NEW YORK STATE OF OPPORTUNITY. Department of Health

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TO: Healthcare Providers, Clinical Laboratories, Hospitals, Long-Term Care Facilities, Pharmacies, and Local Health Departments

FROM: NYSDOH Bureau of Immunization

HEALTH ADVISORY:

INFLUENZA PREVENTION AND CONTROL: 2016-2017

For healthcare facilities: please distribute immediately to the Infection Control Department, Emergency Department, Infectious Disease Department, Director of Nursing, Medical Director, Director of Pharmacy, Laboratory Service, and all patient care areas.

PURPOSE

The New York State Department of Health (NYSDOH) is providing this advisory to assist health care providers in preparing for the 2016-17 influenza season. This informational message highlights some of the current recommendations regarding the prevention and control of influenza.

PREVENTION AND CONTROL OF INFLUENZA WITH VACCINES

On August 26, 2016, the Centers for Disease Control and Prevention (CDC) published the annual recommendations of the Advisory Committee on Immunization Practices (ACIP) on the prevention and control of influenza with vaccines. (MMWR; August 26, 2016; 65 (R-55)); 1-54). The document is accessible at:
http://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.htm?s_cid=rr6505a1_e.

Highlights of the ACIP recommendations include:

- Live Attenuated Influenza Vaccine (LAIV) is not recommended for use in the 2016-17 influenza season.
- Vaccine formulation and composition for the 2016-17 U.S.-licensed influenza vaccines.
- Annual influenza vaccination is recommended for all persons aged 6 months and older who do not have contraindications (no change from prior season).
- Algorithm for determining the appropriate number of doses of flu vaccine for children aged 6 months through 8 years of age (no change from prior season).
- Updated recommendations for influenza vaccination of those with an egg allergy.
- New and updated influenza vaccine product approvals.

LIVE ATTENUATED INFLUENZA VACCINE (LAIV)

On June 22, 2016, the ACIP issued an interim recommendation that live attenuated influenza vaccine or LAIV (FluMist Quadrivalent vaccine), should not be used during the 2016-17 flu season. This was due to the demonstrated low effectiveness against influenza A(H1N1)pdm09 in the United States during the 2013–14 and 2015–16 seasons. This recommendation was finalized and published by the CDC on August 26, 2016. CDC vaccine effectiveness (VE) study results from the last three influenza seasons for FluMist Quadrivalent did not demonstrate statistically significant effectiveness in children 2-17 years of age in the US. The CDC acquired preliminary data on the effectiveness of LAIV among children 2 years through 17 years during 2015-2016 season when it became available in late spring from the U.S. Influenza Vaccine Effectiveness Network. That data showed the estimate for LAIV vaccine efficacy (VE) among study participants in that age group against any flu virus was 3 percent. This 3 percent estimate effectively means no protective benefit could be measured. In comparison, IIV (flu shots) had a VE estimate of 63 percent against any flu virus among children 2 years through 17 years. The influenza vaccine supply for New York State residents has not been impacted by this recommendation. Inactivated influenza vaccine (IIV) and recombinant influenza vaccine (RIV), which are injectable (flu shots) vaccines, are available and being distributed.

VACCINE FORMULATION AND COMPOSITION

Influenza VE fluctuates from season to season based on differences in circulating influenza strains as well as strains contained in the vaccines. More than 100 national influenza centers in over 100 countries conduct year-round surveillance for influenza. Twice a year, the World Health Organization (WHO) organizes a consultation with the Directors of the WHO Collaborating Centers, essential regulatory laboratories and representatives of key national laboratories and academies and makes recommendations on the composition of the influenza vaccine. For the 2016-17 influenza season:

- U.S.-licensed trivalent influenza vaccines will contain:
    - A/California/7/2009 (H1N1)-like virus (unchanged from the 2015-16 vaccine)
    - A/Hong Kong/4801/2014 (H3N2)-like virus (new strain) and
    - B/Brisbane/60/2008-like virus (Victoria lineage) (was in the 2015-16 quadrivalent, but not trivalent, vaccine)
- Quadrivalent vaccines will also include an additional vaccine virus:
    - B/Phuket/3073/2013-like virus (Yamagata lineage) (unchanged from the 2015-16 quadrivalent vaccine).

Various influenza vaccine products will be available during the 2016-17 season. Complete product information is available in the MMWR publication.

GROUPS RECOMMENDED FOR VACCINATION AND TIMING OF VACCINATION

Routine annual influenza vaccination is recommended *for all persons aged 6 months or older who do not have contraindications to the vaccine*. As always specific groups of persons with certain medical conditions who are at risk for severe complications from influenza must be considered when beginning vaccination.

There is no preferential recommendation for any of the flu vaccines available this season. *Influenza vaccination should not be delayed to obtain a specific vaccine preparation* if an appropriate one is already available. In addition, the CDC and ACIP have not expressed a preference for any indicated flu vaccine for people 65 and older. Immunization should begin as

soon as vaccine is available before it is circulating in the community, preferably before the end of October. Vaccination should continue to be offered as long as influenza viruses are circulating. Flu vaccines, as with all types of vaccines, should never be used after their expiration date.

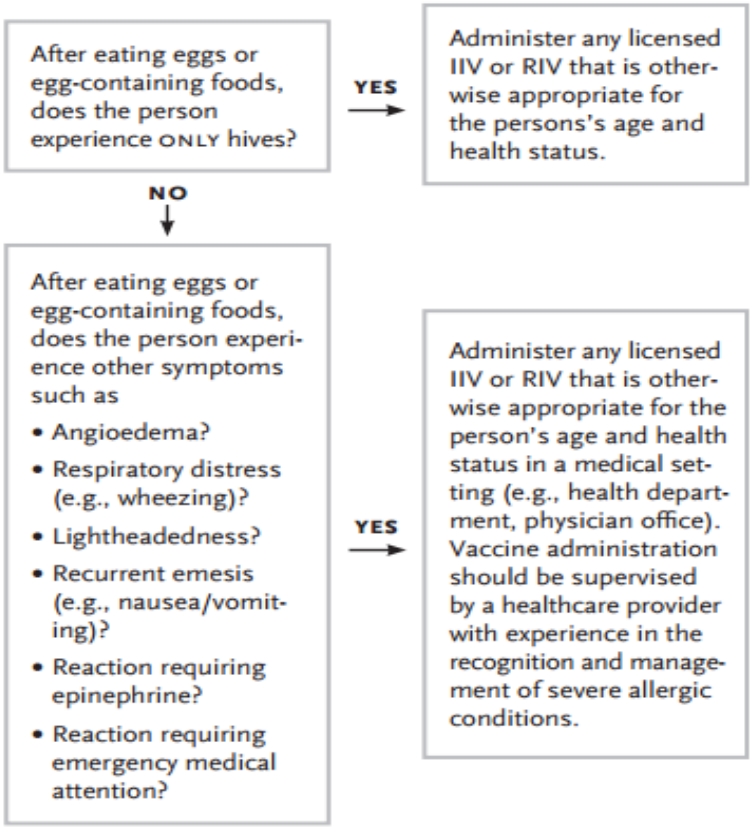
VACCINATION OF THOSE WITH AN EGG ALLERGY

As is the case for other vaccines, influenza vaccines contain various components that might cause allergic and anaphylactic reactions. Not all such reactions are related to egg proteins. Currently available influenza vaccines are prepared by propagation of virus in embryonated eggs, with the exceptions of RIV3 (Flublok) and ccIIV4 (Flucelvax Quadrivalent). Not all manufacturers disclose ovalbumin (egg protein) content in their package inserts. Among influenza vaccines for which ovalbumin content was disclosed during the 2011–12 through 2014–15 seasons, reported maximum amounts were ≤1 μg/0.5 mL dose for IIVs and <0.24 μg/0.2 mL dose for LAIV4, well below the minimum level of ovalbumin that has been documented to cause allergic reactions (130 μg). Of the two vaccines produced using non-egg based technologies, RIV3 (Flublok) and ccIIV4 (Flucelvax Quadrivalent), only Flublok is considered egg-free. Ovalbumin is not directly measured for Flucelvax, but it is estimated by calculation from the initial content in the reference virus strains to contain a maximum of $5x10^{-8}$ μg/0.5 mL dose of total egg protein (Seqirus, unpublished data, 2016).

For the 2016–17 influenza season, ACIP recommends the following updates:

- Persons with a history of egg allergy who have experienced only hives after eating eggs or egg-containing foods should receive influenza vaccine. Any licensed and recommended influenza vaccine (i.e., any age-appropriate IIV or RIV3) that is otherwise appropriate for the recipient's age and health status may be used.
- Individuals who report having had reactions to egg involving symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may similarly receive any licensed and recommended influenza vaccine (i.e., any age-appropriate IIV or RIV3) that is otherwise appropriate for the recipient's age and health status. The selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic conditions.
- The ACIP no longer recommends a 30 minute observation period following vaccination of an egg-allergic individual. Providers are reminded that the ACIP recommends observing all patients for 15 minutes after any vaccine (not limited to influenza vaccine) to decrease the risk for injury should they experience syncope.
- A previous severe allergic reaction to a dose of influenza vaccine is a contraindication to future receipt of the vaccine.
- Please refer to detailed guidance in the MMWR for vaccination recommendations of persons who have an egg allergy. Recommendations for specific flu vaccines are made to help provide protection for individuals with special health conditions.

Recommendations regarding influenza vaccination of persons who report allergy to eggs – Advisory Committee on Immunization Practices, United States, 2016–17 influenza season



www.immunize.org/catg.d/p3094.pdf • Item #P3094 (9/16)

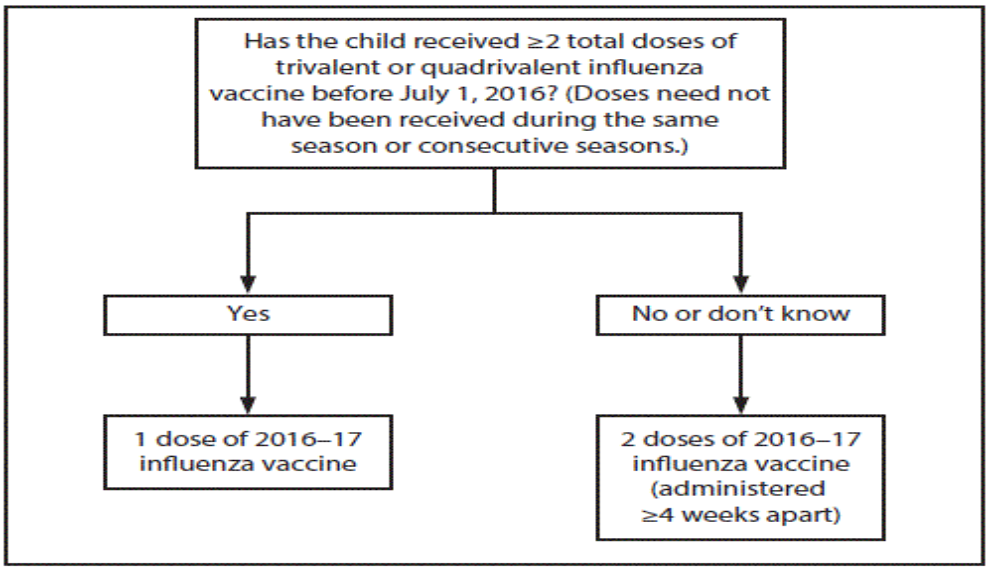
THE PEDIATRIC POPULATION AND INFLUENZA VACCINE DOSING

Children aged 6 months through 8 years require 2 doses of influenza vaccine (administered ≥4 weeks apart) during their first season of vaccination to optimize immune response.

- For 2016–17, ACIP recommends that children aged 6 months through 8 years who have previously received ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1, 2016, require only 1 dose for 2016–17. The two previous doses need not have been given during the same season or consecutive seasons.

- Children in this age group who have not previously received a total of 2 doses of trivalent or quadrivalent influenza vaccine before July 1, 2016 require 2 doses for 2016–17. The interval between the 2 doses should be at least 4 weeks.

Influenza vaccine dosing algorithm for children aged 6 months through 8 years - Advisory Committee on Immunization Practices, United States, 2016–17 influenza season



NEW AND UPDATED INFLUENZA VACCINE PRODUCT APPROVALS

- In December 2014, the FDA approved Fluzone Intradermal Quadrivalent for persons 18 through 64 years; it is expected that this will replace trivalent Fluzone Intradermal in the 2016-17 season.
- In November 2015, the FDA approved MF59-adjuvanted trivalent inactivated influenza vaccine (aIIV3), Fluad for persons aged 65 and older. It is anticipated that Fluad will be available during the 2016-17 season.
- May 2016 FDA approved a Quadrivalent (ccIIV4) formulation of Flucelvax for persons aged 4 years or older.
- Please refer to the MMWR for all available U.S.-licensed influenza vaccines for the 2016-17 season.

VACCINE INFORMATION SHEETS

The CDC announced that it will no longer be updating influenza Vaccine Information Sheets (VIS) annually. The most recent Influenza (IIV) VIS was published in August 2015 and may be used for this and future years, until there are significant changes in IIV recommendations that require changing them. As with all vaccines, immunization against influenza should not be delayed while waiting for an updated VIS.

ADDITIONAL INFORMATION

Other resources on influenza are available on the NYSDOH public website at http://www.health.ny.gov/diseases/communicable/influenza/seasonal/ and on the CDC website at http://www.cdc.gov/flu/.

For additional information please contact the Bureau of Immunization at 518-473-4437.