

# Pediatric Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccines: Perceptions and Attitudes From the Food and Drug Administration Public Commentary

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Authorization of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines for children has ushered in a new phase of the immunization campaign to address the pandemic but has been received with mixed responses from parents, children, and opinion leaders. Herein we consider perceptions and attitudes towards pediatric SARS-CoV-2 vaccines from a Food and Drug Administration (FDA) public commentary reflecting more than 63 000 comments.

**Keywords.** SARS-CoV-2 vaccines; pediatric; vaccine attitudes; perceptions.

Although severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines have been available for adults through Emergency Use Authorization (EUA) in the United States since December 2020, vaccines for children have lagged. Pediatric SARS-CoV-2 vaccine trials commenced only after safety and efficacy were initially assessed in adult vaccine trials. In the spring of 2021, a 2-dose series of BNT162b2 (Pfizer BioNTech) vaccine for children aged 5–11 years old was selected for further evaluation in phase 2/3 trials, with vaccine efficacy of 90.7% (95% confidence interval, 67.7–98.3%) [1]. Within the limits of the study size (N = 2268) and follow-up period (1 month after the second dose), the 2-dose series appeared to be safe with associated local and systemic adverse events similar to those seen in the corresponding adult phase 3 studies. On 29 October 2021, the Food and Drug Administration (FDA) granted an EUA for administration of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine in children aged 5–11 years [2]. Although the EUA contributes to the arsenal of tools to prevent COVID-19 and curb the pandemic, the public commentary from the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting highlighted concerns regarding SARS-CoV-2 vaccinations for children and

adolescents and may shed light on public perceptions regarding the immunization of 5–11-year-old children, with important implications for promoting vaccine uptake.

To understand public attitudes toward pediatric COVID-19 vaccination and identify challenges and opportunities for public health and clinical communications in support of vaccine decision making, we undertook a rapid thematic assessment of public commentary submitted to FDA in the period leading up to the VRBPAC meeting of 26 October 2021 that focused on the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years.

## METHODS

We downloaded the corpus of 63 656 submitted comments submitted via a public online forum prior to the 26 October 2021 date of the VRBPAC meeting to a spreadsheet. Comments were reviewed by the team and assessed for favorability toward pediatric vaccination for SARS-CoV-2. An example of language construed as opposed to pediatric vaccination is, “I am firmly against the Covid vaccine for children and adults,” and language construed as favoring pediatric vaccination is, “I support vaccine mandates for children attending public school.” High-level notes were taken by the team, working independently, to understand the perspectives in the submitted comments. Notes were shared and further reduced by the team into major (overarching) themes. The process was rapid and impressionistic given the size of the corpus and objective of identifying and categorizing main ideas to guide ongoing pandemic mitigation efforts, consistent with a previously used approach [3]. To ensure data integrity, the database was queried for duplicate names where possible and de-duplicated. Identical comments or phrases were found for unique names,

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and not de-duplicated given that different individuals may borrow language from each other or work from shared text in submitting comments. Comments and the corpus overall are public and exempt from institutional review board (IRB) review.

## RESULTS

### Themes From the VRBPAC Docket

Favorable and unfavorable views toward granting EUA for pediatric COVID-19 vaccines were expressed. A small minority of comments that supported EUA highlighted the following: (1) need to ameliorate child isolation and afford safe participation in social and educational activities; (2) importance of protecting immunocompromised children from COVID-19; and (3) urgency of pursuing all available approaches to support a “return to normal” and school for individuals, families, and communities. The vast majority of comments were counter to granting EUA due to the following: (1) lack of evidence for safety and time to assess safety signals; (2) rejection of vaccine mandates for children and the perception that mandates violate American and constitutional values for autonomy; (3) concern for the unique developmental vulnerability of children without sufficient understanding of the potential for future harms; and (4) endorsement and diffusion of misinformation, including assertions of substantial known and often hidden patterns of pediatric vaccine injury arising from vaccination for COVID-19, belief that children are not susceptible to nor experience severe COVID, and presumption of financial profiteering driving vaccine promotion ([Supplementary Table 1](#)). Issues of special interest regarding pediatric vaccine approval are discussed below.

### Balancing Child and Societal Risk-to-Benefit Assessments

Many comments directed toward SARS-CoV-2 pediatric vaccination raised difficult questions regarding the risk–benefit ratio for pediatric vaccine approval. Most comments lacked awareness of the broader set of harms befalling children and youth. The ethical complexity of decision making is heightened where harms to the child may arise via a broad set of harms (ie, mental health problems, developmental delays), issues that were not reflected in many comments, for example:

“The risk–benefit analysis for the COVID-19 vaccines points to a high potential risk versus no benefit for children and young people. Transmission of SARS-CoV-2 from children to adults is minimal and adults in contact with children do not have higher COVID-19 mortality. It is unethical to put children and young people at risk to protect adults.”

This comment like many others focused almost exclusively on mortality rates and did not reflect harms to mental health, development, or persons around children and youth who may be infected through exposure to an infectious child.

### Concerns About Applying a Novel Vaccine Technology in Children Given Uncertainty and Low Trust

Absence of evidence and changing epidemiology are especially problematic when decision making is made on behalf of a developing, hence vulnerable, child. Parents have a natural motivation to protect their children and avoid harm and comments reflected deep parental concern. However, rampant misinformation and misdirection was apparent regarding what is known about the safety of SARS-CoV-2 vaccines for children and youth, and the risks to children and youth from COVID-19. Some worries were grounded in fundamental misconceptions about the relatively new mRNA vaccine platform, with concerns that the vaccine involves “gene therapy.” Some commentators asserted they were not “anti-vaxxers” and have ensured standard vaccinations for their children but are concerned about new vaccines:

“We are not universally opposed to vaccines. We are absolutely and vehemently opposed to these vaccines being given to children. It is self-evident that these vaccines and their side effects are not well known enough to risk giving them to children.”

Others reflect the effects of politicization of vaccination and polarization of vaccine-related beliefs. Cynicism regarding Big Pharma and presumptions of vaccine profiteering were evident, too.

### Equating EUAs With Vaccine Mandates and Concerns Regarding a “Slippery Slope”

Consideration of vaccine mandates was not the purview of the US FDA VRBPAC, yet this controversial topic was raised repeatedly in the public comments, and federal committee members received urgent and even threatening messages as part of this process [4]. Confusion was evident regarding the meaning and limits of EUA. On the one hand, comments reflected understanding of authorization as an emergency measure in the setting of crisis and uncertainty; however, for some, this increased suspicion and mistrust: Why authorize something we don’t fully understand for use with a vulnerable population? On the other hand, EUA was construed as a step toward or equal to a broad vaccination requirement, with potential to lead to other health mandates:

“An EUA of this stature would open the door for all sorts of ‘mandates’ in schools—forcing every parent who is

opposed (there's millions of them!), to start homeschooling.”

While the case for pediatric SARS-CoV-2 vaccine mandates has been articulated [5], recommendations regarding mandates were explicitly not part of the VRBPAC charge. Moreover, several committee members expressed their personal views on the public record [6] that they supported authorization of mRNA vaccines for use by families who wished to immunize their children, but that the vaccines should not be mandated for 5–11-year-old persons at least until more safety data were accumulated—that is, via post-authorization active and passive surveillance [7].

## DISCUSSION

This rapid thematic assessment revealed substantial and deep public concern regarding pediatric SARS-CoV-2 vaccines. Significant levels of mistrust and opposition to pediatric SARS-CoV-2 vaccines were found together with acute concern for ethical and evidentiary challenges to establishing a favorable benefit-to-risk ratio for vaccination. Many comments reflected general openness to vaccines along with questions about the quality of evidence for pediatric SARS-CoV-2 vaccines at this time rather than blanket antivaccination views. Opposition centered on worry for children's developmental vulnerability and illustrated low trust, confusion, and cynicism about the meaning, limits, and processes of EUA and the governing authorities. Results build on a prior review of concerns expressed in public commentary [3], where themes regarding vaccine safety and efficacy, trust in and transparency of the processes for developing vaccines, granting EUA, and public health decision making were apparent.

Overwhelmingly, comments ignored or erroneously refuted threats of harm to children from SARS-CoV-2 and COVID-19 disease. While serious outcomes of COVID-19 (eg, hospitalizations and deaths) are much less frequent in pediatric compared with adult populations [8], it is estimated that more than 700 children have died of COVID-19 in the United States [9]. Rates of SARS-CoV-2 infection have increased in children and adolescents in the period when the Delta variant dominated [10], with concern that the emergence of Omicron will intensify the burden of pediatric SARS-CoV-2 infection and COVID-19 disease [11]. In addition, little is known regarding potential chronic effects of COVID-19 on children (“long COVID”) [12]. Indirect effects of childhood SARS-CoV-2 infection are substantial. Although contradictory information regarding transmissibility of SARS-CoV-2 from children to adults has been published [13, 14], more recent studies demonstrate transmission to adults, especially by younger infants [15]. Children may transmit SARS-CoV-2 to those in their household who may be more vulnerable to poor outcomes.

Disruption of the family on this level is significant, with worse case scenarios resulting in morbidity and mortality among caregivers. It is currently estimated that approximately 167 000 children in the United States lost a caregiver (parent, custodial grandparent, or grandparent caregiver) due to COVID-19–related deaths [16, 17]. The heavy burden of indirect effects of COVID-19 disease on children includes mental health disorders that stem from school closures, social isolation, and stigma from testing positive [18, 19], as well as negative effects on child development [20]. Increased emergency department visits for mental health–related events in children younger than 18 years have increased during the COVID-19 pandemic [21], and the pediatric mental health crisis is negatively affecting the healthcare system's capacity to address other important healthcare needs [22].

Addressing the interdependence of child and adult and explaining indirect effects in public health messaging is difficult given evidentiary uncertainties. New frameworks for balancing traditional ethical principles of respect for autonomy, nonmaleficence, beneficence, and justice [23] to guide health decision making in the setting of uncertainty are emerging [24]. Precedents for immunizing one group of individuals to predominantly protect another exist (ie, infant rubella vaccination) [25]. However, the measles-mumps-rubella (MMR) vaccine has been studied extensively and any safety concerns are known [26], distinguishing it from pediatric SARS-CoV-2 vaccinations and the need to act rapidly without complete safety and efficacy data.

Findings from this review highlight the challenges inherent in pediatric vaccine decision making and point to an urgent need for guidance and outreach to families. The requirement for rapid clinical and public health decision making to protect vulnerable groups in the setting of uncertainty sets an extraordinarily high bar. Barriers to effective communication include the following: (1) the heterogeneity of the US population and low levels of scientific and health literacy [27], (2) the complexity and fragmentation of conventional and social media channels through which information is disseminated, (3) the politicization of the debate regarding the best approach to address the coronavirus pandemic, (4) the need for concision in the media which imposes limits on how well complex and rapidly evolving information can be explained, and (5) the attitude among some academicians that it is poor form to conduct major media interviews in an era wherein communication of science to the public is vital [28].

Solutions are needed to overcome these barriers, including potentially (1) supported time by major media outlets for delivery of digestible public health guidance during periods of peak viewership; (2) moderated discussions at local community centers, school boards, and sites of religious worship regarding public health measures to address the pandemic; (3) investment in sustainable public health communications offices tied to

local communities to ensure prepared, credible, and reliable sources of information and guidance; (4) improved surveillance of and response to misinformation transmitted through social media; and (5) provision of transparent, thoughtful, accessible, and respectful content in media that is popular among parents of children.

### Limitations

This rapid thematic analysis of public comments submitted to the VRBPAC for pediatric SARS-CoV-2 vaccines provides a high-level summary of major issues of concern by volunteer commentators. The approach is helpful for scoping and summarizing observations, informing hypotheses, and providing insight for ongoing public health activity. However, our observations are limited. They are not definitive conclusions about public opinion, nor do they provide a summary of the large and important discourse around this topic, which merits a separate historical investigation. Associations among concerns and the characteristics of persons/groups who raised them were not possible given the public nature of the docket and absence of information about persons who submitted comments. Persons who submit comments are not population representative; hence, themes and findings cannot be generalized to the population. Moreover, comments were submitted in English, from persons with motivation, internet access, and awareness of the opportunity to comment. Key viewpoints are likely missing.

### Conclusions

Pediatric immunization holds substantial promise to address the SARS-CoV-2 pandemic, especially as new variants of concern emerge. However, difficult questions need attention regarding how we balance risks and benefits and speak to safety concerns for administering novel products to developing youth. Understanding perceptions regarding pediatric SARS-CoV-2 vaccination is crucial to effective communication that supports vaccine decision making. Ultimately, positions supporting and opposing pediatric vaccinations shared the single overarching concern for child well-being. Acknowledging shared values and goals may provide the basis for dialogue and progress.

### Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

### Notes

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### References

1. Walter EB, Talaat KR, Sabharwal C, et al. Evaluation of the BNT162b2 Covid-19 vaccine in children 5 to 11 years of age. *N Engl J Med* **2022**; 386(1):35–46
2. US Food and Drug Administration. FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 through 11 years of age. FDA, 2021. Available at: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>. Accessed 22 November 2021.
3. Weitzman ER, Sherman AC, Levy O. SARS-CoV-2 mRNA vaccine attitudes as expressed in U.S. FDA public commentary: need for a public-private partnership in a learning immunization system. *Front Public Health* **2021**; 9:695807.
4. Tracking the FDA advisory panel meeting on Covid-19 vaccines for kids. STAT. 2021. Available at: <https://www.statnews.com/2021/10/26/pfizer-covid-19-vaccine-kids-vrbpac-fda/>. Accessed 29 November 2021.
5. Plotkin SA, Levy O. Considering mandatory vaccination of children for COVID-19. *Pediatrics* **2021**; 147:e2021050531.
6. US Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Announcement. 2021. Available at: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement>. Accessed 19 December 2021.
7. Knipe DM, Levy O, Fitzgerald KA, Mühlberger E. Ensuring vaccine safety. *Science* **2020**; 370:1274–5.
8. Centers for Disease Control and Prevention. Healthcare workers. 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html>. Accessed 23 November 2021.
9. Centers for Disease Control and Prevention. Provisional COVID-19 deaths: focus on ages 0-18 years. Data. Available at: <https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3>. Accessed 21 December 2021.
10. Delahoy MJ. Hospitalizations associated with COVID-19 among children and adolescents COVID-NET, 14 states, March 1, 2020–August 14, 2021. *MMWR Morb Mortal Wkly Rep* **2021**; 70:1255–60.
11. Prinsloo L. Omicron variant in South Africa: kids under 2 are 10% of hospital cases. Bloomberg. Available at: <https://www.bloomberg.com/news/articles/2021-11-29/young-kids-make-up-10-of-hospital-cases-in-omicron-epicenter>. Accessed 19 December 2021.
12. Zimmermann P, Pittet LF, Curtis N. How common is long COVID in children and adolescents? *Pediatr Infect Dis J* **2021**; 40:e482.
13. Centers for Disease Control and Prevention. Science brief: transmission of SARS-CoV-2 in K-12 schools and early care and education programs—updated. 2020. Available at: [https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission\\_k\\_12\\_schools.html](https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html). Accessed 29 November 2021.
14. Lee B, Raszka WV Jr. COVID-19 transmission and children: the child is not to blame. *Pediatrics* **2020**; 146:e2020004879.
15. Paul LA, Daneman N, Schwartz KL, et al. Association of age and pediatric household transmission of SARS-CoV-2 infection. *JAMA Pediatr* **2021**; 175:1151–8.
16. Centers for Disease Control and Prevention. The hidden U.S. COVID-19 pandemic: orphaned children. 2021. Available at: <https://www.cdc.gov/media/releases/2021/p1007-covid-19-orphaned-children.html>. Accessed 23 November 2021.
17. COVID Collaborative. Hidden pain: children who lost a parent or caregiver to COVID-19 and what the nation can do to help them. Available at: <https://www.covidcollaborative.us/initiatives/hidden-pain>. Accessed 19 December 2021.

18. Magson NR, Freeman JYA, Rapee RM, Richardson CE, Oar EL, Fardouly J. Risk and protective factors for prospective changes in adolescent mental health during the COVID-19 pandemic. *J Youth Adolesc* **2021**; 50:44–57.
19. Lee J. Mental health effects of school closures during COVID-19. *Lancet Child Adolesc Health* **2020**; 4:421.
20. de Araujo LA, Veloso CF, de Souza MC, et al. The potential impact of the COVID-19 pandemic on child growth and development: a systematic review. *J Pediatr (Rio J)* **Jul-Aug 2021**; 97(4):369–377.
21. Leeb RT, Bitsko RH, Radhakrishnan L, Martinez P, Njai R, Holland KM. Mental health–related emergency department visits among children aged <18 years during the COVID-19 pandemic United States, January 1–October 17, 2020. *MMWR Morb Mortal Wkly Rep* **2020**; 69:1675–80.
22. Ni B, Gettler E, Stern R, et al. Disruption of medical care among individuals in the southeastern United States during the COVID-19 pandemic. *J Public Health Res* **2021**; 11:2497.
23. Holm S. *Principles of biomedical ethics*, 5th ed. Beauchamp T L, Childress J F. Oxford University Press, 2001, £19.95, pp 454. ISBN 0-19-514332-9. *J Med Ethics* **2002**; 28:332.
24. Rus M, Groselj U. Ethics of vaccination in childhood—a framework based on the four principles of biomedical ethics. *Vaccines (Basel)* **2021**; 9:113.
25. Centers for Disease Control and Prevention. Pregnancy and rubella. 2021. Available at: <https://www.cdc.gov/rubella/pregnancy.html>. Accessed 29 November 2021.
26. Centers for Disease Control and Prevention. Measles, mumps, rubella (MMR) vaccine. 2021. Available at: <https://www.cdc.gov/vaccinesafety/vaccines/mmr-vaccine.html>. Accessed 30 November 2021.
27. Center for Health Care Strategies. Health literacy fact sheets. Available at: <https://www.chcs.org/resource/health-literacy-fact-sheets/>. Accessed 22 December 2021.
28. Shaw J. Why aren't there more academic experts in the media? Wonkhe. Available at: <https://wonkhe.com/blogs/why-arent-there-more-academic-experts-in-the-media/>. Accessed 30 November 2021.