AAP: Include children in COVID-19 vaccine trials

by Melissa Jenco, News Content Editor


The AAP is calling for manufacturers to include children in their COVID-19 vaccine trials and for federal officials to use a rigorous scientific process for reviewing vaccines.

"If we do not add children to these research trials very soon, there will be a significant delay in when children are able to access potentially life-saving vaccines. This is unconscionable," AAP President Sara "Sally" H. Goza, M.D., FAAP, said in a news release. "More than 1 million children have been infected with this virus since the beginning of the pandemic, and children have suffered in numerous other ways. This includes disruptions to their education, harms to their mental and emotional health, and greatly diminished access to critical medical services. It is unjust to allow them to take on these burdens, but not give them the opportunity to benefit from a vaccine."

Pfizer Inc. and Moderna Inc. recently announced their phase 3 trials in adults have found 90% and almost 95% effectiveness, respectively, based on interim data. Both could request emergency use authorization from the Food and Drug Administration (FDA) in the coming weeks, but neither is expected to include children initially. Pfizer just recently started enrolling children as young as 12 years in its trials.

"Assuming that one or more of these vaccines are shown to be safe and effective in adults, in order for parents to be comfortable giving these vaccines to their children, we must have studies showing they are safe and effective in children as well," said Yvonne A. Maldonado, M.D., FAAP, chair of the AAP Committee on Infectious Diseases. "This research takes time. If this does not begin soon, it will be less likely a vaccine will be available for children before the next school year. We know that children can be infected with COVID-19 and can transmit it to others. In order to reduce the spread of this virus and control the pandemic as well as for their own safety, it's crucial that children be included in the national vaccination program, and that vaccines are made available to children as soon as possible."

The AAP also is urging federal officials to take steps to increase public confidence in a future vaccine. It is one of seven medical groups that sent a letter today to the leaders of Operation Warp Speed, the federal effort to
develop COVID-19 vaccines and therapeutics.

The groups called for the FDA to adhere to transparent requirements for COVID-19 vaccines and for vaccine candidates to be thoroughly vetted by scientists and physicians from FDA and Centers for Disease Control and Prevention (CDC) vaccine committees.

"These steps are important because authorizing a vaccine that has not been thoroughly vetted in a transparent fashion and demonstrated to be safe and effective would result in a significant lack of confidence among the scientific and medical community and the American public, seriously damaging vaccine delivery efforts," the groups wrote.

The letter was signed by the AAP, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American College of Physicians, American Medical Association, Infectious Diseases Society of America and Pediatric Infectious Diseases Society.

The groups also stressed the need for new ways of engaging the public, especially when vaccine misinformation is rampant on social media. Polls from the Pew Research Center and Gallup this fall found just half of U.S. adults would be willing to get a COVID-19 vaccine.

The groups offered to partner with federal officials "so that your mission to eliminate SARS-CoV-2 infection in the United States, which in truth is all of our mission, will succeed."

**Resources**

- [Information from the CDC about COVID-19 for health care professionals](#)
- [Information about COVID-19 from the AAP](#)
- [Information about COVID-19 from the AAP Red Book](#)
- [Information for parents from HealthyChildren.org on coronavirus](#)