

# Behind the wait on vaccinating younger children against COVID-19

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Full Food and Drug Administration (FDA) approval of the Pfizer-BioNTech vaccine for those 16 or older marked another important milestone in the fight against COVID-19. But many questions remain about the timeline for authorizing vaccines in younger children as the school year gets underway.

The process takes time, according to Paul Offit, MD, director of the Vaccine Education Center and an attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia. To his knowledge, vaccine manufacturers have yet to submit data to the FDA for review in 5-to-12-year-olds.

"My sense is we may not have a vaccine until winter for children," said Dr. Offit, co-inventor of the RotaTeq vaccine for rotavirus and a member of the FDA Vaccines and Related Biological Products Advisory Committee.

This is unfortunate given that school has started and fall's coming soon, creating a ripe environment for the highly contagious Delta variant of SARS-CoV-2, which spreads more easily in cooler, drier climates, said Dr. Offit.

In a recent episode of the "AMA COVID-19 Update," he explained why it's taking longer to approve the shots in younger children, and the barriers that remain in vaccinating the public.

## Vaccine safety comes first

The copious data available on 16- to 17-year-olds made it easy to extend the Pfizer-BioNTech vaccine to 12-year-olds, explained Dr. Offit. Not a huge difference exists between these age groups, and the dose and dosing intervals are the same: 30 micrograms and three weeks, respectively.

But the clinical trial process gets more complicated once you start testing the vaccine in much younger children. Research goes through several phases, testing various dosing levels and intervals and examining immune responses in thousands of children.

While it's frustrating to wait, "you want to make sure it's safe because you're about to give it to millions of children," he stressed.

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## Sluggish vaccine uptake among teens

Health systems are seeing more disease and hospitalizations in children in addition to "long COVID" syndrome, he said. Some 400 children in the United States have died from COVID-19.

Yet less than one-third of all 12- to 17-year-olds have received the Pfizer vaccine despite its wide availability over the past few months. Dr. Offit has heard many reasons why parents are hesitant to vaccinate their children or themselves.

Some, for example, are concerned that the Pfizer COVID-19 vaccine hasn't been around long enough to be assured of its safety. While it's true that vaccines can cause serious adverse events, historically there's never been an adverse event that's occurred beyond six weeks after vaccine administration, said Dr. Offit. Other parents, meanwhile, are misled into believing utter falsehoods or turn to the internet to fuel their inchoate doubts.

Having grown up during the polio epidemic, Dr. Offit recalls how the public then readily embraced vaccination.

"Polio had no friends. This virus has friends," he noted plaintively. "I mean, vaccine denialists, conspiracy theorists, science denialists, people who ban mask mandates, people who ban vaccine mandates—these are all friends of the virus."

Anthony Fauci, MD, chief medical advisor to President Biden, has speculated that the United States could possibly return to normal life in the spring of 2022. That goal is conditioned on the unvaccinated

getting vaccinated, Dr. Offit noted. And kids are a key part of the equation.

“We're not going to get on top of this pandemic until we vaccinate this population and children less than 18 represent about 20% of the population,” he said.

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