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COMMENT

What are the key pediatric public policy priorities as the COVID-19 pandemic persists?

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IMPACT:

- The COVID-19 pandemic is not over, and its impact is just beginning to be felt on children.
- COVID-19 vaccines protect both the pregnant patient and newborns, and breastfeeding provides a key component of passive protective immunity.
- "Long COVID" has contributed to the current crisis in pediatric mental health, and vaccines confer protection against this long-term complication of COVID-19 disease.
- Vaccine misinformation is not only impacting compliance with maternal and pediatric COVID-19 immunization efforts, but also other routine childhood vaccinations.
- As a public health priority, we must improve our response to vaccine misinformation and find novel strategies to improve vaccine compliance.

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We are now well into the third year of the COVID-19 pandemic. In spite of the rapid development of antiviral therapies and effective vaccines, this pandemic has already outlasted the influenza pandemic of 1918,[1] and cases continue to surge, driven by the ongoing emergence of new SARS-CoV-2 variants. Indeed, as of early 2023, COVID cases are increasing, not regressing, with a 7-day rolling average of approximately 70,000 a week, an increase of over 15% compared to December, 2022 (https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html). The American Academy of Pediatrics, in partnership with the Children's Hospital Association, has, as of this writing, reported over 15,000,000 child COVID-19 cases during the pandemic—representing nearly 20% of total cases (https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/). Moreover, 1600 deaths in children ages 0–18 years have been reported over the 3 years of the pandemic to date. Here, we discuss the current state of the COVID-19 pandemic as it relates to child health. Using two papers in the current issue of *Pediatric Research* as a springboard for discussion, we raise important questions about public health priorities for COVID-19 vaccination: maternal immunization aimed at improving pregnancy outcomes, and pediatric vaccination as a measure to reduce the risk of post-COVID long-term complications in children.

IMPACT OF COVID-19 ON INFANTS AND CHILDREN

Although COVID-19 is a less severe illness in children than in adults, it nonetheless causes considerable morbidity, and occasional mortality. As has been pointed out,[2] SARS-CoV-2 has accounted for more pediatric deaths than seasonal influenza in children (over comparable time windows) during the COVID-19 pandemic. Since 2004–2005, influenza deaths in U.S. children have ranged from 37 to 188 deaths per year, with the notable exception of 358 pediatric flu-related deaths that were reported during the 2009 H1N1 influenza pandemic (https://www.cdc.gov/flu/highrisk/children.htm). Approximately 80% of the children that died of influenza were not fully vaccinated against flu. Thus, routine immunization of children against SARS-CoV-2 holds the promise of reducing mortality in children on a par with the protection conferred by annual influenza immunization. The benefits of pediatric COVID immunization must also be considered in the context of multisystem inflammatory syndrome of childhood (MIS-C), a complication of SARS-CoV-2 infection in children characterized by a severe inflammatory response to infection that leads to multisystem organ damage.[3] It was initially suggested that the immune response induced by COVID-19 vaccines could run the risk of inducing MIS-C in some children, through some undefined molecular mimicry or genetic susceptibility mechanism.[4] However, more recent evidence indicates that the prevention of SARS-CoV-2 infection through pediatric vaccination actually *reduces* the overall risk of MIS-C.[5] Hence, prevention of this complication of COVID-19 provides another strong reason to vaccinate children.

Against this background, two papers in the current issue of *Pediatric Research* are relevant to the ongoing discussions about the role of COVID-19 vaccination in the protection of pediatric patients from complications of SARS-CoV-2 infection. The first manuscript, from Bode et al. at the University of California, San

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Diego, examined the depth and breadth of antibody responses in breast milk from 21 lactating mothers who presented with a history of COVID-19 disease and who had a confirmed SARS-CoV-2 infection between March and September of 2020.[6] The second paper, from Garai et al. at Semmelweis University in Budapest, Hungary,[7] provides a detailed descriptive analysis of the history, clinical presentation, and findings observed in 97 children who presented between March and May of 2021, and met the National Institute for Clinical Excellence guidelines case definition criteria for long COVID (LC) syndrome.[8] Although these studies focus on very different pediatric populations, both manuscripts are relevant to policy discussions focusing on the continuing challenge we face to ensure that we are maximizing our efforts to encourage compliance with current COVID-19 vaccine recommendations.

MATERNAL COVID VACCINATION AND PROTECTING THE NEWBORN INFANT

The paper from Bode et al. examined the pattern of antibody responses in 21 lactating mothers who had a history of COVID-19 infection (identified by RT-PCR), or who were symptomatic and had at least one breast milk sample that was positive for SARS-CoV-2 RNA. Subjects were recruited in 2020, prior to licensure of the COVID-19 vaccine. Breast milk samples were examined for both IgG and IgA antibodies. Interestingly, the IgA response was dominated by responses to the nucleocapsid (N) protein (~43% of mothers) and to a lesser extent the spike (S) protein (~24% of responses). IgG responses were similar. Notably, there was striking dissimilarity in maternal responses with respect to antibody reactivity with different domains of N and S proteins, as well as highly diverse kinetic profiles. The data suggest that a diverse repertoire of SARS-CoV-2 antibody targets is recognized following infection, and that highly heterogeneous profiles exist among lactating women. The authors suggest that infants may benefit from the anti-COVID antibody responses conferred by breastfeeding, but that there may be variability in the quantity and quality of SARS-CoV-2 antibodies received. Since the currently licensed COVID-19 vaccines in the US are based on the S protein, the data from this paper suggest that continued analysis of correlates of protection associated with other SARS-CoV-2 proteins, including N, should be a research priority.

However, it is important to acknowledge that incomplete knowledge about the immune responses to virally-encoded proteins that are associated with protective antibodies (either those that protect the mother or those that are present in breast milk) should not deter continued, concerted efforts to improve COVID-19 vaccine *compliance* during pregnancy. COVID-19 infection in pregnancy is associated with substantial increases in severe maternal morbidity, and in mortality, and is also associated with neonatal complications.[9,10] In a landmark study by Halasa et al.[11] that spanned both the delta and omicron COVID-19 waves of the pandemic (July 2021–March 2022), maternal vaccination with two doses of mRNA vaccine was associated with a reduced risk of hospitalization for COVID-19, including for critical illness, among infants younger than 6 months of age. COVID-19 antibodies are passed transplacentally, but are also present in breast milk, and both mechanisms likely confer an element of protection for the newborn infant.[12,13] We believe that cautionary statements about unfounded risks that might be attributable to the low-level presence of COVID mRNA in breast milk following COVID vaccination[14] are unwarranted, unsupported by any evidence, and may do harm by discouraging breastfeeding among vaccinated mothers or, conversely, discouraging immunization among women who plan to breast-feed.

The uptake of COVID-19 vaccine during pregnancy is clearly suboptimal. Many pregnant women avoid vaccination, unaware (or unconvinced) that infection with the SARS-CoV-2 virus poses far greater risks to both fetus and mother than vaccination—which has been demonstrated to be safe and highly effective in multiple studies. Misinformation is rife. A Kaiser Family Foundation study found that nearly 25% of women incorrectly believed that pregnant women should not get a COVID-19 vaccine; 17% wrongly believed it is unsafe for women who are breastfeeding to be immunized; and, dismayingly, 16% believed that COVID-19 vaccines can cause infertility (https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-pregnancy-misinformation-may-2022/). Update of COVID-19 vaccine amongst pregnant patients in the US is approximately 40%, compared to a general population background vaccine uptake rate of 63%.[15] The maternal vaccine situation is ever more dismal when global analyses are performed. A systematic review and global meta-analysis of >700,000 pregnant women found that the overall proportion immunized against COVID-19 was only 27.5%.[16] As an urgent public policy priority, strategies must be refined to educate women of child-bearing age about the safety and importance of COVID-19 vaccination during pregnancy. Furthermore, future approaches to novel vaccine development should, in contrast to first-generation COVID-19 vaccine clinical trials, seek earlier inclusion of both pregnant people[17] and children.[18] This strategy, in turn, will aid in dispelling the safety concerns and misinformation that are fed by lack of data on vaccine safety and efficacy in these vulnerable populations.

"LONG COVID" IN CHILDREN: THE INTERSECTION BETWEEN COVID-19 AND THE PEDIATRIC MENTAL HEALTH CRISIS

The impact of LC is substantial. Often debilitating, it is believed to occur in at least 10% of individuals with SARS-CoV-2 infection (with at least 65 million LC patients worldwide), and it has been linked to >200 different symptoms impacting multiple organ systems.[19] Although research in pediatric patients has lagged behind studies in adults, LC is being increasingly recognized in children.[20] In the paper by Garai et al., in this issue of *Pediatric Research*,[7] the clinical profile of LC is described in children and adolescents (89 patients with a mean age of 11.4) presenting with persistent symptoms (mean symptom duration, 18 weeks) following a documented COVID-19 infection. The authors describe a "Quality of Life" component that was also included in the study questionnaire, which was measured by questions focused on 12 items on a 5-grade scale from "no difficulty" to "extreme difficulty/cannot do". The range of systemic complications was extensive, in keeping with the known ability of SARS-CoV-2 to disseminate widely to all organ systems,[21] but of particular concern in this study was the magnitude of the neuropsychiatric manifestations. Seventy-two percent of the children in this study reported having mental health concerns at some point during their disease; psychiatric consultation was common, resulting in diagnoses such as major depression and/or anxiety disorders in 23% of patients. The lack of a control group limits conclusions about the extent to which mental health symptoms in this study were due to LC vs. effects from pandemic-related issues like school closure, although other large studies that included these controls have also documented increased long-term mental health consequences of COVID-19 in children.[22]

This emerging recognition of LC is another compelling reason to accelerate the pace of pediatric immunization, and to focus advocacy efforts not only on the role of SARS-CoV-2 vaccination in ameliorating COVID-19 disease, but also with respect to the vaccine's ability to improve overall pediatric mental health and quality of life. Notably, there is evidence that vaccination can *protect against LC*.[23] In a study of >2500 healthcare professionals working in nine Italian centers from March 2020 to April 2022, unvaccinated individuals were nearly three times as likely to have serious symptoms for longer than 4 weeks. In addition, COVID-19 immunization might provide a benefit for individuals already suffering from LC. In an uncontrolled study in the United Kingdom,

survey data of >25,000 individuals found a 13% reduction in long-term symptoms after a first dose of COVID vaccine.[24] There is a critical need to extend these observations to pediatric LC, and to study the impact of vaccination on the incidence and persistence of this syndrome.

COVID-19 immunization uptake has been extremely disappointing in children. In its most recent report of vaccination trends in the US, the American Academy of Pediatrics reported that, among children 5–11 years of age, only 34% had received at least one dose of COVID-19 vaccine (https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/). That percentage falls to a meager 11% for children from 6 months to 4 years of age. In addition, significant health disparities exist in COVID-19 vaccine uptake, with the lowest vaccination rates observed for Black and Latino children.[25] The embrace of vaccine misinformation has profoundly impacted parental compliance in vaccinating their children against COVID-19. From a public policy perspective, it is vital that pediatricians work to find strategies to address these fonts of vaccine misinformation. We propose that, once they are fully FDA approved (COVID-19 vaccines are still under an emergency use authorization for younger teens and children), more aggressive efforts need to be made to help parents and politicians encourage the acceptance of COVID-19 vaccines as part of *standard immunization practice* in children, toward a long-term goal of ensuring that all children are vaccinated prior to school attendance.[26] Schools have, for decades, recognized that encouraging immunization against other dangerous and highly communicable diseases, such as whooping cough, measles, and polio, is a valuable public health strategy.[27,28] Two states, California and Illinois, have even considered COVID-19 vaccine mandates for school attendance; on the other hand, several other states have enacted bans on requiring COVID-19 vaccination as a condition of in-person learning. Encouraging the linkage of school attendance to COVID vaccination, though a politically charged issue, is good public health policy. The key would appear to be finding an approach that leaves families and communities with a sense that they are free to choose vaccination, but to make it clear that such a choice is an intuitive and obvious option: indeed, this could be said for all school-based vaccine initiatives.

Another policy strategy to consider that may improve vaccine compliance is to couple pediatric COVID vaccination programs with the goal of improving pediatric mental health and neurodevelopmental outcomes. The recognition that the COVID pandemic has a profound impact on the mental health of children is something that there can be widespread agreement on. Given public and political recognition of the ongoing crisis in pediatric mental health, we are hopeful that there can be agreement across the political spectrum about the urgency of developing intervention strategies for this emergency. As the LC paper in the current issue of *Pediatric Research* illustrates,[7] one could consider COVID-19 vaccine as (not only) a preventative tool to limit the severity of symptomatic acute infection, but also as a potential preventative measure that improves long-term mental health outcomes. Reframing COVID-19 immunization as an intervention that could reduce depression and anxiety in children, by prevention of LC as well as reduction of school absenteeism, could go a long way toward improving public acceptance of the vaccine.

LOOKING FORWARD: WHAT POLICY RECOMMENDATIONS CAN IMPROVE PEDIATRIC OUTCOMES DURING THE CONTINUING PANDEMIC?

Policy opportunities to address the continuing COVID-19 pandemic in pediatric practice continue to be complex, driven by political considerations, anti-vaccination sentiment, and an overarching distrust, in some circles, of science. Both excessive attention and resources are focused on investigations that provide few direct, tangible benefits to pediatric health, such as investigating the putative origins of the COVID-19 virus in a Wuhan laboratory (the "lab leak" theory). We recommend that advocacy efforts be primarily focused on the following high-priority areas:

1. Continued investment in COVID-19 basic science and immunobiology. It is vital that tracking efforts put into place during the course of the pandemic be sustained and expanded. Wastewater tracking, for example, has been an invaluable public health resource in predicting and planning for COVID-19 surges. This technology has now proven to be valuable in tracking influenza outbreaks.[29] Expansion of this technology to other viruses with epidemic and pandemic potential, such as influenza, RSV, and enteroviruses (including polio) would represent a major public health advance, and could prove to be invaluable in recognition of future sentinel events that might signal the onset of the next pandemic. In addition, the application of these molecular tools can inform and direct efforts in the development of "next-generation" monoclonal antibody therapies, antivirals, and improved vaccines.
2. Education and increased implementation of COVID-19 vaccination during pregnancy. As pediatricians, we recognize that maternal health is synonymous with child health. The benefits of COVID-19 immunization during pregnancy are clear. The American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine both strongly recommend that pregnant individuals be vaccinated against COVID-19, but vaccine coverage is still deeply disappointing. One source of uncertainty came from the World Health Organization (WHO), which seemed to offer advice that was incongruous with the Centers for Disease Control and Prevention recommendations. Specifically, WHO recommended vaccination in pregnant women "when the benefits of vaccination to the pregnant woman outweigh the potential risks", citing examples such as "pregnant women at high risk of exposure to COVID-19" or pregnant women with comorbidities that placed them in a "high-risk group for severe COVID-19" (https://www.who.int/publications/m/item/update-on-who-interim-recommendations-on-covid-19-vaccination-of-pregnant-and-lactating-women). One of the reasons offered by the WHO for its measured recommendation for vaccination during pregnancy was the lack of enrollment of pregnant women in the initial safety and efficacy trials. Harmonization of safety and efficacy recommendations for the use of COVID-19 vaccines during pregnancy is an important public policy objective. In addition, the COVID-19 vaccine experience should remind us of the importance of including pregnant people, as well as children—groups historically underrepresented in clinical trials—in *all phases* of clinical research.[30]
3. Increased emphasis on, and development of new strategies to ensure, broad compliance with all pediatric immunizations—both for COVID-19 and for other vaccine-preventable diseases. One of the unexpected but dangerous results of the dismayingly poor COVID-19 vaccine uptake in children has been the decline in compliance with other vaccine recommendations. The reasons are complex, and included the lack of ready access to primary care that was due to clinic closure resulting from the COVID-19 lockdown at the height of the pandemic. However, promulgation of vaccine misinformation has been a major contributor, not only to the disappointingly low compliance with COVID-19 vaccines, but also the decline in compliance with other immunizations in the routine childhood series.[31] Implicit in this effort will be an increased emphasis on education about how

vaccines work, how they are vetted for safety and effectiveness, and how they have impacted human health. As mentioned above, framing the use of COVID-19 not only as an approach to prevent or mitigate the effects of SARS-CoV-2 infection, but also as a strategy to prevent long-term complications such as LC, could be a valuable component of this strategy.

4. Increased funding specifically focused on pediatric COVID-19 disease is an essential component for long-term control and enhanced outcomes. In 2021—at the height of the pandemic—President Biden proposed $88.2 billion over five years to build up biodefense and pandemic preparedness, as well as an additional $9.25 billion to fund new vaccines and therapeutics. However, in the omnibus spending bill passed by Congress in the spring of 2022, no new COVID-19 relief funding was included. We are thus poised to transition to a private sector/third-party payor model for access to COVID vaccines, antivirals, and testing—a transition that is likely to exacerbate existing inequities. A sense of complacency appears to have emerged, coupled with a lack of political will to fund ongoing disease control measures. However, an objective analysis of the current status of COVID-19 most assuredly indicates that life has not "returned to normal". The emergence of novel SARS-CoV-2 variants refractory to available vaccines and therapies; the continuing knowledge deficits about the correlates of protective immunity; the threat to healthy pregnancies that COVID-19 represents; the long-term neuropsychiatric manifestations of LC; the misinformation that has not only limited COVID-19 vaccine uptake but now has begun to threaten hard-earned gains in disease control for other vaccine-preventable infections; and the health disparities that have been worsened by the pandemic all serve to remind us that the pandemic is still very much impacting the health of our children. Now is not the time for complacency. As leaders in pediatric medicine, it is imperative to raise our voices in unison to influence COVID-19 vaccine policy, toward the goal of improving health outcomes for our children.

Data availability and policy

We acknowledge that *Pediatric Research* adheres to Springer Nature's Data Policy Type 3. This means that our submission to *Pediatric Research* implies that materials described in the manuscript, including all relevant raw data, would be freely available to any researcher wishing to use them for non-commercial purposes, without breaching participant confidentiality. It also means that a Data Availability Statement is required by the journal (see below where we provide this statement).

DATA AVAILABILITY

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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All authors made substantial contributions to the conception, design, acquisition of information, and writing for this commentary. M.R.S. drafted the commentary, and S.R.P. and C.C.J. critically revised the commentary for intellectual content and added additional material. All authors approved the final version. All authors made substantial contributions to the conception, design, and acquisition of information used in this commentary and approved the final version.

COMPETING INTERESTS

M.R.S. is a consultant for Moderna vaccines. S.R.P. is a consultant for Pfizer, Moderna, Dynavax, Hoopika, and Merck CMV vaccines, and leads sponsored programs on CMV vaccines with Moderna and Dynavax. C.C.J. declares no competing interests.

ADDITIONAL INFORMATION

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