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CDC panel OKs adding COVID vaccines to immunization schedules; discusses new RSV product for infants

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

A federal vaccine committee recommended adding COVID-19 vaccines to next year's child, adolescent and adult immunization schedules.

During a meeting Thursday, the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) also discussed a new monoclonal antibody for respiratory syncytial virus (RSV) in infants and heard updates on existing vaccines for meningococcal disease and flu.

COVID-19 vaccines

The addition of COVID-19 vaccines to the immunization schedules does not change recommendations around these vaccines. Instead, it acknowledges the ongoing need to vaccinate children, adolescents and adults. ACIP voted 15-0 in favor.

"When I think about the routine immunization schedule as a practicing pediatrician, I think about it as an opportunity in my patients to prevent serious disease and death," said ACIP COVID-19 Vaccines Work Group Chair Matthew F. Daley, M.D., FAAP. "… If something is added to the schedule, it's because … the benefits continue to strongly outweigh the risks."

ACIP members debunked false claims that adding COVID-19 vaccines to the immunization schedules would result in mandates for school entry.

“We recognize there is concern around this, but moving COVID-19 to the recommended immunization schedule does not impact what vaccines are required for school entrance, if any,” said ACIP member Nirav D. Shah, M.D., J.D., director of the Maine Center for Disease Control and Prevention. “Indeed, there are vaccines that are on the schedule right now that are not required for school attendance in many jurisdictions such as seasonal influenza. Local control matters, and we honor that.”

Yesterday, ACIP voted 15-0 to add COVID-19 vaccines to the Vaccines for Children (VFC) program once commercial distribution begins. That move also does not impact mandates but ensures equitable access to the vaccines for all children. The VFC program provides free vaccines for Medicaid-eligible, uninsured, underinsured and American Indian/Alaska Native children.

The final immunization schedules will be published in February 2023 after they receive approval from the CDC director, the AAP and other medical groups.

RSV monoclonal antibody

A monoclonal antibody to protect infants from RSV could be available next year.

RSV can cause severe lower respiratory tract disease such as bronchiolitis or pneumonia and is a leading cause of hospitalization in infants.

AstraZeneca and Sanofi presented clinical trial data to ACIP on their nirsevimab product that has been studied in just over 3,000 infants. Efficacy in trials was 76%-79% against medically attended illness, hospitalization and very severe RSV. Reactogenicity was low, and rash, injection site reactions and pyrexia were uncommon. There were no serious adverse events, cases of anaphylaxis or deaths related to nirsevimab.

ACIP will continue to look at data on nirsevimab in February 2023 and could vote on its use in June if the Food and Drug Administration (FDA) has granted a license by that point.

The product has been proposed as an intramuscular injection with a pre-filled syringe. ACIP’s work group is discussing whether to use it for infants under 8 months entering their first RSV season and all infants born during the RSV season. The manufacturers have proposed giving it to infants born in April-October at a clinician’s office before the start of the season. Those born in November-March (during the season) would get it in the hospital at birth.

ACIP also will decide whether to recommend it for children under 24 months entering their second RSV season who remain at increased risk of severe disease.

Meningococcal vaccines

The FDA recently authorized a new one-dose vial of GlaxoSmithKline’s (GSK’s) Menveo meningococcal conjugate (MenACWY) vaccine that is expected to be available in spring 2023.

While the one-vial formulation is very similar to the current two-vial formula, the age indications are different. The new one-vial formulation does not need reconstitution and is authorized for people ages 10-55 years, while the two-vial formulation is for people ages 2 months to 55 years.

GSK will be sending letters to providers to introduce them to the new formulation.

GSK and Pfizer are each working on their own pentavalent vaccines that would combine their existing MenACWY and serogroup B meningococcal disease (MenB) vaccines.

Both companies' MenABCWY vaccines are being studied in people ages 10-25 years. Both are looking at two-dose schedules. Pfizer also is assessing a single dose of pentavalent as an alternative to MenACWY vaccine.

ACIP will continue to look at data throughout the next year and could vote in October 2023.

Flu

The new flu season has just begun, and flu activity is low but increasing, according to the CDC.

About 2.6% of outpatient visits were for flu-like illness in the week ending Oct. 8, just slightly above baseline. Flu activity is very high in Washington, D.C., and high in Georgia, Texas, New York City, South Carolina and Tennessee.

Data from the Southern Hemisphere show some shifting in the start and end of flu seasons in 2021 and 2022. After low levels of flu earlier in the COVID-19 pandemic, regular flu activity seems to have resumed in these countries, according to the CDC. Influenza A(H3) has predominated in most of the countries the CDC tracks.

Data presented to ACIP Thursday showed vaccine effectiveness last season among U.S. children ages 6 months to 17 years was 45% in preventing outpatient visits, 19% in preventing emergency department visits and 31% in preventing hospitalization. Flu vaccines have been updated this season to better match the strains expected to circulate. The AAP and CDC recommend everyone 6 months and older get vaccinated.