

U.S. to Begin Roll-out of COVID Vaccines for Babies as Young as 6 Months



The roll-out of COVID-19 vaccines for the nation's youngest children could begin as soon as Tuesday. The Centers for Disease Control and Prevention's (CDC) advisory panel on Saturday unanimously recommended COVID vaccines for children as young as 6 months despite the low risk COVID poses to children, scarcity of data, concerns over safety and lack of efficacy.

Federal regulators authorized the Moderna vaccine for children ages 6 months to 6 years, and the Pfizer-BioNTech vaccine for children ages 6 months to 5 years. Moderna's vaccine for infants and toddlers consists of two 25-microgram shots, while Pfizer's vaccine is a triple-dose regimen of 3-microgram shots each.

All children 6 months and older, including those who have already been infected with the virus should get a COVID vaccine, Dr. Rochelle P. Walensky, the CDC's director, [said in](#)

[a statement](#).

“Together, with science leading the charge, we have taken another important step forward in our nation’s fight against COVID-19,” she said. “We know millions of parents and caregivers are eager to get their young children vaccinated, and with today’s decision, they can.”

The Pfizer-BioNTech vaccine has an estimated efficacy of 80% in children under 5, Pfizer’s scientists said on Friday. But the calculation was [based on only three children](#) in the vaccine group and seven in the placebo group, making it a completely unreliable metric, CDC advisers noted.

But the advisory panel signed off on the shots anyway.

“We should just assume we don’t have efficacy data,” said Dr. Sarah Long, an infectious diseases expert at Drexel University College of Medicine. But Long said she was “comfortable enough” with other data supporting the vaccine’s potency.

“These numbers are ridiculously small – the 80% may not stand” if more kids are included in the numbers, [said pediatrician Dr. Liz Mumper](#) who live-blogged on CHD.tv during Friday’s meeting.

There were also concerns expressed about Moderna’s vaccine, which is only between 37% and 51% effective, depending on the age of the child receiving it. Moderna reported its vaccine was even less effective in March for the 2- to 6-year age group but changed the number to 51% prior to submitting their request for emergency use authorization.

The FDA required 50% efficacy to authorize a COVID-19 vaccine for all other age groups but waived the requirement for the nation’s youngest children after data continued to show pediatric vaccines didn’t work.

Mumper also pointed out the shots being considered during the

meeting over the weekend were based on the original Wuhan strain that is no longer circulating.

“It is not so important how good a vaccine is at generating antibodies to Wuhan strain,” Mumper said. “[We] need long-term data about the impact of the shot on the number of kids who get COVID in [the] community and have severe or mild [cases].

There was NO STATISTICAL SIGNIFICANCE in the vaccine study cited by FDA & CDC to recommend the vax in babies through kids<5. Any respected medical journal would normally reject this study for publication. How does the CDC so vigorously recommend this with such strong language?
<https://t.co/2Go9jjXfme>

– Marty Makary MD, MPH (@MartyMakary) [June 20, 2022](#)

The advisers debated whether Moderna and Pfizer’s COVID vaccines [enhance protection](#) against severe disease in children who have already been infected. Neither Pfizer nor Moderna properly studied the safety and efficacy of their vaccines in children with natural immunity.

According to the CDC’s most recent numbers from February, [75% of adolescents](#) have already had COVID meaning the vast majority of children who get a COVID vaccine will likely have already had the virus.

Since there is [little information available](#) on how vaccines work in those with natural immunity, the group decided to recommend the shots across the board with no regard to the potential risks – like antibody-dependent enhancement (ADE) – of vaccinating children who have already been infected.

According to the [Children’s Hospital of Philadelphia](#), ADE occurs when the “antibodies generated during an immune response recognize and bind to a pathogen, but they are unable to prevent infection. Instead, these antibodies act as a

“Trojan horse,” allowing the pathogen to get into cells and exacerbate the immune response.”

“U.S. VAERS data from Dec. 14, 2020, to June 3, 2022, for 6-month-olds to 5-year-olds show 1,658 adverse events, including 63 cases rated as serious and 3 reported deaths,” Mumper said. The risk of a child dying if they have a diagnosis is $1,086/10,700,00$ or $1086/10700000 = 0.00010149532$. The risk of any child dying of COVID-19 over this time period is $1,086/73000000 = 0.00001487671$.”

Florida only state not to pre-order vaccine doses for kids

Florida is the [only state in the nation](#) that did not place an order with the federal government for COVID vaccine doses for young children prior to U.S. health agencies authorizing the vaccines.

The deadline for placing a pre-order was June 14, and 49 other states met the cutoff date.

The Florida Department of Health (DOH), said in a statement to Politico on Wednesday that it did not pre-order vaccines for kids 5 and under because it doesn't advise all children get vaccinated.

“States do not need to be involved in the convoluted vaccine distribution process, especially when the federal government has a track record of developing inconsistent and unsustainable COVID-19 policies,” the DOH statement said.

Jeremy Redfern, press secretary for Florida's DOH, [confirmed](#) the department “chose not to participate” in the vaccination program.

“It is also no surprise we chose not to participate in distribution of the COVID-19 vaccine when the department does

not recommend it for all children,” Redfern said. “Doctors can order vaccines if they are in need, and there are currently no orders in the department’s ordering system for the COVID-19 vaccine for this age group.”