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Covid-19: US and China prepare for mass vaccination of children under 12

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The United States is likely to begin administering the Pfizer-BioNTech coronavirus vaccine to children aged 5-11 as soon as the first week of November, after a Food and Drug Administration advisory committee voted by 17 to 0, with one abstention, to recommend emergency authorisation in that age group.

China approved its Sinovac vaccine for use in children aged 3-17 in June. Since then the vaccine has mostly been restricted to young children with extra risk factors. But in the past week municipal and regional governments in Fujian, Hainan, Hubei, Hunan, and Zhejiang provinces have announced that all children aged 3-11 will be required to get their shots in order to attend school.

While dozens of countries are vaccinating adolescents over 12, China and the US will join only a small handful that are immunising younger children. Cuba began on 16 September, vaccinating children aged 2-10 with its homegrown Abdala and Soberana vaccines. On 17 September Cambodia began vaccinating children aged 6-12 with Sinovac and, as one of the world's most vaccinated countries, is already planning a third paediatric booster dose.

Chile began vaccinating children aged 6-11 with Sinovac on 27 September. The United Arab Emirates has been giving another Chinese vaccine, Sinopharm, to children aged 3-17 since early August.

The US will become the first country to give an mRNA vaccine to young children outside a clinical trial. While the mRNA vaccines already have an extraordinarily good safety record, their most recognised serious adverse effects—pericarditis and myocarditis—have been concentrated in young people, particularly adolescent males.

The FDA argued to the advisory committee that the benefit would clearly outweigh the risk in all but the lowest viral transmission scenarios and that vaccination might still be preferable even then, as the pericarditis and myocarditis cases to date had mostly been mild, causing no deaths.¹

These side effects were not seen in the vaccine's paediatric trial, but the roughly 4500 participants were not numerous enough for the trial to detect such rare events, which occurred less than once in 200 000 doses in the vaccine adverse event reporting systems of Europe and the US.²

The paediatric dose, which is one third (10 µg) of the adult dose with two doses given three weeks apart, was 90.7% effective at preventing symptomatic coronavirus, the study found.³ The FDA noted that 1.9 million children aged 5-11 had been infected by the coronavirus in the US, more than 8300 had been admitted to hospital, and 94 had died.

Bottleneck

Some members of the advisory committee argued that the FDA's estimates of likely future transmission rates were too high, skewing the risk-benefit assessment. But several nodded their agreement when William Gruber, Pfizer's chief of vaccine development, argued that the benefit of facilitating a return to in-person learning for children might prove just as valuable as the protection against disease.

Some of those who voted to approve the vaccine's emergency authorisation spoke to the *Washington Post* afterwards, saying that they did not necessarily endorse the wholesale vaccination of the youngest age groups.⁴

James E K Hildreth Sr, chief executive of Meharry Medical College, said that he had voted to recommend authorisation because he wanted "to make sure that the children who really need this vaccine, primarily the black and brown children in our country, get the vaccine."

Cody Meissner of Tufts Medical Center voted for authorisation but said that he opposed any vaccine mandate in children until more data were available.

The sole abstainer, Michael G Kurilla of the National Institutes of Health, said that high risk children needed the vaccine, but he recommended, "for many others, one dose or no dose, even. If they've had prior covid infection, they may not need anything more."

The White House said that it had already purchased enough vaccine to immunise all 5-11 year olds in the US, but a poll last month by the Kaiser Family Foundation suggested that demand, not supply, was the real bottleneck.⁵ Only 34% of more than 1500 parents polled said that they would vaccinate their 5-11 year old child as soon as shots became available. Another 32% said that they would "wait and see," while 7% answered, "only if required," and 24% replied, "definitely not."

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