Covid-19: US public health officials urge FDA to decide on booster vaccines

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The vaccine advisory committee of the US Centers for Disease Control and Prevention (CDC) has expressed concern that the Food and Drug Administration has yet to decide whether immunocompromised people should receive booster shots of covid-19 vaccines.

Some immunocompromised people “have taken matters into their own hands, and many are proceeding with additional doses of vaccine as they see fit,” said Camille Kotton, committee member and a specialist in solid organ transplantation at Massachusetts General Hospital in Boston.

The FDA has given emergency use authorisation for three vaccines: the two dose mRNA vaccines made by Pfizer-BioNTech and Moderna and the single dose vaccine made by Janssen, a subsidiary of Johnson & Johnson. To make booster doses available the FDA would have to amend its emergency use authorisation, or it could make the vaccines available under a Biologics License Application, which would permit “off label” use.

At present doctors cannot prescribe the vaccines “off label” unless the drugs have received full FDA approval. Both Pfizer-BioNTech and Moderna have applied for full approval of the present two dose regimen. Pfizer-BioNTech has also applied for approval of a third, booster dose.

Sara Oliver, a CDC epidemiologist, said at the advisory committee’s meeting on 22 July that efficacy of the mRNA vaccines was much lower in immunocompromised patients, who make up about 2.7% of the US population.1

Small studies suggest that a booster dose in immunocompromised patients enhances antibody response and increases the proportion who respond to vaccines. Among patients who had no detectable antibody response after an initial mRNA dose, 33-50% developed an antibody response after a third dose in several studies, said Oliver.

France and Israel have allowed a booster dose for some immunocompromised people, and the UK is considering a booster for all adults.

Risks and benefits

Immunocompromised patients in the US should continue with precautions such as wearing a mask, social distancing, and avoiding crowds and poorly ventilated indoor spaces, said Oliver, and close contacts of such patients should be encouraged to be vaccinated.

She added that further studies were needed to look at the safety and efficacy of a booster in immunocompromised people and to determine the best dosing schedule and mix-and-match schedules of vaccines.

The advisory committee also heard a review of reports of small numbers of adverse effects: Guillain-Barre syndrome and thrombosis with thrombocytopenia syndrome after the Janssen vaccine and myocarditis after the mRNA vaccines.

Hannah Rosenblum of the CDC said that the risk of Guillain-Barre syndrome was highest among older men during the 42 days after vaccination. The risk of thrombosis with thrombocytopenia was highest in women aged 30 to 49. Myocarditis after the mRNA vaccines was highest in men aged 18 to 29.

Vaccinations prevented thousands of illnesses and hospital admissions and many deaths, said Rosenblum.

She concluded that “the benefits of covid-19 vaccination far outweigh the potential risks” and that the balance of risks and benefits varied by age and sex.


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