

# Pfizer says its COVID jab safe for children aged 5-11

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Pfizer and BioNTech on Monday said trial results showed their coronavirus vaccine is safe and produces a robust immune response in children aged five to 11, adding that they would seek regulatory approval shortly.

The [vaccine](#) would be administered at a lower dosage than for people over 12, they said.

"In participants five to 11 years of age, the vaccine was safe, well tolerated and showed robust neutralising antibody responses," US giant Pfizer and its German partner said in a joint statement.

They plan to submit their data to regulatory bodies in the European Union, the United States and around the world "as soon as possible".

Ashish Jha, dean of Brown University School of Public Health and a leading COVID expert in the US, called it the "good news" many parents had been waiting for.

If all goes well and approval follows, "my 9-year will get a shot by Halloween!" he tweeted.

The trial results are the first of their kind for children under 12, with a Moderna trial for 6-11 year olds still ongoing.

Both the Pfizer and Moderna jabs are already being administered to adolescents over 12 in several countries, as well as to adults around the globe.

England, Scotland and Wales became the latest to join the list of nations vaccinating younger teenagers, rolling out jabs for 12 to 15 year-olds this week. Northern Ireland is to follow suit next month.

## **Delta worries**

Although children are considered less at risk of severe COVID, there are concerns that the highly contagious Delta variant could lead to more serious cases.

Innoculating children is also seen as key to keeping schools open and helping end the pandemic.

"We are eager to extend the protection afforded by the vaccine to this younger population," said Pfizer CEO Albert Bourla, noting that "since July, paediatric cases of COVID-19 have risen by about 240 percent in the US".

Kids in the 5-11 age group received a two-dose regimen of 10 microgrammes in the trial, compared with 30 microgrammes for older age groups, the companies said. The shots were given 21 days apart.

The 10 microgramme dose was "carefully selected as the preferred dose for safety, tolerability and immunogenicity" for that age group, the statement said.

The side effects were "generally comparable to those observed in participants 16 to 25 years of age", it added.

Among the most commonly reported side effects in the past have been pain and swelling at the injection site as well as headache, chills and fever.

The Pfizer-BioNTech statement made no mention of the rare side effect of myocarditis, an inflammation of the heart muscle that has been linked to the vaccine, mostly among younger males.

## **Under-5s before year-end**

The Pfizer vaccine received full, formal approval in the US in August and is therefore technically available to younger children if prescribed by a doctor, but US authorities have cautioned against doing this until the safety data was in.

The US regulator, the Food and Drug Administration (FDA), said in a statement earlier this month it would "carefully" review emergency authorisation requests for vaccines for under -12s, a process it expected to take "weeks rather than months".

Israel has already given special authorisation to vaccinate children aged 5-11 who are "at significant risk of serious illness or death" from COVID, using the Pfizer jab at the lower dosage.

Pfizer and BioNTech are also trialling their vaccine on infants aged six months to two years, and on children aged two to five.

The topline results for those trials are expected "as soon as" the fourth quarter of this year, the companies said.

All together, up to 4,500 [children](#) aged six months to 11 years have enrolled in the Pfizer-BioNTech trials in the US, Finland, Poland and Spain.

Like its Moderna rival, the Pfizer jab is based on novel mRNA technology that delivers genetic instructions to cells to build the coronavirus spike protein, in order to evoke antibodies when bodies encounter the real virus.

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