Received: 8 April 2022 | Revised: 24 May 2022 | Accepted: 25 May 2022

DOI: 10.1111/apa.16430

ACTA PÆDIATRICA NURTURING THE CHILD WILEY

A DIFFERENT VIEW

The benefits of COVID-19 vaccination programmes for children may not outweigh the risks

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Vaccines have saved millions of lives, and these include the vaccines against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which were developed in record time. In May 2021, the United States Food and Drug Administration and the European Medicines Agency (EMA) authorised the use of the Pfizer–BioNTech vaccine, Comirnaty, for children aged 12–15 years. On 25 November 2021, the EMA extended that authorisation to children aged 5–11 years.

The decision to vaccinate children poses many challenges, since COVID-19 is much milder in this age group, making the risk–benefit ratio less clear. Reports on serious adverse events were documented soon after the vaccine was introduced on a large scale. The suspicion that messenger ribonucleic acid (mRNA) vaccines could cause myocarditis and pericarditis, especially in adolescents and young adults, was soon confirmed by well-designed studies.[1,2]

There are four key points that need to be addressed with regard to vaccinating children.

The first is the potential benefits to children. The vaccines were developed to prevent the SARS-CoV-2 infection, severe COVID-19 and mortality. We must evaluate disease severity in children to understand the actual benefits of vaccination. The risk of being hospitalised due to severe COVID-19 is extremely low in children. A nationwide English study that included every child hospitalised during the first year of the pandemic with COVID-19 showed that 229/251 (91%) of those admitted to paediatric intensive care units (PICUs) had underlying conditions or comorbidities.[3] This was before the availability of vaccines and when the Alpha variant was dominant. There were also 312 PICU admissions for multisystem inflammatory syndrome in children (MIS-C). Overall, PICU admissions related to COVID-19 or MIS-C represented 0.005% of the paediatric population in England, which was 12.02 million.[3]

From the beginning of the pandemic until March 2022, children and adolescents under the age of 20 who tested positive for SARS-C0V-2 represented 0.1% of the total pandemic-related deaths in high-income countries. About 75% of childhood deaths up to the age of 19 years occurred in those with comorbidities, according to UNICEF. The risk of myocarditis 1–28 days after being infected with SARS-CoV-2 was evaluated by a study that had more than 3 million participants who were at least 16 years old. This found that the risk was 10 cases per million (95% confidence interval 7–11) in the exposed population under the age of 40.[2]

To our knowledge, there are no data to prove that the current vaccines prevent myocarditis associated with the SARS-CoV-2 infection. The only two cases of myocarditis associated with SARS-CoV-2 that we have observed were in fully vaccinated adolescents.

So far, the data suggest that the major risk associated with the SARS-CoV-2 infection in healthy children is MIS-C. Can vaccines prevent this complication? Two studies have demonstrated that MIS-C was about 90% lower in vaccinated than non-vaccinated children.[4,5] However, it is important to consider the timing and design of the studies. Since these studies were conducted immediately after vaccination, the number of SARS-CoV-2 infections was expected to be much lower in the vaccinated group. Although these results are promising, the assumption that the vaccine prevents MIS-C must be examined by comparing the MIS-C rates in vaccinated and unvaccinated children who have been infected with SARS-CoV-2. These studies also reported that seven fully vaccinated children developed MIS-C.[4,5] Previous studies had already pointed out that MIS-C can develop after breakthrough infections in vaccinated children. Another potential argument for vaccinating children is to ameliorate the social and psychological impact of the pandemic. As physicians, we must remember that a vaccine is a medical intervention

Abbreviations: EMA, European Medicines Agency; MIS-C, multisystem inflammatory syndrome in children; mRNA, messenger ribonucleic acid; PICU, paediatric intensive care unit; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

to prevent disease and should never be used to avoid restrictions imposed by health authorities or governments.

The second point is the potential benefits to others. Vaccines have been used to eradicate diseases through herd immunity and have also been used to protect family members or vulnerable individuals in a community. Herd immunity occurs when a large portion of a population develops immunity to a disease, making the spread of disease from person to person unlikely. This protects the whole community, not just those who are vaccinated. Herd immunity varies from disease to disease, depending on the level of contagiousness. It should be noted that herd immunity is only possible if immune individuals do not get infected or transmit the disease. We now know that this is not the case with SARS-CoV-2 and that both previously infected and vaccinated individuals can get infected and transmit the disease, making herd immunity impossible to achieve. Nonetheless, the risk of infection is lower following vaccination and vaccinating a child could be justified in selected cases if, for example a vulnerable family member had a medical condition that meant they could not have the vaccine. On the other hand, if all adult members of a family are fully vaccinated, then there is less logic in vaccinating children to protect the vaccinated adults.

The third point is the potential risks associated with mRNA vaccines. The major safety concern with mRNA vaccines is the risk of myocarditis, which has been well established in adolescents who have received the SARS-CoV-2 vaccine.[1,6] One study showed that this risk was highest after the second dose, affecting 390 male and 49 female adolescents per million second doses administered.[7] The reported incidence of myocarditis was lower in children aged 5–11 years, affecting 4.3 males and 2.0 females per million doses administered. This was still significantly higher than the background incidence of myocarditis in this age group. Although most cases of post-vaccine myocarditis were mild, and the patients recovered, there have been severe cases of cardiogenic shock and at least five deaths reported, including two teenage boys and a 22-year-old man.[6,8] The medium- and long-term complications of the vaccine remain unknown, and patients with myocarditis may subsequently develop dilated cardiomyopathy, possibly years later. These data indicate that the risks are not the same for every child, and the risk of the vaccine may outweigh the benefits, especially for a healthy adolescent boy.

The fourth point relates to the Omicron variant. The studies cited in this paper were carried out before the emergence of the Omicron variant, which seems to have a milder disease course than previous variants of concern. The risk–benefit ratio for the Omicron variant appears to support withholding vaccination in children, in view of the possibility of vaccine evasiveness demonstrated by multiple studies of antibody neutralisation.[9] A February 2022 paper from the New York State Department of Health studied vaccine effectiveness among children before and after the emergence of the Omicron variant. This showed a marked reduction in the vaccine's effectiveness against the Omicron variant, from 66% to 51% for children aged 12–17 years and from 68% to 12% for those aged 5–11 years. The vaccine's effectiveness against hospitalisation also declined 85% to 73% and 100% to 48% respectively.[10] Portugal has the fourth highest vaccination rate in the world, with more than 90% of its population being fully vaccinated. Despite this, it recorded 1.25 million new SARS-CoV-2 infections in January 2022, with vaccinated individuals accounting for most of these cases.

These four key points demonstrate that the decision to provide universal vaccination to prevent healthy children from getting infected with SARS-CoV-2 is not straightforward. The current worldwide dominance of the Omicron variant suggests that the benefits may not outweigh the risks associated with mRNA vaccines. It would be more sensible to recommend that only selected children are vaccinated, including children with risk factors that make them more susceptible to severe COVID-19 and those who are in close contact with vulnerable family members who cannot be vaccinated. When we make decisions about vaccinations during this ongoing pandemic, we must remember that children are not small adults and that we have an obligation to first do no harm.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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How to cite this article: Abecasis F. The benefits of COVID-19 vaccination programmes for children may not outweigh the risks. Acta Paediatr. 2022;00:1–3. https://doi.org/10.1111/apa.16430