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Academy reviewing possible return of nasal spray flu vaccine

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Melissa Jenco, News Content Editor

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The Academy is reviewing a federal health committee's recommendation to bring back a nasal spray flu vaccine next season.

The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted on Wednesday to add the quadrivalent live attenuated influenza vaccine (LAIV4, FluMist) as an option for the 2018-'19 season after pulling it for the past two influenza seasons due to poor effectiveness, especially during H1N1 seasons. However, the CDC director still needs to approve ACIP's recommendation in order for it to be CDC policy.

The AAP Committee on Infectious Diseases (COID) will make its own recommendations at the spring meeting based on how COID views the evidence on LAIV effectiveness.

"AAP values the importance of vaccines and influenza vaccine especially given the high rate of hospitalizations and deaths in children from this disease, and we are always very thoughtful regarding improving the benefit of influenza vaccines as well as the uptake of these vaccines," said Yvonne A. Maldonado, M.D., FAAP, vice chair of COID. "COID looks forward to considering the return of a recommendation for LAIV use once we have an opportunity to carefully review all of the data on the newly reformulated vaccine."

LAIV, which is given by intranasal spray to healthy patients ages 2 through 49 years, was a popular option for those reluctant to get a shot. However, in 2016, ACIP reviewed data showing no effectiveness, especially against H1N1 strains, and did not recommend it for the 2016-'17 or 2017-'18 seasons.

On Wednesday, Raburn Mallory, M.D., senior director of clinical development for FluMist manufacturer MedImmune, told the committee it had changed to a new H1N1 strain (A/Slovenia) that is producing better antibody responses than the previous strain (A/Bolivia). He also presented data on shedding of the vaccine strain and on seroconversion. However, because there has been little circulation of influenza A/H1N1 in the past two years, there are no efficacy data for the new formulation against H1N1 which was the strain for which LAIV performed poorly in the 2013-'14 and 2015-'16 seasons.

"The studies showed the new strain induced significantly higher seroconversion rates than the old strain," Dr. Mallory said. "These results validate the changes and improvements we've made to our strain selection process, and this improved process is being applied to all future LAIV strains."

The CDC also presented new analyses of LAIV effectiveness data from several studies. Given the available data, ACIP felt that adding a non-injectable option might improve influenza immunization rates since some individuals would prefer to avoid a shot. Use of LAIV during an influenza season will allow evaluation of efficacy of the new LAIV formulation.

“I think the evidence is pretty clear this vaccine is better than not being vaccinated and there are kids who will not be vaccinated without this option, so let’s put it out there as an option, let’s give clinicians and parents a chance to talk it over and figure out what they want to give their kids,” said ACIP member Cynthia Pellegrini, senior vice president of public policy and government affairs for March of Dimes.

But Henry H. Bernstein, D.O., M.H.C.M., FAAP, *Red Book* Online associate editor, said influenza vaccination rates haven’t gone down since LAIV was removed, and he questioned whether MedImmune’s data on shedding was a sufficient indicator it would be effective.

“The part that really worries me the most is the fact if we reinstate LAIV4 without knowing its vaccine effectiveness during an H1N1 season and then we have an H1N1 season and it results in increased morbidity and mortality … that is likely to undermine administration of flu vaccine for the public, potentially lowering all coverage rates and negatively impacting the country’s overall flu vaccine program,” said Dr. Bernstein, who voted against the recommendation.

ACIP ultimately voted 12-2 to recommend using any age-appropriate vaccine — inactivated influenza vaccine, LAIV, or recombinant influenza vaccine. There was significant discussion among the committee related to how to message the reinstatement of LAIV. The group acknowledged the Vaccines for Children program already has placed orders and likely would not have LAIV available for VFC vaccine recipients for 2018-’19.

If the CDC director approves ACIP’s recommendation, it will be published as an official recommendation in the *Morbidity and Mortality Weekly Report*. The Academy typically releases its own influenza policy in September.

The current influenza season has been widespread and severe with high hospitalization rates and 84 pediatric deaths to date. Despite a 36% vaccine effectiveness rate, influenza immunization prevents millions of influenza-like illnesses and many cases of severe influenza disease and hospitalizations. The Academy and CDC continue to recommend everyone 6 months and older be vaccinated as the virus may continue to spread for several more weeks.

Resources

- AAP policy "Recommendations for Prevention and Control of Influenza in Children, 2017 – 2018"
- Information from the CDC about flu
- Information for parents on flu vaccine from HealthyChildren.org
- AAP News stories on flu
- Pediatrics seasonal flu article collection