

## Pfizer Says COVID-19 Vaccine Safe for Children Ages 5 and Up



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Given that children and adolescents can get sick with COVID-19, attending K-12 schools in-person remains a risk. According to the American Academy of Pediatrics, children accounted for 25.7% of US cases for the week of 16 September (American Academy of Pediatrics, 2021), while hospitalisations averaged 311 children/day (Centers for Disease Control and Prevention, 2021). Children ages 12 and up are now eligible for the vaccine, but younger children still need to wait for clinical trial results and regulatory approval. This is an issue because children can be easily exposed while attending school in-person.

“Since July, paediatric cases of COVID-19 have risen by about 240% in the US - underscoring the public health need for vaccination,” Pfizer Chief Executive, Albert Bourla, said in a news release (Pfizer Inc, 2021).

On Monday, 20 September, Pfizer/BioNTech announced their phase 2/3 trial results for their COVID-19 vaccine. The study enrolled children in the United States, Finland, Poland, and Spain from more than 90 clinical trial sites. Like vaccine recipients ages 16 to 25 years old, children ages 5 to 11 showed a favourable safety profile and robust neutralising antibody responses comparable to adults. Children received a two-dose regimen of 10 µg given 21 days apart. This dose is one-third of that (30 µg) administered to adults and children ages 12 and up.

A rapid authorisation could greatly help the safe return of school children to in-person classes. This data will be included in regulatory applications submitted by the end of September to the US Food and Drug Administration for Emergency Use Authorization and the European Medicines Agency for EU Conditional Marketing Authorization. If approved, this could make the vaccine available to children by Halloween.

Pfizer/BioNTech will also continue collecting safety and efficacy data for full approval. Data on younger age cohorts (children ages 2 to 5 and ages 0.5 to 2) are expected later this year (fourth quarter).

Pfizer Chief Executive, Albert Bourla, added “We are eager to extend the protection afforded by the vaccine to this younger population, subject to regulatory authorisation, especially as we track the spread of the Delta variant and the substantial threat it poses to children.”

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