



Department of Health

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TO: Healthcare Providers and Local Health Departments
FROM: New York State Department of Health (NYSDOH), Bureau of Immunization

INFORMATIONAL MESSAGE:
LIVE ATTENUATED INFLUENZA VACCINE (FLU NASAL SPRAY)
NOT RECOMMENDED FOR 2016-17 FLU SEASON

Please distribute to the Medical Director, Vaccine Coordinator, and all healthcare providers that order or administer influenza vaccines.

SUMMARY

- On June 22, 2016, the Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) voted in favor of an interim recommendation that live attenuated influenza vaccine (LAIV), also known as the "nasal spray" flu vaccine, should not be used during the 2016-17 flu season.
- The ACIP recommendation must be reviewed and approved by the CDC's Director, and the final recommendations will be published in a CDC Morbidity and Mortality Weekly Report (MMWR) in late summer or early fall.
- The ACIP and NYSDOH continue to recommend annual flu vaccination, with either the inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) for everyone 6 months and older.
- The ACIP vote follows data showing poor or relatively lower effectiveness of LAIV from 2013 through 2016.
- Overall, IIV vaccine efficacy was 49% in the 2015-16 season, indicating that millions of people were protected against flu last season.
- The ACIP vote may have implications for vaccine providers who have already placed flu vaccine orders for the 2016-17 season.
- Based on manufacturer projections, the CDC expects that supply of IIV for the 2016-17 season should be sufficient to meet any increase in demand resulting from the ACIP recommendation.
- The NYS Vaccines for Children (VFC) Program will make every effort to fill VFC influenza vaccine orders, as supply allows. VFC providers will be notified when influenza vaccine orders open for the 2016-17 season.
- Healthcare providers who have purchased or pre-ordered private influenza vaccine should consult with the vaccine manufacturer or vaccine distributor. Providers seeking to purchase additional doses of private IIV or RIV vaccine may need to check more than one supplier or purchase a flu vaccine brand other than the one they normally select.
- The NYSDOH will share any additional information about influenza vaccines and the upcoming flu season as information becomes available. Healthcare providers can also check for updated immunization information on the NYSDOH Immunization News web page (http://www.health.ny.gov/prevention/immunization/immunization_news.htm).

LAIV VACCINE EFFICACY

The June 2016 ACIP recommendation that LAIV not be used in the 2016-17 season was made on the basis of vaccine efficacy (VE) data. During the 2015-16 season, VE data provided by the U.S. Flu VE Network indicated that LAIV had offered no significant protection against influenza A (H1N1) virus, the predominant flu virus circulating last season, among study participants ages 2 through 17 years of age. The preliminary VE for LAIV against any influenza virus in studied children was 3% (95% CI: -49% to 37%) compared with 63% VE for IIV (95% CI: 52% to 72%). There was evidence that VE for IIV was statistically better than LAIV for influenza A (H1N1) virus but not for influenza B viruses; VE for influenza A (H3N2) viruses could not be assessed due to insufficient data.

The disappointing LAIV VE data from the 2015-16 flu season followed two previous seasons (2013-14 and 2014-15) which also showed poor and/or lower than expected VE for LAIV.

For the 2014-15 flu season, the ACIP and CDC had issued a preferential recommendation for the use of LAIV in healthy children 2 through 8 years of age. The 2014-15 recommendation had been based predominantly on data from two randomized control trials of LAIV and IIV which had measured superior efficacy of LAIV among young children during the 2002-03 and 2004-05 flu seasons. However, in February 2015, the ACIP and CDC did not renew the preferential recommendation for LAIV, on the basis of data showing poor VE of LAIV against influenza A (H1N1) in the 2013-14 and 2014-15 seasons.

The reason for the poorer overall performance of LAIV compared to IIV over the last few flu seasons is not well understood. It was initially hypothesized that the reduced effectiveness was due to reduced vaccine stability caused by a single amino acid mutation in the strain of influenza A (H1N1) that was contained in LAIV in the 2013-14 season. As a result a new H1N1 vaccine virus was used in LAIV formulations for the 2015-16 season. However, despite the change in the H1N1 virus component of the LAIV vaccine, VE data for the 2015-16 season again found that LAIV was less effective than IIV.

INFLUENZA VACCINE SUPPLY

The CDC anticipates that the supply of IIV for the 2016-17 season should be sufficient to meet any increase in demand resulting from the ACIP recommendation. Vaccine manufacturers have projected that as many as 160 million doses of IIV and RIV will be made available for the 2016-17 season. However, healthcare providers seeking to order additional doses of private IIV or RIV vaccine may need to check more than one supplier or purchase a flu vaccine brand other than the one they normally select. Healthcare providers who have purchased or pre-ordered private influenza vaccine will need to consult with the manufacturer or vaccine distributor.

One influenza vaccine was recently FDA-approved for an expanded age indication, and a second is awaiting FDA decision later this year on an expanded age indication. In May 2016, the FDA approved an expanded age indication for quadrivalent Flucelvax (cell culture-based IIV; Seqirus, Inc.) for immunization of persons 4 years of age and older against influenza virus subtypes A and B. Flucelvax had initially been FDA approved in November 2012 for vaccination of adults ages 18 and older. The FDA is also anticipated to issue a decision in November 2016 regarding GSK's application for an expanded age indication for Flulaval (IIV; GSK) for persons 6 months of age and older. It is not yet known what impact these age indications will have on vaccine availability in the 2016-17 season.

VACCINES FOR CHILDREN PROGRAM

The NYS VFC Program will make every effort to fill VFC influenza vaccine orders this coming season, as vaccine supplies allow. Influenza vaccine is not yet available for the 2016-17 season, and it is not yet known how VFC influenza vaccine availability will be impacted by the ACIP recommendation. VFC providers will be notified when influenza vaccine orders open for the 2016-17 season, and the NYSDOH will share information regarding vaccine availability as such information becomes available.

RESOURCES

- CDC. ACIP votes down use of LAIV for the 2016-2017 flu season. www.cdc.gov/media/releases/2016/s0622-laiv-flu.html.
- FDA Vaccines, Blood & Biologics. Flucelvax. www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm328629.htm.
- Flu Supply News. List of Distributors. www.flusupplynews.com/www.flusupplynews.com/Navigation/FluSeason/ListofDistributors/List_of_Distributors.aspx.
- National Adult and Influenza Immunization Summit. Influenza Vaccine Availability Tracking System – IVATS. www.izsummitpartners.org/ivats/.
- NYSDOH. Seasonal Influenza Information for Health Care Providers. www.health.ny.gov/diseases/communicable/influenza/seasonal/providers/.
- NYSDOH. New York State Vaccines for Children Program. www.health.ny.gov/vfc.
- CDC. What You Should Know for the 2016-2017 Influenza Season. www.cdc.gov/flu/about/season/flu-season-2016-2017.htm.
- NYSDOH. Immunization News. www.health.ny.gov/prevention/immunization/immunization_news.htm.