

New Miller School Study Will Evaluate COVID-19 Vaccine Effectiveness among Adolescents and Children

The University of Miami Miller School of Medicine has launched a new study focused on COVID-19 vaccine effectiveness and infection incidence in pediatric populations.



The study will monitor children of all ages.

The goals of the study, titled “Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT),” are to monitor the incidence of infection among children of all ages, and examine the impact of currently recommended vaccines for adolescents and younger children. The study is being led by Alberto Caban-Martinez, D.O., Ph.D., M.P.H., C.P.H., associate professor of public health sciences, assistant provost for research integrity, and M.D./M.P.H. Program deputy director,

and Lisa Gwynn, D.O., M.B.A., M.S.P.H., associate professor of clinical pediatrics and public health sciences, interim division chief for child and adolescent health, and program director of Pediatric Mobile Clinic and School Health at the Miller School. They seek to enroll 1,630 children ages 6 months to 17 years in the United States. Researchers hope PROTECT will be especially valuable in combating the COVID-19 pandemic.

“Public health practice is about bringing people and resources together to improve and protect community health across the life course,” Dr. Caban-Martinez said. “Partnering with Dr. Gwynn and our pediatrics colleagues in this timely national COVID-19 research project will allow our research teams to improve our understanding of COVID-19 infection and vaccine effectiveness for all children and adolescents.”

There are currently three COVID-19 vaccines that have received emergency use authorization in the U.S.: the Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen vaccines.

Approval vs. Authorization

To date, only the Pfizer-BioNTech vaccine has received full approval by the Food and Drug Administration (FDA) for individuals 16 years of age and older and authorization for use in children aged 5 years and older. The Moderna and Johnson & Johnson/Janssen vaccines have received authorization for use in adults aged 18 years and older.



Dr. Alberto Caban-Martinez

Both the Pfizer-BioNTech and Moderna vaccines have demonstrated efficacy of over 90% at preventing COVID-19 infection, hospitalization, and death across the different age groups. The Johnson & Johnson/Janssen vaccine has shown over 66% effectiveness based on evidence from clinical trials.

Clinical trials to test the vaccines' efficacy among younger children began in March 2021. Additional requests for emergency use authorization in children to the FDA and preliminary results are expected by the end of the year.

"Our pediatric mobile team is thrilled to collaborate with Dr. Caban-Martinez on this research project. Gaining a better understanding of COVID-19 infection trends and vaccination uptake in children will hopefully lead to improved mitigation strategies to reduce the spread of the virus," Dr. Gwynn said.

Multi-Center Study

The study will be implemented in four locations across the country: Miami; Temple, Texas; Salt Lake City, Utah; and

Tucson, Arizona.



Dr. Lisa Gwynn.

Children accounted for approximately 14% of all COVID-19 cases that were reported to state health departments from April 2020 to May 2021. Although overall COVID-19 cases have decreased since the start of the pandemic, the proportion of new COVID-19 cases among children has increased.

Data in the week ending on May 13, demonstrated a 24% pediatric incidence of COVID-19 among all COVID-19 cases. According to a recent report from the American Academy of Pediatrics, there was also a 9% increase from early to mid-September in the cumulated number of child COVID-19 cases since the beginning of the pandemic. The increase has been equivalent to 469,350 new cases, which raises the total number of child COVID-19 cases from 5,049,465 to 5,518,815.

COVID-19 vaccination not only protects children, but also the entire family. For instance, pediatric influenza vaccination has been proven to prevent transmission and hospitalization in

the elderly.

Co-principal investigators of the study include Manjusha Gaglani from Baylor Scott and White Health, Sarang Yoon and Kurt Hegmann from the University of Utah, Jeffrey Burgess from the University of Arizona, Mark Thompson and Ashley Fowlkes from the CDC National Center for Immunization and Respiratory Diseases Influenza Division, and Lauren Olsho from Abt Associates. The PROTECT study is a collaboration between Baylor Scott and White Health, the University of Miami, the University of Utah, the University of Arizona, the Centers for Disease Control and Prevention, and Abt Associates.

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