

What to expect as US weighs COVID shots for younger kids

October 7 2021, by Lauran Neergaard



Parents accompany their children outside PS 179 elementary school in the Kensington neighborhood in the Brooklyn borough of New York, in this Tuesday, Sept. 29, 2020, file photo. Pfizer asked the U.S. government Thursday, Oct. 7, 2021, to allow use of its COVID-19 vaccine in children ages 5 to 11—and if regulators agree, shots could begin within a matter of weeks. Credit: AP Photo/Mark Lennihan, File



The Food and Drug Administration is considering whether to allow COVID-19 vaccinations in children ages 5 to 11—using kid-sized doses.

Until now, only people 12 and older could be vaccinated in the U.S., with shots made by Pfizer and its partner BioNTech. That's been a huge frustration for many pediatricians and parents, especially as the extracontagious delta variant has raged through poorly vaccinated communities—and the schools in them.

On Thursday, the companies <u>formally applied</u> for emergency use of a lower dose for 5- to 11-year-olds. Here's what to expect:

Q: Why do younger kids need a vaccine?

A: The virus generally causes more serious disease in <u>older adults</u> than in children. But it can sometimes be severe in youngsters, too. According to the American Academy of Pediatrics, COVID-19 has killed at least 520 children in the U.S.

The delta variant also caused a jump in child infections, making it more difficult to keep schools fully open and students in class. A recent Kaiser Family Foundation survey found nearly a quarter of parents with kids in class this fall say they've already had to quarantine a child because of possible virus exposure.

Q: How soon could vaccinations begin for kids under 12?

A: First under consideration are shots for 5- to 11-year-olds. Advisers to the FDA are expected to publicly deliberate Pfizer's evidence on Oct. 26, setting the stage for the agency to declare if the shots are safe and effective for the roughly 28 million youngsters in that age group.

If it does, there's another step: Advisers to the Centers for Disease



Control and Prevention will decide whether to recommend kids actually get the vaccinations. The CDC makes the final call.

FDA vaccine chief Dr. Peter Marks has <u>said</u> the agency would decide "hopefully within a matter of weeks" after Pfizer submitted its data.

Q: Would younger kids get the same dose as teens and adults?

A: No. Pfizer aims to give 5- to 11-year-olds one-third of the dose that's given to everyone 12 and older.

Q: What's the evidence the kid-sized shots work?

A: Pfizer studied the lower dose in 2,268 volunteers in this age group, giving two-thirds vaccine and the rest dummy shots. The company says vaccinated 5- to 11-year-olds developed coronavirus-fighting antibody levels that were as strong as what teenagers and <u>young adults</u> get after the regular-strength shots.

Q: Was the vaccine safe for youngsters?

A: The <u>young kids</u> experienced similar or fewer temporary side effects such as sore arms and achiness than teens.

One exceedingly rare risk of both the Pfizer and Moderna vaccines is heart inflammation, usually in young men or boys. The CDC estimates that for every million fully vaccinated 12- to 17-year-old boys, the shots would prevent about 5,700 COVID-19 cases, 71 hospitalizations and two deaths while causing no more than 69 cases of heart inflammation. It's difficult for scientific studies to detect such a rare problem so regulators will have to debate the possibility of that risk with the lower-dose shots for younger kids.



Q: If it's cleared, will the kid-sized vaccine come in special packages?

A: Yes, to avoid any dosing mix-ups Pfizer plans to ship vials specially marked for pediatric use containing the lower dose.

Q: What about vaccinations for kids younger than 5?

A: Stay tuned: Study results are expected later this year.

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Citation: What to expect as US weighs COVID shots for younger kids (2021, October 7) retrieved 4 May 2024 from https://medicalxpress.com/news/2021-10-covid-shots-younger-kids.html

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