



Expert panel calls for simplification of COVID vaccines

January 27, 2023

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Article type: [News](#)

Topics: [COVID-19](#), [Infectious Diseases](#), [Public Health](#), [Vaccine/Immunization](#)

Editor's note: For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>

A federal panel of vaccine experts is recommending several moves to simplify COVID-19 vaccine administration and address changing variants.

The Food and Drug Administration's (FDA's) Vaccine and Related Biological Products Advisory Committee (VRBPAC) voted 21-0 in favor of using the same vaccine composition in the primary series and booster doses. Members also generally agreed those strains should be updated periodically and that the schedule should be simplified.

"As we turn the corner from a pandemic phase to an endemic phase, today's vote marks a big practical win for the American people," said Ofer Levy, M.D., Ph.D., director of the Precision Vaccines Program at Boston Children's Hospital. "This is going to really simplify things, benefit public health. There's more work ahead ... but this will be a big win."

The recommendations followed a full day of presentations from the FDA, Centers for Disease Control and Prevention (CDC) and vaccine manufacturers. None of the recommended changes take effect immediately. The FDA and CDC will be reviewing them and could make a formal decision on how to proceed in the coming weeks and months.

FDA officials brought the proposals to the committee as the SARS-CoV-2 virus continues to evolve and vaccinators juggle a complex web with over a dozen vaccine presentations and multiple schedules.

Harmonizing primary series, booster strains

The primary series is a monovalent vaccine that uses the original SARS-CoV-2 strain while boosters are bivalent vaccines consisting of the original strain and omicron BA.4/5. While all circulating strains are omicron variants, prevalence of subvariants continues to change. About 49% are XBB.1.5, 27% are BQ.1.1 and 13% are BQ.1, [according to CDC data](#).

Use of bivalent boosters began in September 2022. CDC data show adults who received a bivalent booster had a 16 times lower risk of hospitalization for COVID compared with those who are unvaccinated. Those with a bivalent booster also had a three times lower risk of hospitalization compared with those vaccinated without a bivalent booster.

VRBPAC members on Thursday voted in favor of using the same composition for primary series and booster vaccines, citing the need for simplicity and the desire to match circulating virus strains.

“There’s so much confusion about these different formulations that anything we can do to ease up on the confusion and simplify things is going to be a good thing,” said VRBPAC member Archana Chatterjee, M.D., Ph.D., dean of the Chicago Medical School at Rosalind Franklin University of Medicine and Science.

VRBPAC member Amanda Cohn, M.D., a pediatrician and medical epidemiologist with the CDC, said she hopes the move will help improve vaccination rates among young children. Only 3.5% of children under 2 years have completed a primary series along with 5.3% of 2-4-year-olds, 32.5% of 5-11-year-olds and 61.5% of 12-17-year-olds, [according to CDC data](#). However, Dr. Cohn urged families to vaccinate children now instead of waiting for bivalent primary series vaccines to become available.

“I don’t want to forget we also saw data that the monovalent primary series was working quite well against symptomatic infection in younger children,” Dr. Cohn said.

Vaccine composition

No final decisions were made on what the new composition of the vaccines would be. However, committee members supported periodic updates whether annually like the flu vaccine or more frequently. VRBPAC likely will meet in late May or early June to discuss what strain or strains to use in a fall vaccine campaign.

“I think it is critically important that we pay attention to the epidemiology and what is happening with emerging variants, how the vaccines are continuing to hold up against them,” Dr. Chatterjee said. We’ve had much discussion today about not wanting to chase variants and I agree with that but on the other hand we do have to be mindful, pay attention to make sure vaccines continue to be effective.”

Several members also stressed the need to focus not only on mRNA vaccines but also other platforms that may provide broader protection.

Dosing schedule

VRBPAC members also agreed the dosing schedule for COVID vaccines should be simplified, especially given so much of the population has already been vaccinated, infected or both. One potential strategy the FDA provided would be one dose for young children who have been previously immunized, older children and adolescents and most adults. Young children who have not been previously immunized, people with compromised immunity and high-risk older adults likely would need multiple doses.

“We have a lot of population immunity and I think we need persistence studies to answer this question and I think those need to include broad immunogenicity studies ... T cell, B cell, mucosal combined with efficacy

data, combined with persistence data,” said Hayley Gans, M.D., professor of pediatrics at Stanford University Medical Center.

Some members noted there would need to be more discussion on whether the goal is to prevent severe illness or all illness. Members also called for more data specific to dosing for young children, some of whom currently receive a three-dose primary series.

Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research, said the FDA will continue to monitor safety and effectiveness and collect more of the requested data.

“We’ll also look forward to working with scientists inside of government and outside of government, in academics and industry towards a next generation of COVID vaccines that will hopefully have ... the greater depth and breadth of protection that we’d like to see,” he said.

Resources

- [CDC clinical considerations for administering COVID-19 vaccines](#)
- [AAP COVID vaccination resources](#)
- [AAP pediatric COVID-19 vaccine dosing quick reference guide](#)
- [CDC COVID Vaccination Field Guide](#)
- [AAP/Health and Human Services COVID vaccine toolkit](#)
- [Information for parents on COVID vaccines from HealthyChildren.org](#)