[14] For example:

- While many children experience mild or asymptomatic COVID-19 disease, severe COVID-19 in children is serious and can require respiratory support and intensive care admission.[15]
- Children with severe COVID-19 may develop respiratory failure, myocarditis, shock, acute renal failure, coagulopathy and multi-organ system failure. Some children with COVID-19 have developed other serious problems such as intussusception or diabetic ketoacidosis.[1] Other presentations include: vaso-occlusive crises in the setting of sickle cell anaemia, diabetic ketoacidosis, seizures, circulatory collapse and gastrointestinal tract symptoms.
- Of the children who have developed severe illness from COVID-19, most have had underlying medical conditions.[16] Similar to adults, children with obesity, diabetes, asthma or chronic lung disease, sickle cell disease, or immunosuppression might also be at increased risk of severe illness from COVID- 19.[17]
- Children infected with SARS-CoV-2 are also at risk for developing Multisystem Inflammatory Syndrome in Children (MIS-C), also termed Paediatric Multisystem Inflammatory Syndrome – Temporally Associated with SARS-CoV-2 (PIMS-TS). Children with MIS-C were more likely to be in the 6-12 year old age group, be of Black (non-Latinx) ethnicity and have no chronic

underlying medical conditions, compared to children with severe COVID-19.[18] Cases of MIS-C have been confirmed in Australia.[19]

Thus, while the majority of children who contract SARS-CoV-2 will be asymptomatic or experience mild symptoms, because some children do experience severe disease (particularly those with underlying medical conditions who are at higher risk), the physiological benefits of vaccination to those individual children is high.

Another potential benefit of vaccination to this age cohort is reduced transmissibility of the virus. Vaccination would have the overall benefit of fewer children being infected with SARS-CoV-2 and being at risk, however small, of severe illness. In addition, lower circulation of the virus among this age group will contribute to minimising outbreaks and the need to manage them. This in turn, means that individual children will benefit from the potential for reduced disruption of their schooling, reduced social isolation and reduced access to a full spectrum of life opportunities, as well as the likelihood of improved overall mental health.[b]

A review of the literature on transmissibility of COVID-19 in children under 12 is included in the summary of scientific literature below and in the section that follows. As increased transmission of the Delta strain cannot yet be ruled out, vaccination of children may contribute to the reduction of transmission of the virus. Even if this impact is small when compared to the effect of lowered transmission by vaccinating the majority of eligible adults and older children, this contribution should not be discounted.

Best interest argument

Given the current evidence on safety and the potential benefits of vaccination to the individual child, it may be in the best interest of children aged 5-11 years to be vaccinated. There is evidence to support that children with some underlying medical conditions are at higher risk of severe disease and therefore may receive more individual benefit from a vaccine.

Community interests and support for the common good

Another ethical consideration is whether vaccinating children benefits the community and contributes to the common good and whether these benefits outweigh any risks to children of being vaccinated. Common goods are integral to a well-functioning society. They are created and maintained through the actions of all members of society contributing to these goods in order to sustain our individual and collective well-being. Individuals cannot create such goods alone, nor can they protect themselves as individuals from relevant harms. For example, public health is a common good and vaccination is a means to protect public health. Like quarantine, it is a measure that is undertaken by individuals to protect the spread of the virus in the community and thus protect the community as a whole.

[b] The psycho-social benefits listed here presume the continued use of quarantining and/or stay-at-home measures as outbreak management strategies.

As discussed in the previous section, while larger studies are needed to fully establish the safety of the vaccine in this age group, it appears from the evidence we have that there are no major risks of vaccinating this cohort.

Community benefits of vaccinating the 5-11 cohort involve the extent to which vaccination of this cohort would have a meaningful impact on reducing the impact of COVID-19 on adults and older children via reduced transmission of the virus, including in younger children.

With high rates of adult vaccination in Australia, a trend toward an increasing proportion of COVID-19 cases being in unvaccinated or less vaccinated age groups is likely. Key findings from NCIRS (September 2021) is that transmission rates in schools, childcare services and households seen during the current SARS-CoV-2 Delta variant outbreak in NSW are 5.2 times higher than those seen throughout 2020.[20] The risk presented by these rates of transmission is that unvaccinated children may become infected in a school or childcare setting and take the virus home to infect their household. Household members would be significantly at risk if not adequately vaccinated.

Furthermore, even incremental increases in overall reduction in transmission in the community may be a worthy objective as a means of decreasing the likelihood of new variants emerging.

It is not only older children and adults that would benefit from lower community transmission of the virus and reduced spread of variants. Younger children themselves, as part of the community, would share in the benefits brought about by living in a community with low transmission rates. Such community conditions might be thought of as a common good.

Community interest and common good argument

Given the current evidence on safety of the vaccine and the benefit to the community of lower transmission of COVID-19 (which could be achieved by vaccinating children aged 5-11) vaccinating this cohort may be in the community's interest.

Other considerations

Children should not be treated as a means to an end

A possible argument against vaccination of children under 12, when they derive little benefit from the vaccine themselves, is that they should not be used as merely a means to an end. That is, children should not be vaccinated only to protect adults from COVID-19 if children don't need protection from COVID-19 themselves. An even stronger version of this argument may be made if vaccination policy is motivated by the idea of providing protection for adults who themselves have chosen not to be vaccinated. However, as highlighted in Figure 1, vaccinating children for COVID-19 in a pandemic does provide children with benefits, even if they don't gain any individual protection themselves from severe disease. For example, children do derive a benefit from any additional protection afforded to adults from COVID-19 and children, in addition, are protected against disruptive social measures and economic instability that arise as a result of rapid and uncontrollable spread of the virus.

Justice and equity

Ethical arguments for the introduction of public health measures, such as vaccination, generally include reference to the importance of justice as a value or principle. Many accounts of justice will

incorporate the concept of equitable access and/or outcomes. In the context of vaccination of young children, it is important to specifically consider the effectiveness of a vaccination program on the reduction of transmission in disadvantaged communities such as indigenous and remote and rural communities. The objective of using vaccination in these communities to reduce transmission can only be achieved if issues of access and appropriate communication are addressed.

Comparisons with other vaccine programs

There are a number of existing vaccination programs that either include children under 12 or are specifically targeted to them, although many of these programs are directed toward infants and children under 5 years of age. These include the varicella vaccine and combined vaccination programs such as measles, mumps and rubella (MMR) and diphtheria, pertussis and tetanus (DTP).

The low risk of hospitalisation and death from COVID-19 might be used as an argument against this vaccination. However, Zimmerman points out that the risk from COVID is similar or even higher than that for other diseases for which vaccines are routinely given, such as varicella, rubella, hepatitis A and influenza.[21]

The argument for childhood vaccination in the service of reducing harm to others (even when there is no immediate individual benefit to the vaccinated child, such as in the case of rubella) can also be used to support vaccination of children against COVID-19.

A related issue is the potential impact of a program to vaccinate children under 12 against SAR-CoV-2 on participation rates and trust in childhood disease vaccination programs that already have wide public support. For example, vaccine hesitancy amongst parents with respect to a SARS-CoV-2 vaccine could suppress participation in other vaccination programs.

Distributive justice

Issues of global distributive justice need to be considered if vaccines are being provided to children who do not suffer from severe illness or hospitalisation from COVID-19 disease given the need to provide access to vaccines in other countries where larger numbers of adults and older children remain unvaccinated. This issue, captured by the ethical principle of distributive justice, is a prominent argument in the public health ethics literature generally and, more specifically, as related to vaccination.[22]

Background

Summary of the ethics literature

Despite a substantial literature on vaccination for SAR-CoV-2 addressing both scientific and ethical issues, the literature on the ethics of vaccinating children, specifically, is limited. This literature is largely focused primarily on vaccinating children for SAR-CoV-2 in the 12-18 age group and, secondarily, on other childhood vaccination programs (i.e. for diseases other than COVID-19) for children under 2 years of age. This is largely a function of the recency of this issue. However, there is a robust collection of news articles dated August – November 2021 from sources such as ABC News, BBC News, The Nuffield Council, the New York Times, the Royal Australian College of General Practitioners (RACGP) and The Conversation as well as coverage of key new events by news outlets around the world.

All of the more current journal articles focus on the difficulty of conducting a reliable risk-benefit analysis given the paucity of reliable evidence on vaccine risk in children under 12 and none take a firm stand on whether vaccinating this cohort at this point in time is, definitively, ethically sound. In contrast, the news articles strongly skew toward presenting vaccination of children under 12 as either ethically appropriate or imperative, with heavy reliance on the opinions of paediatricians or others with claims to expertise in paediatric vaccination. Most of these articles also strongly support parents being given the option to consent to vaccination of their children.

Summary of the scientific literature

Severity of COVID-19 disease in children under 12

This advice builds on NCHRAC Advice 20, Severity of COVID-19 illness in children and young adults. This advice sought to identify if there was increasing incidence of infection in children and young adults (i.e. up to 30 years of age), and if they are experiencing more severe illness from infection of SARS-CoV-2 due to the variants of concern or other risk factors. The full advice is attached at Appendix 2.

NCHRAC Advice 20 was produced in May 2020, so does not take into account the now dominant Delta strain. A recent review into the pathogenesis, disease spectrum and management of COVID-19 in children concluded that acute COVID-19 is typically mild in children which appears to be largely unchanged as a result of the Delta variant but requires further evaluation. Downstream complications including MIS-C and long COVID-19 need to be prioritised for further research.[6]

Transmissibility and case rates of COVID-19 in children under 12

There is mixed evidence in the literature on the rate of transmissibility of COVID-19 in schools as well as COVID-19 susceptibility and infectiousness in school aged children.[23] A report on the susceptibility to infection and infectiousness for children published by the Scientific Advisory Group for Emergencies (SAGE) in the UK reported with high confidence that children's susceptibility to COVID-19 infection is less than adults and that there is some evidence of differences in susceptibility to infection between older and younger children, with evidence from contact tracing studies suggesting that pre-school and primary aged children are less susceptible to infection.[24] This report was published on 22 February 2021, when the alpha variant B.1.1.7 was prevalent in the UK.

Much of the transmissibility data in the literature relates to the original or earlier variant strains of COVID-19. There is still uncertainty on the relative transmissibility of infection between adults and

children,[2] and it may not be appropriate to assume lower age related susceptibility and infectiousness in children for the Delta strain.

A Morbidity and Mortality Weekly Report analysis of a COVID-19 outbreak in an elementary school in California attributed the rapid transmission to be likely a combination of the children's vulnerability because of ineligibility for vaccination coupled with the high transmissibility of the Delta variant.[3]

In the US, a CDC Morbidity and Mortality Weekly Report on COVID-19 trends in children and adolescents in from August 2020 to August 2021 reported that during the time when Delta has been a predominant variant (since July 2021), the rate of new COVID-19 cases and COVID-19–related emergency visits increased for persons aged 0–4, 5–11, and 12–17 years. It was also found that hospital admissions of patients with confirmed COVID-19 increased for persons aged 0–17 years. It was suggested that these increases could be related to increased transmission, although attribution to increased severity is also possible.[4]

Vaccination of children under 12 – international perspectives

COVID-19 vaccination of children under the age of 12 is occurring in the Middle East, the Americas and the Asia-Pacific region. A summary table of the countries administering vaccines in young children is included at Appendix 1.

The recent approval by the United States Food and Drug Administration (FDA) of the Pfizer-BioNTech COVID-19 vaccine for children aged 5-11 years on 29 October 2021 has been followed by approval in other countries, including the United Arab Emirates and Bahrain (Appendix 1).[32] It has also been reported that Malaysia will proceed with procurement of the Pfizer/BioNTech vaccine for children aged 5 to 11 pending approval from their regulator.

The European Union's regulator, the European Medicines Agency, is evaluating the use of Pfizer and BioNTech's COVID-19 vaccine in 5 to 11-year-old children with an outcome expected in late 2021, unless supplementary information is required.[25] The UK is currently offering a single dose of a COVID-19 vaccine to children aged 12-15 (with double doses only available to children at high risk) and have not approved vaccination in under 12s.[26] The UK Joint Committee on Vaccination and Immunisation (JCVI) has provided advice on the safety and benefit of the Pfizer-BioNTEch vaccine for this age group, highlighting that the rate of myocarditis is higher following a second dose of mRNA vaccine, compared with the first dose.[27]

In China, emergency approval for Sinopharm and Sinovac COVID-19 vaccine for 3-11 year olds has been in place since June 2021, but mass vaccination of that age group had been delayed until recently.[28,29] Following a new surge of cases, China has commenced a national campaign for children aged 3-11 years.[30] Some regions in China have mandated COVID-19 vaccination for children over 3 years in order to attend school.[31] Sinopharm and Sinovac COVID-19 vaccines are also being administered to children under the age of 12 in several countries (Appendix 1).

Safety information of COVID-19 vaccines for children under 12

The FDA evaluation of the safety data for the Pfizer-BioNTech vaccine in 5-11 year olds considered the benefits to outweigh the risks in 5-11 year olds. This is based on a trial conducted by Pfizer with 4,600 participants including 2 month safety follow-up of 1,444 vaccine participants.[32] The FDA have published a briefing document on their amendment of the Emergency use Authorisation (EUA) for the Pfizer-BioNTech vaccine to be extended to 5-11 year olds. This report is publically available and includes a review of safety and effectiveness data, the benefit-risk assessment and pharmacovigilance activities.[9] The incidence of myocarditis and pericarditis (most commonly observed in 12-17 year old males) versus the risk of hospitalisation, ICU admission and death

associated with COVID-19 infection was modelled by the FDA. In the risk-benefit assessment, the myocarditis and pericarditis risk was assumed to be the same as that of adolescents as data is not yet available for 5-11 year olds, which was considered conservative. Vaccine efficacy of 70% against COVID-19 infection and 80% against COVID-19 associated hospitalisation was assumed based on real world data during circulation of the Delta variant.[33] Several incidence rates of COVID-19 were modelled. Benefits of the vaccine in children aged 5-11 were found to outweigh the risks when the COVID-19 incidence rates were modelled on data from several periods, including the Delta surge peak. When the lowest COVID-19 incidence was modelled, the hospitalisations due to vaccine-related myocarditis/pericarditis were predicted to exceed the number of prevented hospitalisations.[9]

Moderna has recently announced that they are intending to submit results of their KidCOVE trial of their mRNA COVID-19 vaccine in children aged 6-11 years to the FDA. Moderna have reported that their two dose schedule is generally well tolerated and that immunogenicity endpoints were met.[34]

Approach

A PubMed search for 2021 was conducted for articles that examined the transmissibility of the Delta strain in children. The key words (SARS-CoV-2) OR (COVID-19), transmission, children and delta were used and revealed 21 articles of which 7 were used for the synthesised narrative.

A web search for international practice of COVID-19 vaccination of children was also conducted.

Grey literature was identified via newsletters, internet searches and email alerts and led to the identification of additional references.

Attachments

- Appendix 1: COVID-19 Vaccination for Children Under 12 - International Practice
- Appendix 2: see NCHRAC advice 20 Severity of COVID-19 illness in children and young adults

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[1] Shekerdemian LS, Mahmood NR, Wolfe KK, et al. Characteristics and Outcomes of Children With Coronavirus Disease 2019 (COVID-19) Infection Admitted to US and Canadian Pediatric Intensive Care Units. JAMA Pediatr. 2020;174(9):868–873. doi:10.1001/jamapediatrics.2020.1948

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[5] https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.

[6] Howard-Jones AR, Burgner DP, Crawford NW, Goeman E, Gray PE, Hsu P, Kuek S, McMullan BJ, Tosif S, Wurzel D, Bowen AC, Danchin M, Koirala A, Sharma K, Yeoh DK, Britton PN. COVID-19 in children. II: Pathogenesis, disease spectrum and management. J Paediatr Child Health. 2021 Oct 25. doi: 10.1111/jpc.15811. Epub ahead of print. PMID: 34694037.

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[8] Dawson (2005).

[9] EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age. FDA Briefing Document. *Vaccines and Related Biological Products Advisory Committee Meeting*. (26 October 2021)

[10] Epidemiology update – 25 to 31 October 2021. Novel Coronavirus (COVID-19). Australian Government Department of Health National Incident Room

[11] Number and proportion of all students enrolled in schools by school level and sector, Australia 2020. Australian Curriculum, Assessment and Reporting Authority. https://www.acara.edu.au/reporting/national-report-on-schooling-in-australia/national-report-on-schooling-in-australia-data-portal/student-numbers#dataset

[12] Nature News (27 Oct 2021). This source also reports that, on 25 October, vaccine maker Moderna said that a low dose of its mRNA-based jab for children aged 6 to 11 is safe and effective. Moderna is also conducting a trial with children as young as six months old.

[13] Epidemiology update – 25 to 31 October 2021. Novel Coronavirus (COVID-19). Australian Government Department of Health National Incident Room

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COVID-19 Vaccination for Children Under 12 - International Practice

A summary of countries and regions where COVID-19 vaccination is approved in children under 12 is included in Table 1. Every effort has been made to include all countries; however, the list may contain omissions. Wherever possible, the official health ministry or regulator website has been referenced, but in some instances, the media references were relied on.

Table 1: Countries and regions who have approved or are reportedly soon to approve COVID-19 vaccination in children under the age of 12 (as at 16 November 2021)

COUNTRY /REGION	VACCINE APPROVED	AGE GROUP APPROVED	DATE APPROVED	REGULATORY DETAILS	COMMENTS	REFERENCES
Middle East						
UAE	Sinopharm	3+	August 2021			▪ Protect Yourself Against COVID-19 Choose To Vaccinate (doh.gov.ae) ▪ UAE approves Pfizer Covid-19 vaccine for children aged 5 to 11 (thenationalnews.com)
	Pfizer-BioNTech	5+	1 Nov 2021	Approved on emergency basis	Previously approved for children 12 +	
Bahrain	Sinopharm	3+	27 October 2021			▪ Factbox: Countries vaccinating children against COVID-19 | Reuters ▪ Bahrain gives emergency approval to Pfizer coronavirus shots for kids 5-11 | The Times of Israel
	Pfizer-BioNTech	5+	2 November 2021			
Americas						
Cuba	Soberana 02	2+	3 September 2021	CECMED authorized the use of emergencies for ages 2-18 years	Cuban developed vaccine	▪ mr-july-2021b.indd (mediccreview.org) ▪ Cuba begins vaccinating children as young as two against COVID-19 | Coronavirus pandemic News | Al Jazeera ▪ Cuba Soberana COVID-19 Vaccine — Precision Vaccinations

COUNTRY /REGION	VACCINE APPROVED	AGE GROUP APPROVED	DATE APPROVED	REGULATORY DETAILS	COMMENTS	REFERENCES
US	Pfizer-BioNTech	5+	29 October 2021	FDA authorized the emergency use		▪FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age | FDA
Chile	Sinovac Biotech	6+	6 September 2021			▪Chilean health regulator approves CoronaVac use among children over age 6 | Reuters
Canada*					Decision expected mid-end November 2021	▪Canada says decision on allowing Pfizer's COVID-19 vaccine for children still weeks away | Reuters
El Salvador	Sinovac	6+	13 September 2021			▪https://bit.ly/30RiKe7 ▪US approves Pfizer for children as young as five, as India prepares to vaccinate toddlers against COVID-19 - ABC News ▪Information for U.S. Citizens and Lawful Permanent Residents - U.S. Embassy in El Salvador (usembassy.gov)
Argentina	Sinopharm	3+	1 October 2021	Recommended that the Ministry of Health of the Nation grant authorization for emergency use of the SINOPHARM vaccine in this group		▪COVID-19 Vaccine FAQs | Argentina.gob.ar ▪Argentina approves Sinopharm vaccine for children aged 3 to 11 - The Rio Times (riotimesonline.com) ▪Buenos Aires Times | Government approves Sinopharm vaccine for children aged 3 to 11 (batimes.com.ar)
Ecuador	Sinovac Biotech	6+	18 October 2021 commencement			▪Factbox: Countries vaccinating children against COVID-19 | Reuters ▪Feature: Ecuador begins to vaccinate children aged 6-11 with Chinese vaccine - Xinhua (news.cn)

COUNTRY /REGION	VACCINE APPROVED	AGE GROUP APPROVED	DATE APPROVED	REGULATORY DETAILS	COMMENTS	REFERENCES
Asia-Pacific						
China	Sinovac Biotech	3+	4 June 2021	China has approved emergency use of Sinovac Biotech's (SVA.O) COVID-19 vaccine in people aged between three and 17		▪ China to vaccinate children as young as 3, one of a few countries (cnbc.com) ▪ Vaccination for children aged 3-11 launched across China amid rebound of COVID-19 cases - Global Times ▪ Sinovac's COVID-19 vaccine gains China nod for emergency use in kids, adolescents | Reuters ▪ China to Vaccinate Children Over 3 as COVID-19 Cases Spread | Time
	Sinopharm	3+	June 2021			
Indonesia	Sinovac	6+	1 November 2021			▪ Indonesia authorises Sinovac COVID-19 vaccine for children aged 6-11 | Reuters ▪ Indonesia authorises Sinovac COVID-19 vaccine for children aged 6-11 - Society - The Jakarta Post
Malaysia*	Pfizer-BioNTech	5+		Malaysia on Oct. 29 said it would procure the Pfizer/BioNTech vaccine for children aged 5 to 11, following a U.S. expert panel's recommendation		▪ Factbox: Countries vaccinating children against COVID-19 | Reuters ▪ Health Ministry: Covid-19 vaccination for children below 12 in Malaysia to begin next year | Malaysia | Malay Mail
India*	Bharat Biotech's	2+		An advisory committee to the Indian regulator recommended emergency use of Bharat Biotech's COVID-19 shot in the 2 to 18 age-group. Regulatory approval pending.		▪ Factbox: Countries vaccinating children against COVID-19 | Reuters

COUNTRY /REGION	VACCINE APPROVED	AGE GROUP APPROVED	DATE APPROVED	REGULATORY DETAILS	COMMENTS	REFERENCES
Cambodia	Sinovac	5+	Commenced 1 November 2021 for 5 year olds		Vaccinations for 2 million children age 6 to 11 began Sept. 17 and are nearly complete. There are about 300,000 5-year-old children and they will be given Sinovac	▪Cambodia, starting to reopen, begins vaccinating 5-year-olds - The Washington Post ▪Cambodia starts coronavirus vaccinations for young children | Reuters ▪Cambodia to vaccinate 5-year-old children with China's Sinovac vaccine, SE Asia News & Top Stories - The Straits Times
Europe						
European Union*	Pfizer-BioNTech	5+		Oct. 18, the EU's medicines regulator said it had started evaluating the use of Pfizer and BioNTech's COVID-19 vaccine in 5 to 11-year-old children		▪Factbox: Countries vaccinating children against COVID-19 | Reuters ▪EMA starts evaluating use of COVID-19 vaccine Comirnaty in children aged 5 to 11 | European Medicines Agency (europa.eu)
Slovakia	Pfizer-BioNTech	5+	9 September 2021	Must have approval from paediatrician		▪Vaccination against Covid open for children older than five in Slovakia - spectator.sme.sk ▪Australia may soon follow America in vaccinating children as young as five | Alexandra Martiniuk and Elizabeth Elliott | The Guardian

*regulatory approval pending