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Editorial

Paediatric vaccination against COVID-19 beyond adolescence. Another reality[☆]



Vacunación pediátrica frente a la COVID-19 más allá de la adolescencia. Otra realidad

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Introduction: From adolescent immunisation

«Children and adolescents deserve a better future.» *The Lancet*

At the onset of the COVID-19 pandemic, it was thought that children might play an important role in its epidemiology, as is the case for other respiratory infections, such as influenza (with children being the primary and first spreaders in the community) and respiratory syncytial virus. Early on, the incidence of the pandemic disease was lower and, generally speaking, it was clinically less severe in the paediatric age group, compared to the high frequency and greater severity and mortality in adults from the age of 60 years and onwards. Age has been proven to be the first and most important risk factor for developing a severe form of the disease. Children were assumed to be less susceptible and spread the disease less, a fact that has been subsequently nuanced and weighted over the course of the last 2 waves.^{2–4}

However, over the course of the pandemic, 2 years after it began (January 2020 to January 2022, the closing date of this work), the impact of the pandemic on children has been confirmed by a series of different events: the description of a serious, albeit rare, post-infectious complication in April 2020, namely multisystemic inflammatory syndrome in children (MIS-C), which can also be observed, albeit more rarely, in adults; a progressive increase in the incidence with circulation of the delta and, above all, the omicron variants, due to their increased contagiousness and transmissibility, closely

linked to their escape from vaccine-induced and natural immunity, and the non-negligible number of hospitalisations or admissions to Intensive Care Units (ICU) and deaths (49 patients under 20 years of age since the start of the pandemic),⁵ most of whom were children and adolescents belonging to groups at risk. Therefore, the impact of the pandemic should not be dismissed as insignificant, nor should it be underestimated for children and adolescents.

Other important pandemic effects for children, sometimes mistakenly referred to as “indirect”, have to do with repercussions on physical and mental health (obesity, emotional disorders, depression, persistent COVID-19, poorer monitoring of healthy and chronically ill children, reduced vaccination coverage, etc.), and with social and school restrictions that can lead to isolation and academic failure, in addition to all the serious mental health problems.

In the light of this evident and growing impact of the pandemic in the paediatric age group, primary prevention, namely vaccination, has been proposed, as for any immunopreventable disease, once preparations have been authorised for this age group, which have been shown to be safe, immunogenic, and effective. Several regulatory authorities, such as the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), among others, have concluded that the benefits of immunisation outweigh its potential risks. Paediatric vaccination has been initiated, but without neglecting the great importance of non-pharmacological preventive measures.

[☆] Please cite this article as: Moraga-Llop F. Vacunación pediátrica frente a la COVID-19 más allá de la adolescencia. Otra realidad. *Vacunas*. 2022. <https://doi.org/10.1016/j.vacun.2022.02.001>

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2445-1460/© 2022 Published by Elsevier España, S.L.U.

Vaccination against SARS-CoV-2, limited to adolescents from 12 years of age until December 2021, has been extended to children aged 5–11 years, starting in Spain on 15 December 2021, 1 year after the first adult vaccination on 27 December 2020.

Clinical trials are ongoing with several vaccines in children under 5 years of age. BioNTech-Pfizer's vaccine (Comirnaty®) could be approved by the FDA in the coming weeks, probably with a 3-dose, 3 µg (1/10 of the adult) primary-booster schedule for the 2–4 years age group,⁶ after 2 doses were found to have immunogenicity that did not meet the non-inferiority criterion (although it did for children aged 6–23 months) and a good safety profile.

Other vaccines not licenced by the EMA are approved by other regulatory agencies for children: Sinopharm (China National Biotech Group [CNBG], ≥3 years), CoronaVac (Sinovac Biotech, ≥3 years), Soberana-2 (Finlay Institute, ≥2 years), Sputnik V (Gamaleya Institute, 8–12 years), Convidecia (CanSino Biologics, ≥6 years), Covaxin (Bharat Biotech, ≥12 years), and ZyCoV-D Vaccine (Zydus Cadila, ≥12 years). mRNA vaccines are being studied in children as young as 6 months of age.

In a recent editorial on adolescent vaccination, which we wrote days before the first vaccine for adolescents aged 12–15 years was authorised in Europe on 28 May 2021 (Comirnaty® vaccine),⁷ 2 important facts have yet to be pointed out. On 22 June, in update number 8 of the COVID-19 Vaccination Strategy in Spain, in the vaccination prioritisations, group 13 was added, which includes people between 12 and 19 years of age⁸ and second, on 23 July, the EMA authorised a second vaccine for the 12–17 year age group (Moderna vaccine, Spikevax®).

The full vaccination schedule for this group of 12–19-year-olds (3.9 million, corresponding to 8.2% of the total Spanish population) has reached 86.8%.⁹ In Catalonia, the vaccination rate broken down by age group is 85.5% among adolescents aged 16–19 and 59.6% in the 12–15 age group.¹⁰

Another fact worth noting is that the Centers for Disease Control and Prevention (CDC) has recommended a booster dose (the third dose) of the Comirnaty® vaccine for this group of 12–17-year-olds, at least 5 months after the first vaccination. The EMA is evaluating a request to extend its use starting at 12 years of age, and in Spain, the booster dose is recommended for non-high-risk individuals beginning at 18 years of age, and at 5 years of age if they are in a high-risk group.

The excellent data on the efficacy of adolescent vaccination have just been confirmed in real life. Effectiveness has been determined in a study involving 445 patients and 777 controls, aged 12–18 years, conducted in the United States during the July to October 2021 period, coinciding with the rising incidence of paediatric hospitalisations associated with COVID-19, when the delta variant became the predominant circulating strain.^{11,12} Two doses of the Comirnaty® vaccine, the only one authorised at the start of the study, were 94% effective against hospitalisation and 98% effective against ICU admission; there were 7 deaths, all in unvaccinated patients. Importantly, 26% of the cases did not belong to the risk groups.¹³

Vaccination of children 5–11 years of age

Vaccination of children aged 5–11 years in Spain, which was agreed by the Public Health Commission on 7 December 2021, was launched on 15 December,¹⁴ following the authorisation of the Comirnaty® vaccine on 25 November by the EMA (already approved by the FDA on 28 October); the Moderna vaccine (Spikevax®) is pending authorisation.

Vaccine coverage for this group of 3.3 million children, comprising 7% of the entire Spanish population, almost 1 month after its inception (report to 13 January 2022), is 40.9% for the first dose, but with a minimum value of 24.6% in the Balearic Islands and a very high maximum of 73.5% in Galicia.¹⁵ According to the 6th Barometer of the Centro de Investigaciones Sociológicas (CIS) on the effects and consequences of the coronavirus (survey conducted from 14 to 17 December 2021, when vaccination had just started),¹⁶ 14.6% of parents of children of this age said they would not vaccinate them. Some 5.9% of parents are undecided or reluctant, 1.8% would do so depending on the circumstances, and 77.4% are willing for their children to receive the vaccine (a percentage lower than the coverage of the routine vaccination schedule, which for the 6-years-old dose is 90%). This contrasts with the fact that 94.8% of respondents said they had already been vaccinated and only 3% refused to be vaccinated. Overall, vaccination of children has been well received, although higher vaccination coverage needs to be achieved.

The review of BioNTech-Pfizer vaccine data for children aged 5–11 years submitted to the FDA and EMA concludes that the benefits outweigh the risks of vaccination. One clinical trial¹⁷ included 2268 children aged 5–11 years, with or without evidence of prior infection, randomised in a 2:1 ratio to receive the vaccine (1517 children) or saline placebo (751 children), with a median follow-up of 2–3 months. The childhood vaccine corresponds to 1/3 (10 µg) of the presentation for those aged 12 years and older (30 µg) and 2 doses separated by an interval of 21 days were administered. The immune response was at least equal to that observed in those aged 16–25 years, as 1 month after the second dose, the ratio of the geometric mean ratio of SARS-CoV-2 neutralising antibody titres in children aged 5–11 years to that of vaccine recipients in the registration trial in subjects aged 16–25 years was 1.04 (95% confidence interval [95% CI]: 0.93–1.18). Immunobridging data comparing vaccine recipients with those in the 16–25-year-old group supported vaccine efficacy of 90.7% (95% CI 67.7–98.3), with 3 cases of symptomatic infection detected in the vaccine recipients compared to 16 in the placebo group, none of whom were hospitalised. Good tolerability was also observed, and side effects of the vaccine were similar but less common than in the comparative age group. The vast majority of reactogenicity manifestations were mild or moderate; systemic manifestations were more common after the second dose, and the median time to onset and resolution was 1–2 days. Local injection site or systemic adverse reactions such as fatigue, fever, headache, chills, and muscle pain occurred; no serious events were observed.

The US Advisory Committee on Immunisation Practices (ACIP) considered the relevance of COVID-19 to be a public health issue and reviewed the balance of benefits and risks with respect to the vaccination of children aged 5–11 years, considering the evidence regarding the known and potential benefits and risks. The evaluation was positive and an interim recommendation was issued, especially for those children with conditions that increase the risk of severe COVID-19.¹⁸ Myocarditis is a controversial issue in this assessment.

Myocarditis and pericarditis are rare adverse events that have been reported mainly in males aged 12–40 years, and following the second dose. In the clinical trial, no cases were reported in children aged 5–11 years, but the small number of participants must be taken into account. However, it should be noted that the baseline risk of myocarditis is much higher in adolescents than in children aged 5–11 years, and that they also receive 1/3 of the vaccine antigen, making this potential adverse event even more unlikely.¹⁹ Subsequently, safety data have been published following the administration of 8.7 million doses between 3 November and 19 December, as reported by the US Vaccine Adverse Event Reporting System (VAERS), a national passive vaccine safety surveillance system²⁰: 97.6% were not considered serious and 11 of the 15 reported cases of myocarditis were confirmed. The incidence of myocarditis is 1.3 cases per million doses administered, but rises to 4.3 for males and after the second dose, and 2 cases among females; the incidence is much lower than that reported for adolescents and young adults (70.2 cases per million in males aged 16–17 years after the second dose).²⁰ This is much lower than the rate observed for COVID-19 and its most severe complication, MIS-C.^{21,22}

What are the benefits of COVID-19 vaccination for the child?

The benefits of vaccination for the child can be classified into 4 interrelated areas:

1) Direct benefit: prevent acute disease and its complications, and persistent COVID-19 in the vaccinated child.

Among the complications, MIS-C is particularly noteworthy given its severity. It is an immune-mediated disease occurring in a small proportion of children, with a median age of 8–9 years, and presenting 2–6 weeks after infection. mRNA vaccines have been shown to be effective (91%; 95% CI 78–97) in preventing this complication.²²

One potentially significant health problem, given its poorly understood incidence, especially in children, is persistent COVID-19 (post-COVID or long COVID syndrome), which is defined as a cluster of multi-organ symptoms, with varying clinical polymorphism, presenting in individuals 3 months after the onset of infection, lasting for at least 2 months, and in the absence of any other diagnosis. The degree of effectiveness of the vaccine in preventing this syndrome is unknown.

Compared to adults, children have a lower incidence of infection, with a predominance of asymptomatic or mild forms,

and a lower risk of severity, hospitalisation or ICU admission, and death, although children with comorbidities constitute an at-risk group.

Nevertheless, the incidence in children has risen over the course of the pandemic at an increasing proportion, although this is partly due to the fact that in the early phases of the pandemic, especially in the first 5–6 months, only severe cases that were admitted were diagnosed and reported (most were adults), and to the strict home confinement of the first wave. In Spain, according to data from the Ministry of Health dated 15 April 2020,²³ the percentages of reported cases in children under the age of 10 years and in those aged 10–19 years were 0.3% and 0.6%, respectively, and hospitalisation was 0.2% for each age group, with 0.4% and 0.1% in the ICU; data in line with those of the first series published in China.²⁴ The data as per the National Epidemiological Surveillance Network (RENAVE) report of 5 January 2022⁵, which includes COVID-19 cases reported with the onset of symptoms and diagnosis since the beginning of the pandemic, by age group, are as follows: of a total of 6 905 244 cases, 20.3% were in the under-20 age group; 7.6% (525 897) were under 10 years of age, of whom 0.7% (3486) were hospitalised, 0.04% (199) required ICU admission, and 25 died (12.6% of the critically ill). Furthermore, in the cumulative incidence rate of cases diagnosed in the last 14 days in the group of children aged 11 years or younger, in the last 2 months, there has been a 30-fold increase: from 86 cases per 100 000 on 10 November 2021 to 2571 cases per 100 000 on 12 January 2022, coinciding with the arrival of the omicron variant, and on 20 January the group of children aged up to 11 years ranks first in incidence.^{25,26} In terms of admissions, however, a distinction should be made between children admitted for COVID-19 and those hospitalised for another cause and with COVID-19.

This progressive increase in incidence has been observed in many countries, such as the United States, where almost 700 children have died from SARS-CoV-2 infection, representing 1 of the 10 leading causes of death in children.^{11,12,27} Anderson et al.²⁸ point out that the direct impact of COVID-19 in children is greater than that observed for other vaccine-preventable diseases with routine vaccines. The average annual number of deaths in the year prior to vaccine introduction in the United States attributable to COVID-19 that could theoretically have been prevented would be much higher than for diseases such as chickenpox, meningococcal ACWY serogroup disease, rubella, hepatitis A, or rotavirus disease.²⁸ In South Africa, hospitalisations due to COVID-19 have increased in recent years in children under 19 years of age during the first 6 weeks of circulation of the omicron variant.²⁹

2) Indirect benefit: decrease spread of infection at school and in the family, and in the wider environment.

However, despite the fact that it has been demonstrated, especially in the early part of the pandemic, that children are most often infected at home rather than at school,^{30–32} they can also become infected and spread the infection to their environment. The role of the child in the transmission of infection has clearly been underestimated and has also

changed with the circulation of the omicron variant.^{2-4,28,30,32} Current vaccines are excellent in preventing severe disease and its consequences, but are less effective against asymptomatic and mild infection, and thus of less benefit until second generation vaccines become available to prevent infection.

3) Population or collective benefit: increase vaccination coverage of the population.

Vaccination of children aged 5–11 years, who account for 7% of the Spanish population, will contribute to significantly increasing overall coverage, which is currently 80.3%.⁹ Herd or group immunity cannot be achieved with current vaccines, which are non-sterilising, that is, they do not prevent infection and its spread, making it necessary to vaccinate the maximum number of people. Furthermore, the threat of the emergence of variants that are of concern because of their increased virulence and that can evade vaccination and natural immunity means that a higher proportion of the population needs to be vaccinated. If children and adolescents are not vaccinated, we will have millions of people capable of keeping the virus in active circulation.

4) Benefit *pro sequitur vitam*: Try to normalise children's lives and keep them fully active.

Immunisation is needed to maintain the stability of the education system in order to keep schools open in a safer way. The benefits are significant both to children, especially for their mental health and in terms of the educational and emotional impact, and to their parents, given the work, economic, and social challenges that school closures pose for them.

Disruption of school activity has been more damaging to children than any side effects of the vaccine, broadening gaps in education, decreasing physical activity, and extracurricular activities, as well as disrupting socialisation and emotional and psychological development.^{27,31,32} Avoiding confinement, isolation, and quarantine, and preventing the possible impact on well-child visits and routine vaccination schedules are other benefits.²⁹

According to data from the Ministry of Education and Vocational Training in Spain, cases and outbreaks during the school year 2020–2021 have been found to be very low, with a very small percentage of classrooms (less than 2%) closed due to lockdown.³³ School-based spread of infection was low, especially in children under 12 years of age, who had almost always been infected at home.³¹ Schools in Spain have functioned impeccably, allowing primary and secondary school pupils to attend school as appropriate to the situation of the pandemic. However, the situation has changed significantly in the current academic year 2021–2022 as of December, and even more so at the beginning of the second quarter, with the circulation of the omicron variant, due to its high contagiousness, which, together with its mild clinical repercussions, prompted the recommendation to increase the number of infected children per classroom to 5 or more for classroom closure, and to decrease the duration of isolation and quarantine periods, in order to enable children to attend school as much as possible and disrupt the family and work life of parents as little as possible.

Conclusions

Vaccination against COVID-19 in the paediatric population aged 5–11 years with 1 of the 2 mRNA-based vaccines (authorisation of the second one is pending) should be recommended as it was for adolescents from the age of 12 years onwards, and even more so at a time when the incidence of infection is very high in this age group. The benefit of vaccination in preventing severe disease far outweighs the risk of possible adverse reactions, including myocarditis and pericarditis, both of which have a very low incidence^{20,21}; moreover, the lower baseline frequency of myocarditis at this age should be taken into account and the fact that the vaccine dose administered corresponds to 1/3 of that of the adolescent. The benefits of vaccination are not limited to disease prevention, as it also has indirect effects on the child's environment (home and school) and on increasing the vaccination coverage of the population. Moreover, in this situation of pandemic, the great "direct" benefit is to attempt to normalise children's lives with the best physical and mental health. We are glad that these benefits were argued in a decision by a court in Avilés on 13 January 2022, which resolves a parental conflict that arose in relation to the vaccination of an 8-year-old child.³⁴ The judge, in this case, did not limit himself to a superficial consideration of the data regarding the incidence of the disease and the results of the clinical trial of the vaccine, but instead took into account and interpreted the entire reality and all the benefits of vaccination. In this case, the judge practised "vaccinological excellence". Yet another lesson learned from the pandemic.³⁵

Conflict of Interests

The author is a member of the editorial board of the journal *Vacunas*.

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