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AAP town hall explores COVID-19 vaccine developments

by Trisha Koriath, Staff Writer

For the latest news on COVID-19, visit <https://www.aapublications.org/news/2020/01/28/coronavirus>.



Pediatricians were updated on COVID-19 vaccine prioritization, safety, efficacy and trials in pediatric populations during a town hall Thursday featuring experts from the Centers for Disease Control and Prevention (CDC) and AAP Committee on Infectious Diseases (COID).

The virtual meeting included discussion of immunization of pregnant health care providers, enrolling pediatric age groups in phase 3 trials and countering vaccine hesitancy.

Panelists Capt. Amanda Cohn, M.D., FAAP, and James Campbell, M.D., M.S., FAAP, have participated in hours of discussions and collaborative work on the monumental task of protecting the nation from the novel disease, said moderator Anne R. Edwards, M.D., FAAP, AAP chief population health officer.

Dr. Cohn is executive secretary of the CDC Advisory Committee on Immunization Practices (ACIP), chief medical officer of the CDC National Center for Immunization and Respiratory Diseases. Dr. Campbell is a COID member, is involved in testing COVID-19 vaccines and is co-chair of the National Institutes of Health (NIH) working group to develop a COVID-19 vaccine protocol for pediatric patients.

Vaccine for health care providers

With the Food and Drug Administration (FDA) expected to grant emergency use authorization for the mRNA COVID-19 vaccines from Pfizer/BioNTech and Moderna, pediatricians are wondering when their **local jurisdictions** might be able to offer the vaccine.

An **interim recommendation** from ACIP on Thursday urged allocating initial supplies to **health care workers** and residents in long-term care facilities.

Women make up 75% of health care workforce, Dr. Cohn said. "We will not have any data for pregnant women at the time when FDA authorizes a vaccine," she said. "We estimate that about 330,000 health care personnel could be pregnant or recently postpartum at the time of vaccine implementation. Data demonstrate potential



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increased risks of severe maternal illness and preterm birth due to COVID-19 disease, but there are no data yet on mRNA vaccines in pregnant or breastfeeding women."

Dr. Campbell, who has assisted on the NIH working group's protocol for pregnant women, said that once development and reproductive toxicity studies are completed, trials can enroll pregnant women who are in the second and third trimester.

Dr. Cohn said the initial phase of vaccine distribution will operate under timing and supply constraints. If health care providers are having trouble securing immunizations for critical staff, they should work with their local jurisdiction.

"We will be able to vaccinate millions of people rapidly but not the entire country," she said.

Health care providers likely can receive the vaccine regardless of whether they had COVID-19 infection, she added.

Dr. Cohn urged pediatricians to promote the vaccine to their staffs and communities even before it is available for children. It will be particularly important to address hesitancy regarding reactogenicity, she said.

Trials showed about 70% to 80% of vaccine recipients experienced mostly mild but noticeable symptoms, such as headache, myalgia and fever, particularly after the second dose. However, a second dose of vaccine is crucial to attain 94% or 95% effectiveness with the Pfizer and Moderna vaccines.

Health care providers should keep these symptoms in mind when they receive both doses of the vaccine so they can ensure adequate coverage of staff at work, Dr. Cohn said.

Because COVID-19 morbidity and mortality are increased for Black and Latinx populations, the CDC is working with organizations representing Black and Latinx health care professionals on ways to ensure access to the vaccine.

The CDC is adapting materials to be more culturally competent and calling on local voices for community engagement. "We need to start building trust in the communities now," she said.

The Vaccine Adverse Events Reporting System and new smartphone-based tool [Vaccine Safety Assessment for Essential Workers](#) will be used to monitor adverse reactions.

"When we're vaccinating millions of people at the same time, we will have to be evaluating adverse events rapidly and carefully," Dr. Cohn said.

When to expect pediatric vaccine

Until more is known about the vaccine in the pediatric population, guidance cannot be provided to pediatricians. Most pediatricians participate in the Vaccines for Children program, which will make it easy to provide COVID-19 vaccines, Dr. Cohn said. "Eventually, we will understand more about these vaccines and how we need to either continue vaccinating or incorporate them into our routine program."

The FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) continues to weigh data on the vaccines in children. VRBPAC has called for safety assessments that include careful evaluation for immune-mediated reactions or enhanced disease to support the benefit-risk considerations for pediatric enrollment in clinical trials and for vaccine authorization or approval in pediatric age groups.



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Pfizer/BioNTech have the only phase 3 trial enrolling participants as young as 12 years old. Moderna will soon be enrolling children ages 12 to 17. (See <https://www.clinicaltrials.gov/ct2/results?cond=COVID-19>.) For 12- to 15-year-old participants, a primary analysis is examining safety and immunogenicity, but COVID-19 disease is not included as a clinical outcome. Protocols also are being developed for age de-escalation studies, Dr. Cohn said.

There are other unknowns, including durability, the correlate of protection (what immune response leads to protection) and possible long-term safety problems or less common adverse effects.

Despite the rapid pace, Dr. Campbell stressed that the same processes for all vaccine development have been at play.

"We don't yet have the evidence for children, but everything is looking in the right direction," he said. "As pediatricians, we should be looking at the data as it's coming along and messaging and what's going on with the adults as adults are getting vaccinated so we'll be prepared months from now that hopefully we'll be able to vaccinate our children."

Resource

- [A COVID-19 Town Hall: COVID-19 Vaccine](#)