Articles that highlight the unique science and art of vaccinology, especially given the ongoing coronavirus 2019 (COVID-19) pandemic, have been assembled in this issue of Pediatric Annals. These topics include an overview of vaccine development, the impact of the pandemic on ambulatory pediatric care, managing vaccine hesitancy, and COVID-19 vaccines furthest along in development.

The need for a safe and effective COVID-19 vaccine is paramount. To that end, clinical trials in adults, involving healthy people age 18 years and older, have quickly moved into Phase III clinical trials. Clinical trials involving children have yet to begin, in part due to concerns about unknown safety risks, adverse events, and immune responses among this younger population. However, these concerns cannot be addressed unless children are ultimately included in carefully designed vaccine trials.

In April 2020, less than 3% of reported COVID-19 cases were among children. However, at this time, the proportion of pediatric COVID-19 cases has more than tripled to account for approximately 10% of the total cases in the United States. This substantial rise has important implications not only for children, but also for family members, in particular grandparents, teachers, and other people to whom children can transmit the disease. Therefore, it is imperative that pediatric trials be conducted sooner, rather than delaying until adult efficacy is established. A delay will only prolong the recovery process and the detrimental effects of COVID-19 on children’s physical and emotional wellbeing, education, and equitable access to opportunities for development and social success. At the time of this guest editorial at least one vaccine manufacturer has expanded its Phase III trial to include adolescents age 12 years and older. It is hoped that additional manufacturers will soon also expand their study populations to include adolescents and subsequently younger children.

In light of the severe acute respiratory syndrome coronavirus 2 pandemic and the unprecedented speed with which vaccines are being developed, there have been questions regarding the normal vaccine development pathway; a process that is complex, costly, and unknown to many. Additionally, there have been concerns about vaccine safety and a lack of confidence in the vaccine development process. This could lead to insufficient uptake of a COVID-19 vaccine and failure to achieve desired herd immunity thresholds to return to pre-pandemic conditions. Thus, in the article entitled “Vaccine Development: From Laboratory to Policy” Hee Su Park, Eliana L. Samuels, and Dr. Joseph A. Bocchini, Jr. aim to promote a clear understanding of the process by which all vaccines are developed and proven to be safe and effective, from basic science research in the laboratory to the formulation of policy. This article outlines each step of the development process and the several checkpoints in place to ensure safety, adherence to regulatory requirements, and receipt of approval from various agencies and advisory committees. With this emphasis on the multiple checkpoints and safeguards, we hope to reduce confusion about the development process, increase public confidence in vaccines, and highlight that no compromises are being made in meeting the requirements to bring a COVID-19 vaccine to licensure.

The COVID-19 pandemic has also changed the way outpatient care is being delivered across the US. Now, because of COVID-19, providers face the additional challenges of maintaining and strengthening routine vaccinations. Community mitigation measures,
such as shelter-in-place orders, have resulted in declines in outpatient pediatric visits and fewer vaccine doses administered, leaving children at risk for vaccine-preventable diseases. As Veronica Valentine McNally and Dr. Bernstein emphasize in their article entitled, “The Effect of the COVID-19 Pandemic on Childhood Immunizations: Ways to Strengthen Routine Vaccination,” that the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics recommend every child continue to receive their routine vaccinations during the COVID-19 pandemic. Well-child visits and vaccinations are essential services and ensure children are protected against vaccine-preventable diseases.

Urgent action is required to maintain and strengthen childhood vaccination during the COVID-19 pandemic. As communities are re-opening, it is vitally important for providers to work with parents to ensure their children stay up to date on routine, universally recommended vaccines. The pandemic is a reminder of the threat of infectious diseases. Providers are well positioned to counsel parents about the value of vaccination. Uptake is highest when parents are aware that their child is due for specific vaccines and when they feel safe about their children receiving those vaccines. Measures may include the implementation of reminder/recall systems, standing orders, and communication with parents regarding how vaccines are being safely administered in outpatient settings during the pandemic. The wellbeing of the world depends on high uptake of routine vaccinations. Providers should not miss this opportunity to strengthen trust in public health and vaccines.

Although vaccine acceptance and uptake are overall high among children in the US, vaccine delays or refusals are of growing concern. In their article, “Strengthening Vaccine Confidence and Acceptance in the Pediatric Provider Office,” Dr. Sarah Mbaeyi, Allison Fisher, and Dr. Amanda Cohn detail steps that can be taken to address vaccine hesitancy, a complex and growing challenge facing pediatric providers. Although there is limited evidence for best practices to address vaccine hesitancy in the provider office, specific communication strategies (ie, using a whole-team approach, recommending vaccines presumptively, incorporating motivational interviewing) and organizational methods (ie, reminder/recall systems, standing orders, providing educational materials) help foster a culture of immunization and improve vaccine uptake and efficiency in clinical practice. These communication strategies and organizational methods are likely to take on increased significance as COVID-19 vaccines continue to be developed.

Worldwide there are currently 45 COVID-19 vaccine clinical trials underway in humans. Two countries, China and Russia, already have a total of six vaccines approved for early or limited use. Multiple vaccines, using various platforms, some novel, are in different phases of clinical evaluation in the US. Those currently in Phase III trials in the US have had accelerated development under Operation Warp Speed (OWS), a partnership among the Department of Health & Human Services (HHS), including the CDC, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority, and the Department of Defense. OWS engages industry and additional federal agencies to coordinate existing HHS-wide efforts, including the NIH’s Accelerating COVID-19 Therapeutic Interventions and Vaccines partnership. The purpose of OWS is to accelerate vaccine development while maintaining standards for safety and efficacy (www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html) through this public-private partnership. In the article, “COVID-19 Vaccines: A Primer for Clinicians,” we discuss the characteristics of the five vaccines currently undergoing, or on the eve of undergoing Phase III clinical trials in the US. Although these vaccines have not yet been studied in children, this is on or near the horizon. Understanding these vaccines will be important to health care providers when the time comes to educate parents about their roles in the prevention of COVID-19 disease.

We have assembled a group of authors with longstanding experience in vaccine trials and the development of vaccine policy. Some have worked with or are currently working at the US Food and Drug Administration or the CDC, two federal agencies with pivotal roles, respectively, in vaccine licensure and policy in the US. They bring their unique insights and expertise on topics of vaccinology to this issue.

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Guest Editorial

About the Guest Editors

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