National Immunisation Advisory Committee (NIAC)

RECOMMENDATIONS ON COVID-19 VACCINATION FOR CHILDREN AGED 5 TO 11 YEARS

NIAC |07.12.2021

About NIAC

NIAC membership includes representatives from the Royal College of Physicians of Ireland, its Faculties and Institutes, the Royal College of Surgeons of Ireland the Irish College of General Practitioners, the National Immunisation Office, the Nursing and Midwifery Board of Ireland, the Infectious Diseases Society of Ireland, the Travel Medicine Society, the National Virus Reference Laboratory, and lay members. Meetings are attended by observers from the Department of Health, the Health Service Executive. Representatives of the Health Products Regulatory Agency attend to provide regulatory advice in relation to vaccines.

NIAC considers new evidence about vaccines and provides advice to the Chief Medical Officer (CMO) and the Department of Health (DOH). The Department and the Minister for Health make policy decisions on vaccines which are implemented by the HSE.

Recommendations

1. COVID-19 vaccination is strongly recommended for those aged 5 to 11 years:
    - with underlying conditions
    - living with a younger child with complex medical needs
    - living with a person who is immunocompromised

   This group should be offered vaccination with the same priority as booster doses for those aged 16 to 49 years with an underlying condition.

2. COVID-19 vaccination should be offered to all other children aged 5 to 11 years because of the favourable benefit risk profile of the vaccine, to protect them from severe disease, the consequences that can follow infection e.g., multisystem inflammatory syndrome in children (MIS-C), long COVID, psychosocial and developmental impacts.

   As this is a primary vaccination course, this group should be offered vaccination with the same priority as booster doses for those under 40 years of age.

3. For children aged 5 to 11 years, the recommended COVID-19 vaccine is Comirnaty. The dose and schedule of Comirnaty for this age group is 10 micrograms, two doses three weeks apart.

4. Children aged 5 to 11 years who are severely immunocompromised should be given a third dose of Comirnaty at least 28 days after the second dose to complete the primary series.

5. Before vaccination, parents or guardians should be informed of the known benefits, risks and uncertainties of COVID-19 vaccination.

   The decision to accept, defer or refuse vaccination for a child should be respected.

6. Every effort should be made to avoid any adverse impact from the COVID-19 vaccination programme for children aged 5 to 11 years on the routine primary childhood and school immunisation programmes.

These recommendations reflect current evidence and will be reviewed when more information becomes available.

1. Executive summary

- Access to and completion of a primary COVID-19 vaccine series in all countries is an essential prerequisite to control the global SARS-CoV-2 pandemic. Until worldwide control is achieved, all countries remain at risk.
- Ensuring that adults and adolescents are optimally vaccinated will help to protect younger unvaccinated children from SARS-CoV-2 infection.
- The observation of all recommended public health and social measures i.e., use of masks, physical distancing, hand hygiene and ventilation of indoor spaces are key to reducing SARS-CoV-2 transmission.
- SARS-CoV-2 infection in those aged 5 to 11 years is usually asymptomatic or mild. Rates of hospitalisation and ICU admission are very low, and COVID-19 related death is extremely rare.
- Although the risk of hospitalisation is higher in children with underlying conditions, previously healthy children can develop severe COVID-19.
- In Ireland, COVID-19 vaccine uptake is high and is 70% in those aged 12 to 15 years.
- Prior to the introduction of vaccination for those aged 12 to 15 years, this age group had similar rates of infection to children aged 5 to 11 years. Children aged 5 to 11 years now have the highest rate of infection of all age groups, three times that of adolescents.
- From 18 November to 2 December, there were 12,304 COVID-19 cases in children aged 5 to 12 years. Of these, only 18 children (0.15%) were hospitalised.
- In Ireland, between March 2020 to November 2021, 212 hospitalised children aged 5 to 11 years were SARS-CoV-2 PCR positive. Of these 12% had an underlying condition, 70% had no underlying conditions and for 18% this was not reported.
- As infections surge, rates in children also rise, with a proportionate increase in hospital and ICU admissions.
- From 27 June to 27 November 2021 there were 322 outbreaks associated with primary schools with 2,089 cases and 7 hospitalisations. The number of outbreaks and cases associated with post primary schools is substantially less.
- The high transmissibility of the Delta variant has contributed to the surge in new infections. The effects of the recently identified Omicron variant have yet to be characterised.
- Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare complication after symptomatic or asymptomatic SARS-CoV-2 infection, including in those without an underlying condition.
- The risk of long COVID-19 is lower in children compared to adults although as case numbers increase there is likely to be a considerable health impact.
- Comirnaty vaccine is effective in preventing COVID-19 in this age group. It is hoped that the reduction in infection and prevention of symptomatic disease will reduce rare complications.
- Vaccination of those aged 5 to 11 years is associated with short term, self-limited side effects. No new safety concerns were observed in the clinical trials. The number of subjects in the trials does not allow detection of rare or very rare adverse events such as myocarditis and follow-up is ongoing.
- Children have suffered significantly from both the direct and indirect effects of the COVID-19 pandemic.
- The decision to offer COVID-19 vaccines to those aged 5 to 11 years is a balance of benefits and risks, informed by ethical considerations.

2. Background

On 25 November 2021, the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) recommended extending the indication for Comirnaty to include use in children aged 5 to 11 years of age.

NIAC has previously recommended COVID-19 vaccination for those aged 12 to 15 years.

This paper provides recommendations for COVID-19 vaccination of children aged 5 to 11 years, taking account of the benefits and risks in the context of current SARS-CoV-2 epidemiology and the direct and indirect impacts of SARS-CoV-2 on children. Consideration is also given to the wider impact of SARS-CoV-2 infection in children on their families and the community, while mindful of the ethical principles underpinning vaccine allocation and use.

3. COVID-19 epidemiology in children aged 5 to 11 years in Ireland

The epidemiology of SARS-CoV-2 infection has evolved. Children were largely spared in the first wave of the pandemic. Lockdown significantly reduced their exposure to the virus, and transmission of the Alpha strain from children was uncommon. Hospitalisation rates were higher because any child diagnosed with SARS-CoV-2 infection was hospitalised regardless of symptom severity.

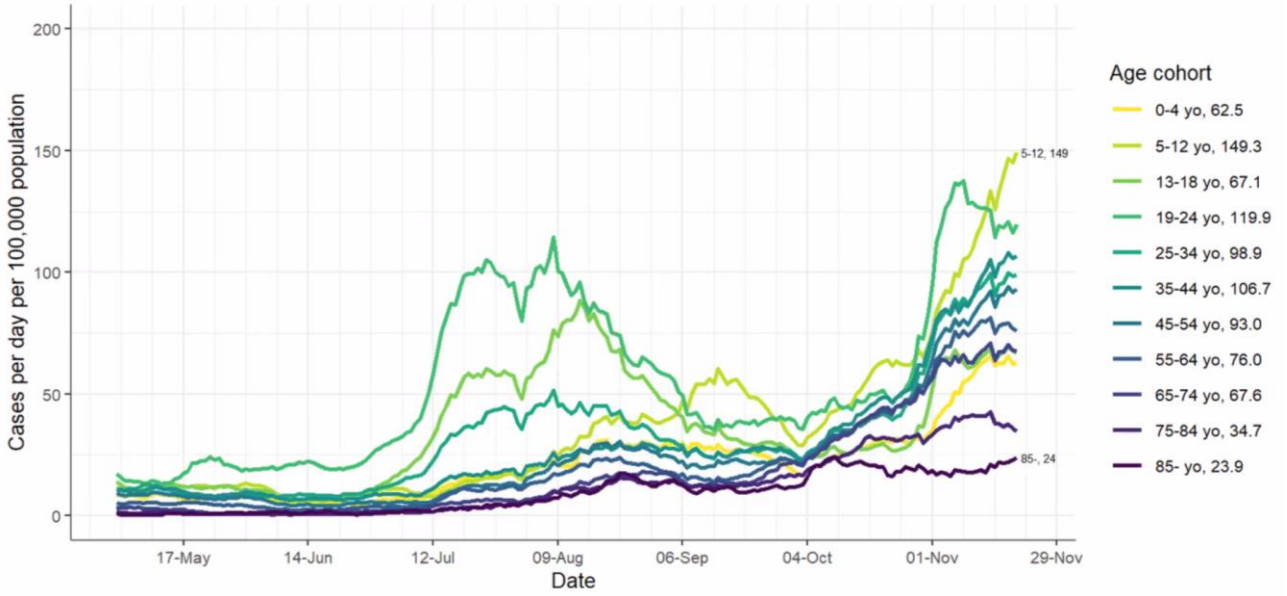
Ireland is experiencing a surge in confirmed COVID-19 cases. COVID-19 vaccine uptake in those eligible is 91%, and a booster vaccination programme is underway. Vaccine uptake in those aged 12 - 17 years at 70% has been followed by a decline in the case numbers in this age group.

The highly transmissible Delta variant remains the dominant SARS-CoV-2 strain. A confluence of factors; the arrival of the Delta variant, waning immunity with reduced protection against infection and transmission, and increase in social mixing have combined to facilitate virus transmission. Younger unvaccinated children have been disproportionately impacted in the recent surge, accounting for one in every six confirmed cases. Now the even more transmissible Omicron variant prevents an even greater threat in terms of rapid viral dissemination although its impact on disease severity remains unclear.

Between 18 November and 1 December, children aged 13 - 18 years, 70% of whom are fully vaccinated, accounted for 6% of all confirmed COVID-19 cases. In contrast, those aged 5 - 12 years who are not yet eligible for vaccination, accounted for 20% of cases, i.e., 12,304 infections.[1]

The age specific incidence of confirmed COVID-19 cases is highest in those aged 5 - 12 years (Figure 1).

Figure 1: Age specific incidence of confirmed COVID-19 cases May – November 2021 Source: HPSC



Although infection rates in this age group are high, SARS-CoV-2 infections in those aged 5 to 11 years are usually asymptomatic or mild and rates of hospitalisation and ICU admission are very low. There have been no COVID-19 related deaths in this age group. Hospitalisation rates were higher in Wave 1 largely because any child diagnosed with COVID-19 was hospitalised regardless of symptom severity (Table 1).

Table 1: Confirmed COVID-19 cases, hospitalisations, ICU admissions and deaths in those aged 5 - 12 years Source: HPSC

	Cases		Hospitalisations		ICU admissions		Deaths
	Number	% total	Number	% total	Number	% total	
Wave 1	299	1.1	19	6.3	3	1	0
Wave 2	3,058	6.8	18	0.6	1	0.03	0
Wave 3	13,836	6.9	84	0.6	5	0.04	0
Wave 4	37,550	14.3	102	0.3	3	0.01	0

Wave 1: March to 1 August 2020. Wave 2: 2 August 2020 to 21 November 2021.

Wave 3: 22 November 2020 to 26 June 2021. Wave 4: 27 June to 21 November 2021.

However, as infections rates in the community rise, rates in children will also increase, with a proportionate increase in hospital and ICU admissions.

In Ireland, between March 2020 to November 2021, 212 hospitalised children, aged 5 - 11 years, were SARS-CoV-2 PCR positive. Of these 12% had an underlying condition, 70% had no underlying conditions and for 18% this was not reported. (*DOH: unpublished data*) Not all of these children were hospitalised because of

COVID-19. In the EU/EEA countries the presence of an underlying condition in those aged 5 - 11 years is associated with approximately 12 times higher odds of hospitalisation and 19 times higher odds or of ICU admission. The majority (78%) of hospitalised children of this age had no reported underlying medical condition.[2]

From 27 June to 27 November 2021 there were 322 outbreaks associated with primary schools with 2,089 cases and seven hospitalisations.[3] There were no ICU admissions and no deaths. The number of outbreaks and cases associated with post primary schools is substantially less (Table 2).

Table 2. Number of outbreaks and associated cases by type of school, 27 June – 27 November 2021. Source: HPSC

Outbreak location	Number of outbreaks	Associated cases
Primary school	322	2,089
Post primary school	38	158

The effects of the recently identified Omicron variant have yet to be characterised.

4. Impact of COVID-19 on children

Clinical disease and risk factors for moderate and severe illness in children aged 5 – 11 years

Pooled data from 10 EU/EEA countries shows that between 5 July to 3 October 2021, the weekly notification rates of symptomatic COVID-19 disease in children aged 5 - 11 years increased eleven-fold from 5.9 to 65 per 100,000 population. The weekly rate of hospitalised cases in children aged 5 - 11 years increased nine-fold, from 0.025 to 0.24 per 100 000 population and there were two deaths.[2]

The overwhelming majority of children with SARS-CoV-2 infection experience a mild self-limited illness. The severity of illness, even in those hospitalised, is generally less than adults. In the UK, the median length of stay for a hospitalised child or adolescent was 2 days, with 89% discharged within 7 days.[4]

Severe COVID-19 can develop even in a previously healthy child, require ICU admission, mechanical ventilation and extremely rarely result in death.

In the UK and Ireland, the median age of 291 children (300 care episodes) admitted to ICU with a positive SARS-CoV-2 PCR from March 2020 to June 2021 was ten years. Invasive ventilation was required in 49% of care episodes for a median of five days.[5,6]

In the UK, between March 2020 and February 2021, 25 children and adolescents died of COVID-19. Of these six (24%) had no underlying condition. Five deaths (20%) were in those aged 5 - 9 years and nine (36%) in those aged 10 - 14 years.[6]

CDC has reported that those less than 16 years of age with confirmed COVID-19 infection are 36 times more likely to develop myocarditis than those without COVID-19 infection.[7]

The presence of an underlying condition significantly increases the risk of hospitalisation and severe disease as outlined in Chapter 5a, Table 5a.2 of the Immunisation Guidelines for Ireland.

From the analysis of pooled data reported by 10 EU/EEA countries between 3 August 2020 and 3 October 2021, the presence of an underlying condition among children aged 5 - 11 years is associated with about 12 times higher odds of hospitalisation and 19 times higher odds or of ICU admission. However, the majority (78%) of hospitalised children of this age had no reported underlying medical condition.[2]

In England, Ward et al looked at risk factors for paediatric ICU (PICU) admission and death amongst children and young people admitted to hospital with COVID-19 and MIS-C during the first pandemic year. The odds of PICU admission with COVID-19 were increased for those with any underlying condition and were highest for those with multiple medical problems. Those with complex medical problems across multiple body systems, and those with neuro-disability were at greatest risk.[8]

In the US, Verma et al. looked at the characteristics of those under 21 years of age hospitalised with SARS-CoV-2 in New York City. Children with any underlying condition were more likely to require critical care (70% vs 37%, P = .008), with obesity as the most common risk factor for critical care (63% vs 28%, P = .02).[6,9]

Having two or more underlying conditions has been identified as a risk factor for severe COVID-19 for those aged 21 and under.[10] Recent cohort studies of hospitalised COVID-19 cases aged 18 and under identified the presence of multiple underlying conditions, obesity,[11,12] chromosomal and neurological disorders[13,14] as independent risk factors for severe COVID-19.

MIS-C

Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare but serious disorder related to prior SARS-CoV-2 infection, in which different organs can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs.

A large international cohort study on children with COVID-19 estimated MIS-C to affect between 0.5%-3.1% of all diagnosed paediatric COVID-19 patients and between 0.9%-7.6% of hospitalised paediatric COVID-19 patients.[15]

Most children recover with appropriate treatment with 60% requiring ICU admission, with an average length of ICU stay of around 5 days and an average total hospital stay of around 10 days.[16] Myocardial involvement was seen in 93% of 286 children and adolescents with MIS-C from 55 centres across 17 European countries.[17] In Norway, data shows that there is an increased risk of MIS-C in children with underlying conditions; being overweight was seen in one quarter of the cases.[18]

Long COVID

The term long COVID is used to describe persisting symptoms following COVID-19. There is wide variation in the reported incidence of long COVID. Symptoms vary and include fatigue, difficulty breathing, cough, chest pain, muscle pain, headache, memory and concentration or sleep problems, anxiety, and depression. Symptoms may worsen after physical or mental activities. More than one third of patients experience more than one persistent symptom. It is not yet known whether long-COVID represents a new syndrome unique to COVID-19 or overlaps with recovery from similar illnesses.

UK data estimates the prevalence for those aged 2 - 11 years to be 0.2%.[19] A review was published in December 2021 of 14 studies that had reported persistent symptoms following COVID in children and adolescents. Almost all the studies have major limitations, including the lack of a clear case definition, variable follow-up times, inclusion of children without confirmation of SARS-CoV-2 infection, reliance on self- or parent-reported symptoms without clinical assessment, nonresponse and other biases, and the absence of a control group. Of the five studies which included children and adolescents without SARS-CoV-2 infection as controls, two did not find persistent symptoms to be more prevalent in children and adolescents with evidence of SARS-CoV-2 infection. The authors concluded that this highlights that long-term SARS-CoV-2 infection associated symptoms are difficult to distinguish from pandemic associated symptoms.[20]

Though the majority of those who develop COVID-19 feel better in days or weeks, in some, including children and adolescents, symptoms persist for months. Duration of symptoms varies depending on premorbid risk factors and illness severity. Hospitalised patients, especially seriously ill patients, are more likely to have a more protracted course than those with mild disease. Overall, the incidence of persistent symptoms in children and young adolescents appears to be less than in adults but for some, return to normal baseline health status following infection can take months.

As a large number of children are likely to be infected, even a low prevalence of persistent symptoms can have significant impact on child health.[20]

Other impacts

Significant detrimental psychosocial effects are difficult to quantify. They include limited access to basic services such as healthcare and child protection, and social isolation due to disruption of school, sports, and social gatherings and can affect the mental and physical well-being of children and their families.

In the US, Leeb et al reviewed all paediatric emergency department visits in the US between January - October 2020 and found that the proportion of mental health related visits for children aged 5 - 11 increased by approximately 24% compared with 2019.[21]

In the US, studies have shown an increase in BMI in children during the pandemic period.[22] (Woolford et al. 2021) Children aged 6 – 11 years experienced the largest increase in their rate of BMI change (0.09 kg/m^2/month), compared to other childhood age groups with a pandemic rate of change that was 2.5 times as high as the pre pandemic rate.[22,23]

There is also evidence of declining childhood vaccination rates. A study of the impact of the COVID-19 pandemic on the administration of selected routine childhood and adolescent vaccinations in 10 US

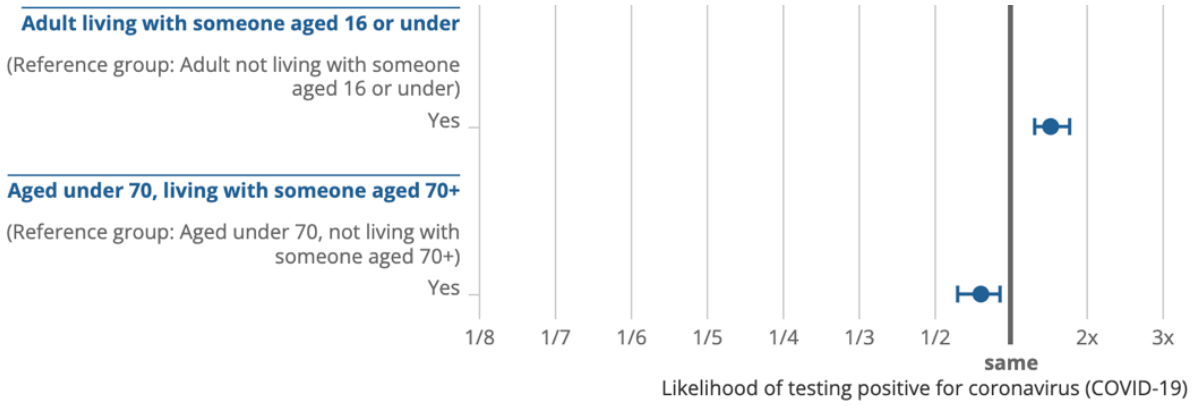
Jurisdictions, between March - September 2020 found MMR vaccine uptake decreased 11.3%, compared with 2018 and 2019 (with similar reductions in HPV and Tdap uptake). [24] In Ireland, primary childhood immunisation uptake rates declined by up to 5% for children aged 12 and 24 months in quarter 2 2021 compared to pre pandemic.[25]

5. COVID-19 transmission by children

Secondary transmission from all age groups, including children aged 5-11 years, has likely increased due to the higher transmissibility of the Delta variant. The transmissibility and effects of the recently identified Omicron variant have yet to be characterised.

Some studies have reported the rate of transmission from an infected child is similar to that from an adult while others have reported lower rates and recent UK data showed an adult was more likely to test positive if living with someone aged 16 and under (Figure 2).[26] [27-30]

Figure 2: Likelihood of testing positive for COVID-19 Source: Coronavirus infection survey, UK office for national statistics



Evidence suggests children and adults infected with SARS-CoV-2 have similar peak viral loads but the duration of respiratory tract viral shedding is shorter in children than adults.[31]

The observation of all recommended public health and social measures i.e., use of masks, physical distancing, hand hygiene and ventilation of indoor spaces are key to reducing SARS- CoV-2 transmission.

Studies from many countries have shown vaccination decreases transmission.[32] ECDC modelling data suggest that vaccinating children aged 5-11 years could reduce SARS-CoV-2 transmission in the whole population by up to 15% in a country with high adult (85%) and child (50-70%) vaccination rates.

6. COVID-19 vaccine in children aged 5 to 11 years

On 25 November 2021, the EMA extended the indication for Comirnaty to include use in children aged 5 to 11 years.[33] The vaccine is already approved for use in those aged 12 and above.

Safety

The safety of Comirnaty 10 micrograms was evaluated in a placebo- controlled trial of 2, 218 children aged 5 to 11 years 95% of whom had at least three months follow up after the second dose. An additional safety group of 2,379 children (1,591 Comirnaty 10 micrograms and 788 placebo) had less than one month follow up. Safety evaluation is ongoing with follow up for 2 years.[34]

The safety profile was similar to that seen in older trial participants. No cases of myocarditis were noted. No new safety concerns were observed. However, the study size did not allow for detection of rare or very rare adverse events or to evaluate whether the characteristics of identified, but rarer risks such as myocarditis differ compared with the adolescent and adult populations. The EMA concluded that the benefit risk balance is considered positive, particularly in children aged 5 - 11 years with underlying conditions.

More than four million first doses and approximately 450,000 second doses have been given to children in this age group in the US.[35] No immediate safety issues have been notified but follow up time has been short.

Myocarditis has also been associated with COVID-19 infection and these events can also occur in all age groups unrelated to vaccines or to COVID-19.[36]

The EMA has evaluated the occurrence of vaccine associated myocarditis as very rare i.e., up to 10 in 100,000 vaccinated people may be affected. The risk is highest in younger males.[37] Studies have shown that after the second dose of Comirnaty there were about 2.6 extra cases of myocarditis per 100,000 males aged 12 - 29 years after seven days and 5.7 extra cases of myocarditis per 100,000 males aged 16 - 24 years after 28 days. The rates for Spikevax were three to five times higher.

Data are very limited on those 5 - 11 years of age, however based on preliminary data from US and Israel, the incidence of myocarditis in those aged 12 - 15 years may be less than in those 16 - 24 years.[38,39] There were no cases of myocarditis or pericarditis observed in the clinical trial but the study size was too small to detect this rare event.

Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. In most individuals, symptoms resolved with conservative management.

For children with a previous history of MIS-C, vaccination should be postponed until clinical recovery has been achieved or until it has been 90 days or more since diagnosis, whichever is the longer.

Immunogenicity and Efficacy

A study in children aged 5 to 11 years showed that the immune response to Comirnaty given at a lower dose (10 micrograms) was comparable to that seen with the higher dose (30 micrograms) in those aged 16 to 25 years. (as measured by the level of antibodies against SARS-CoV-2)[34,40]

In another study in children aged 5 - 11 years without evidence of prior infection who were given the lower dose of Comirnaty, there were three COVID-19 cases in 1,305 children who received the vaccine, and 16 cases in 663 who received a placebo.[34,40] The point estimate for efficacy was 90.7%. (95% CI 67.7, 98.3)The low dose vaccine demonstrated efficacy against the original and Delta strain.[34]

Approximately 20% enrolled in the trial had an underlying condition associated with severe COVID-19 infection including obesity, but specific risk groups or impact on severe disease was not specifically studied and immunocompromised children were not included.

Although vaccination will reduce infection and prevent symptomatic disease, the impact on transmission, asymptomatic infection and duration of immunity in children aged 5 - 11 years is unknown.

Information is not yet available about potential long-term sequelae It is not known if vaccination will have an impact on long COVID or prevent MIS-C.

Comirnaty has been authorised for use in children aged 5 to 11 years in the US following a detailed benefit and risks assessment.[41] Comirnaty has also been authorised for use in children in Canada, Israel and Australia.

Dose and schedule

In children from 5 to 11 years of age, the dose of Comirnaty is 10 micrograms, lower than that for those aged 12 and above (30 micrograms). The recommended schedule is two doses, three weeks apart (as per EMA authorised documentation).

Those who are severely immunocompromised should be given third dose at least 28 days after the second dose.

The dose of Comirnaty depends on the age of the child at the time of the first vaccine i.e., an 11 year old child who receives the first dose of 10 micrograms Comirnaty and who then becomes 12 years of age should receive a further dose of 10 micrograms Comirnaty as their second dose.

Consideration should be given to establishing separate child friendly vaccination clinics for children aged 5 - 11 years. This would minimise distress in young children and reduce likelihood of vaccine error by avoiding having the adult and paediatric formulations of Comirnaty at the same venue.

Co administration

Until there is more evidence, it is prudent to separate COVID-19 vaccine administration in children aged 5 - 11 years from any other vaccine for a period of 14 days.

Vaccination after COVID-19

Vaccination should be deferred until clinical recovery from COVID-19 infection and for at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic. Those with persisting symptoms post COVID-19 may be vaccinated unless there is evidence of recent clinical deterioration.

Serological testing prior to vaccination is not recommended.

7. International recommendations

Vaccination of children aged 5-11 years is underway in Canada, Israel and the US, has been recommended in Czechia, Hungary, Lithuania and is under discussion in Belgium, Croatia, Latvia, Luxembourg, Malta, Netherlands, Poland, Portugal and Spain.

8. Ethical considerations

A key question when considering whether vaccination should be offered to this age group is whether it is in the child's best interest to receive a COVID-19 vaccine? The decision for parents or guardians and their children requires an assessment of a number of factors to take into account the best interests of the health and wellbeing of their child in the context of their family circumstances. It is a matter of individual informed decision, which should be respected.

The risks of remaining unvaccinated and the potential benefits of vaccination are most obvious for children with underlying conditions which increase their likelihood of developing severe disease. Children without an underlying condition remain susceptible to infection and the severe manifestations of disease. Given the significant increase in the rates of infection in this age group, while rates of hospitalisation and ICU admission are very low, absolute numbers are increasing.

Universal vaccination of those aged 5 - 11 years offers children both direct and indirect benefits. Vaccination reduces the risk of serious disease and its complications. It can help maintain access to educational opportunities and facilitate psychosocial development.

While vaccinating younger children could beneficially impact transmission, this is not the primary consideration in NIAC's deliberations. In recommending universal access to COVID-19 vaccination for this age group, a detailed review of the evidence relating to the direct benefits and potential harms of vaccination of children was conducted.

On 8 November 2021, a focus group and two in-depth interviews with parents of young children assessed their views regarding vaccination in this age group. There was concern regarding the administration of novel vaccines and the potential longer-term effects of these vaccines in children. There was also concern that adverse effects may not be immediately apparent in younger children who may not be able to explain them. There was a desire to understand the rationale for vaccinating children when the course of disease is in most cases mild.

Incomplete information regarding long-term effects of vaccine needs to be balanced with known risks of COVID-19 and the uncertain long-term impact of SARS-CoV-2. Prior to offering vaccination, parents or guardians should be informed of benefits and risks of COVID-19 vaccination, the risks of COVID-19 to their age group and the remaining uncertainties. Children should be included in the decision making process and their involvement should be proportionate with their maturity and level of understanding.

Equitable global vaccine distribution is crucial for suppressing virus circulation and the emergence of new variants of concern as underscored by the recent detection of the Omicron variant. The paediatric formulation of Comirnaty is not suitable for use in adults. The burden of the demands of global equity should not be imposed on children. Offering vaccination to children should not compromise discharging the obligation to provide vaccines to those who remain unvaccinated in low and middle income countries.

9. Conclusions

Access to and completion of a primary COVID-19 vaccine series in all countries is an essential prerequisite to control the global SARS-CoV-2 pandemic. Until worldwide control is achieved, all countries remain at risk.

The observation of all recommended public health and social measures i.e., use of masks, physical distancing, hand hygiene and ventilation of indoor spaces are key to reducing SARS-CoV-2 transmission and ensuring that adults and adolescents are optimally vaccinated will help to protect younger unvaccinated children from SARS-CoV-2 infection.

In Ireland, COVID-19 vaccine uptake is high and is 70% in those aged 12 - 15 years. Prior to the introduction of vaccination for those aged 12 - 15 years, this age group had similar rates of infection to children aged 5 - 11 years. Children aged 5 - 11 years now have the highest rate of infection of all age groups, three times that of adolescents.

SARS-CoV-2 infection in those aged 5 - 11 years is usually asymptomatic or mild. Rates of hospitalisation and ICU admission are very low, and there have been no COVID-19 related deaths in this age group in Ireland.

From 18 November to 2 December, there were 12,304 COVID-19 cases in children aged 5 - 12 years. Of these, only 18 children (0.15%) were hospitalised. Although the risk of hospitalisation is higher in children with underlying conditions, previously healthy children may develop severe COVID-19. As infections surge, rates in children also rise with a proportionate increase in hospital and ICU admissions.

Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare complication after symptomatic or asymptomatic SARS-CoV-2 infection, including in those without an underlying condition. The risk of long COVID-19 is lower in children compared to adults although as case numbers increase there is likely to be a considerable health impact.

From 27 June to 27 November 2021 there were 322 outbreaks associated with primary schools with 2,089 cases and 7 hospitalisations. The number of outbreaks and cases associated with post primary schools is substantially less. The high transmissibility of the Delta variant has contributed to the surge in new infections. The effects of the Omicron variant have yet to be characterised.

Comirnaty vaccine is effective in preventing COVID-19 in those aged 5 - 11 years and it is hoped that reduction in infection and of symptomatic disease will reduce rare complications. Vaccination is associated with short term, self-limited side effects. No new safety concerns were observed in the clinical trials, although the numbers in the trials does not allow detection of rare or very rare adverse events and follow-up is ongoing.

Children have suffered significantly from both the direct and indirect effects of the COVID-19 pandemic. ECDC modelling data suggest that vaccinating children aged 5 - 11 years could reduce SARS-CoV-2 transmission in the whole population by up to 15% in a country with high adult (85%) and child (50-70%) vaccination rates.

The decision to offer COVID-19 vaccines to those aged 5 - 11 years is a balance of benefits and risks, informed by ethical considerations.

10. Recommendations

1. COVID-19 vaccination is strongly recommended for those aged 5 to 11 years:
    - with underlying conditions
    - living with a younger child with complex medical needs
    - living with a person who is immunocompromised

   This group should be offered vaccination with the same priority as booster doses for those aged 16 to 49 years with an underlying condition.

2. COVID-19 vaccination should be offered to all other children aged 5 to 11 years because of the favourable benefit risk profile of the vaccine, to protect them from severe disease, the consequences that can follow infection e.g., multisystem inflammatory syndrome in children (MIS-C), long COVID, psychosocial and developmental impacts.

   As this is a primary vaccination course, this group should be offered vaccination with the same priority as booster doses for those under 40 years of age.

3. For children aged 5 to 11 years, the recommended COVID-19 vaccine is Comirnaty. The dose and schedule of Comirnaty for this age group is 10 micrograms, two doses three weeks apart.

4. Children aged 5 to 11 years who are severely immunocompromised should be given a third dose of Comirnaty at least 28 days after the second dose to complete the primary series.

5. Before vaccination, parents or guardians should be informed of the known benefits, risks and uncertainties of COVID-19 vaccination.

   The decision to accept, defer or refuse vaccination for a child should be respected.

6. Every effort should be made to avoid any adverse impact from the COVID-19 vaccination programme for children aged 5 to 11 years on the routine primary childhood and school immunisation programmes.

These recommendations reflect current evidence and will be reviewed when more information becomes available.

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