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Expert group discusses products to protect infants from RSV

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The Centers for Disease Control and Prevention's (CDC's) vaccine advisory committee recently discussed two products to protect infants from respiratory syncytial virus (RSV).

The first is the monoclonal antibody nirsevimab, and the second is a new RSV vaccine that would be given to pregnant women. The Advisory Committee on Immunization Practices (ACIP) also discussed new vaccines to protect older children from meningococcal disease and dengue.

RSV monoclonal antibody for infants

RSV can cause severe lower respiratory tract disease such as bronchiolitis or pneumonia and is the leading cause of hospitalization in infants. There are about 58,000 to 80,000 hospitalizations and 100 to 300 deaths per year in children under 5 years, according to data the CDC presented.

Nirsevimab from AstraZeneca and Sanofi is a form of passive immunization under review by the Food and Drug Administration (FDA). If it receives approval, CDC experts have proposed that infants born in October through March receive one dose at birth or as soon as possible afterward. For infants born in April through September, the ideal timing would be just before or near the start of the RSV season. Timing may be different for some areas that have more variable RSV seasons such as Alaska, Hawaii, Guam and Puerto Rico.

Nirsevimab's efficacy for infants is estimated at 79% against medically attended RSV lower respiratory tract infection and 81% against hospitalization from this infection.

ACIP also is considering use for children under 20 months entering their second RSV season who are at increased risk of severe disease due to certain underlying conditions. These children would get nirsevimab in October or November. Data on efficacy and safety are limited in this group.

The FDA is expected to classify nirsevimab as a drug. Doing so raises questions about whether it could be included in the Vaccines for Children (VFC) program, which provides free vaccines for Medicaid-eligible, uninsured, underinsured and American Indian/Alaska Native children. Classification as a drug also means some health care workers, e.g. medical assistants, may not be allowed to administer nirsevimab in certain jurisdictions. In addition, different adverse event reporting systems are used for drugs and vaccines.

If it is not included in VFC, it likely would be covered under state Medicaid programs, the Children's Health Insurance Program and private insurance, according to the CDC.

Matthew F. Daley, M.D., FAAP, senior investigator at the Institute for Health Research at Kaiser Permanente Colorado, called nirsevimab "incredible" and "transformative," but said he was troubled to learn they may not be able to use the existing vaccine infrastructure and programs.

"I'm concerned we're going to miss a lot of opportunities for disease prevention because we're not going to use a system that we've built for the last 50 years," he said.

CDC officials said they are working with other federal agencies on these issues.

While the cost of nirsevimab is unknown, ACIP did discuss cost effectiveness, with some members saying $300 per dose may be reasonable.

ACIP is expected to continue its discussion of nirsevimab in June.

RSV vaccine for pregnant people

ACIP also heard new data on the RSVpreF vaccine from Pfizer that is proposed to be given to pregnant people at 24-36 weeks' gestation to protect their infants.

Pfizer's data showed about 82% efficacy in preventing severe medically attended lower respiratory tract infection in the first 90 days of life and 69% at 6 months. Looking at these medically attended infections of any severity, efficacy was 57% at 90 days and 51% at 6 months.

Pfizer representatives said the vaccine was well-tolerated and did not present safety concerns for the pregnant participants or their infants in trials.

The FDA has accepted Pfizer's application for priority review and set an action date of August 2023. ACIP will continue to discuss RSVpreF in June and could vote in October if the FDA has licensed it by that time.

Pentavalent meningococcal vaccine

Another vaccine that may be on the horizon for children is Pfizer's pentavalent meningococcal vaccine, which is proposed to be used in people ages 10-25 years. The new vaccine combines Pfizer's MenACWY vaccine that is used in other countries and the serogroup B meningococcal disease (MenB) vaccine used in the U.S.

Clinical trial data presented Thursday show the pentavalent vaccine is noninferior to the two vaccines given separately. However, questions remain about the vaccine's persistence of protection, cost, impact on the immunization schedule and use in high-risk populations.

ACIP will continue to discuss the vaccine in June and could vote in October if the FDA has licensed the vaccine by that time. The group also will be discussing a pentavalent meningococcal vaccine from GlaxoSmithKline later this year.

Dengue vaccine

Takeda presented clinical trial data to ACIP Thursday on its TAK-003 dengue vaccine in children ages 4-16 years.

A CDC analysis of the data found the vaccine protects people with previous dengue infection from disease or hospitalization due to any of the four dengue virus serotypes.

People without previous infection were protected against disease and hospitalization for serotypes 1 and 2 but not 3. Assessment of protection for serotype 4 was limited due to few infections. There appears to be no protection against disease from serotype 4 and unknown protection against hospitalization.

ACIP plans to continue its discussion in June and could vote in October if the FDA has licensed the vaccine. The FDA has granted it priority review.

ACIP will continue its meeting on Feb. 24 to discuss the future of COVID vaccines.