

VACCINATE ADULTS!

from the Immunization Action Coalition — www.immunize.org

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What's New in the Influenza Vaccination Recommendations for the 2016–17 Season

On August 26, CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for influenza vaccination for the 2016–17 season were published in *Morbidity and Mortality Weekly Report, Recommendations and Reports*, Vol 65, No.5, available at www.cdc.gov/mmwr/volumes/65/rr/pdfs/r6505.pdf.

ACIP continues to recommend routine annual influenza vaccination for all persons 6 months of age and older who do not have a contraindication for vaccination.

Two important new recommendations were made for the 2016–17 season.

■ **Live attenuated influenza vaccine (LAIV, FluMist, AstraZeneca) is not recommended to be used in any setting during the 2016–17 influenza season.** This recommendation was made because of evidence of low vaccine effectiveness among children 2 through 17 years of age against the H1N1 strain of influenza virus during the 2013–14 and 2015–16 seasons. Only inactivated or recombinant influenza vaccines should be used during the 2016–17 influenza season.

■ **A history of egg allergy is no longer considered to be a contraindication or precaution to influenza vaccination.** Multiple studies have found

that severe allergic reactions to egg-based influenza vaccines in persons with egg allergy are unlikely. For the 2016–17 influenza season, ACIP recommends that people with a history of egg allergy who have experienced only hives after exposure to egg should receive any inactivated influenza vaccine without specific precautions (except for the recommended 15-minute observation period for syncope for any vaccine). People who report having had an anaphylactic reaction to egg may also receive any age-appropriate influenza vaccine. For individuals who have an anaphylactic reaction to eggs that is more than hives, the vaccine should be administered in a medical setting such as a hospital, clinic, health department, or physician office. Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions. More information on influenza vaccination and egg allergy is available from the Immunization Action Coalition (IAC) as a staff education sheet titled "Influenza Vaccination of People with a History of Egg Allergy" at www.immunize.org/catg.d/p3094.pdf. ♦

Ask the Experts

The Immunization Action Coalition extends thanks to our experts, medical officer Andrew T. Kroger, MD, MPH, and nurse educator Donna L. Weaver, RN, MN, both with the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention (CDC).

Influenza vaccines

Which influenza vaccines will be available during the 2016–17 influenza season?

Multiple manufacturers are producing influenza vaccine for the U.S. market for the 2016–17 season. Inactivated and recombinant (inactivated) vaccines will be produced using egg-based, cell culture-based, and recombinant technologies. Some of the inactivated influenza vaccines will be quadrivalent (contain four strains of influenza virus) rather than trivalent (three strains). Live attenuated influenza vaccine (LAIV, FluMist, AstraZeneca) is expected

to be available but is not recommended to be used during the 2016–17 season (see next question). A complete listing of influenza vaccine products is available from the Immunization Action Coalition (IAC) at www.immunize.org/catg.d/p4072.pdf.

Why did CDC's Advisory Committee on Immunization Practices (ACIP) recommend that LAIV not be used during the 2016–17 season?

This recommendation was made because of evidence of low vaccine effectiveness among children 2 through 17 years of age against the H1N1 strain of influenza virus during the 2013–14 and 2015–16 seasons. The reason for this lack of effectiveness of LAIV is not known. Only inactivated or recombinant influenza vaccines should be used during the upcoming influenza season. Details about this recommendation are available on pages 14–17 of the 2016–17 ACIP influenza recommendations online at www.cdc.gov/mmwr/volumes/65/rr/pdfs/r6505.pdf.

With the ACIP recommendation to not use LAIV during the 2016–17 season, will there be

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Vaccinate Adults

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enough inactivated influenza vaccine (IIV) to meet the demand for the upcoming season?

Influenza vaccine manufacturers project that as many as 157–168 million doses of IIV will be available for the 2016–17 season. Based on these projections, health officials expect that supply of IIV for the 2016–17 season should be sufficient to meet any increase in demand resulting from the ACIP recommendations, though providers may need to check vaccine availability with more than one supplier or purchase a vaccine brand in addition to the one they normally select.

I know that LAIV is not recommended to be used this season. If a dose of LAIV is administered this season, is it a valid dose, or should we repeat it with IIV?

The dose can be counted. It does not need to be repeated with IIV.

Please tell me about Fluad, the new influenza vaccine for people age 65 years and older.

In November 2015, the Food and Drug Administration (FDA) licensed Fluad (Seqirus), a trivalent, MF59-adjuvanted inactivated influenza vaccine, for people age 65 years and older. Fluad is the first adjuvanted influenza vaccine marketed in the U.S. An adjuvant is a substance added to a vaccine to increase its immunogenicity. The MF59 adjuvant is based on squalene, an oil that occurs naturally in many plants and animals. Fluad has been used in Europe since 1997 and is approved in 38 other countries. In contrast to Fluzone High-Dose (Sanofi Pasteur), Fluad is a standard-dose vaccine, containing 15 mcg of hemagglutinin per dose.

In clinical studies, Fluad was more effective than standard-dose unadjuvanted vaccine in preventing laboratory-confirmed influenza in elderly people. Fluad recipients reported more local reactions, such as injection site pain (25% versus 12%) and tenderness (21% versus 11%), than were reported by recipients of an unadjuvanted IIV.

Who is recommended to receive vaccination against influenza?

ACIP recommends annual vaccination for all people age 6 months and older who do not have a contraindication to the vaccine.

When should influenza vaccine be administered?

You can begin administering vaccine as soon as it becomes available.

Is influenza vaccine recommended for pregnant women?

Yes. It is especially important to vaccinate pregnant women because of their increased risk for influenza-related complications. An increased risk of severe influenza infection was also observed in postpartum women (those delivered within the previous 2 weeks) during the 2009–10 H1N1 pandemic. Vaccination can occur in any trimester, including the first. Only inactivated vaccine should be given to pregnant women.

We have noticed that ACIP recommends that we begin vaccinating with seasonal influenza vaccine in September or even earlier. Does protection from seasonal influenza vaccine decline or wane within 3 or 4 months of vaccination? Should I wait until later in the year to vaccinate my elderly or medically frail patients?

ACIP recommends that to avoid missed opportunities for vaccination, providers should offer vaccination during routine healthcare visits and hospitalizations as soon as vaccine becomes available. Antibody to inactivated influenza vaccine declines in the months following vaccination. A study conducted during the 2011–12 influenza season (*Euro Surveill* 2013;18:20388) found a decline in vaccine effectiveness late in influenza season, primarily affecting persons age 65 years and older. While delaying vaccination might permit greater immunity later in the season, deferral could result in missed opportunities to vaccinate, as well as difficulties in vaccinating a large number of people within a more limited time period. Vaccination programs should balance maximizing the likelihood of persistence of vaccine-induced protection through the season with avoiding missed opportunities to vaccinate or vaccinating after influenza virus circulation begins. Revaccination later in the season of people who have already been fully vaccinated is not recommended.

Some of my patients refuse influenza vaccination because they insist they "got the flu" after receiving the injectable vaccine in the past. What can I tell them?

There are several reasons why this misconception persists:

- Less than 1% of people who are vaccinated with the injectable vaccine develop flu-like symptoms, such as mild fever and muscle aches, after vaccination. These side effects are not the same as having influenza, but people confuse the symptoms.

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IAC's "Ask the Experts" team from the Centers for Disease Control and Prevention



Andrew T. Kroger, MD, MPH



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- Protective immunity doesn't develop until 1–2 weeks after vaccination. Some people who get vaccinated later in the season (December or later) may be infected with influenza virus shortly afterward. These late vaccinees develop influenza because they were exposed to someone with the virus before they became immune. It is not the result of the vaccination.
- To many people "the flu" is any illness with fever and cold symptoms or gastrointestinal symptoms. If they get any viral illness, they may blame it on the vaccine or think they got "the flu" despite being vaccinated. Influenza vaccine only protects against certain influenza viruses, not all viruses.
- The influenza vaccine is not 100% effective, especially in older persons. For more information on this topic, go to www.cdc.gov/flu/professionals/vaccination/effectivenessqa.htm.

Is a Vaccine Information Statement (VIS) only recommended or is it mandatory when administering influenza vaccine?

The use of a VIS for influenza vaccine given to any adult or child is mandatory under the National Vaccine Injury Compensation Program. Two VISs are available, one for LAIV (although LAIV is not recommended to be used during the 2016–17 season) and one for IIV. Each can be found at www.immunize.org/vis along with many translations. Beginning in the 2015–16 influenza season, the influenza VIS was modified so that it does not need to be replaced each year. The 2015–16 VIS can be used during the 2016–17 season.

We are trying to provide influenza vaccination to all eligible patients during their stay in our hospital. If a patient does not remember if he or she has already received the vaccine this season, should we go ahead and vaccinate?

If a patient or family member cannot remember if the patient received influenza vaccine this season and no record is available, proceed with administering influenza vaccine, even if it might mean an extra dose is given. When a patient reports that they HAVE received influenza vaccine but does not have written documentation, ACIP states that in the specific case of influenza

(and pneumococcal polysaccharide) vaccination, patient self-report of being vaccinated should be accepted as evidence of vaccination.

What is the latest ACIP guidance on influenza vaccination and egg allergy?

ACIP revised its guidance on vaccination of persons with egg allergy for the 2016–17 season. ACIP recommends that people with a history of egg allergy who have experienced only hives after exposure to egg should receive any inactivated influenza vaccine without specific precautions (except a 15-minute observation period for syncope). People who report having had an anaphylactic reaction to egg (more severe than hives) may also receive any age-appropriate influenza vaccine. The vaccine for those individuals should be administered in a medical setting (such as a health department or physician office). Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions. Although not specifically recommended by ACIP, providers may prefer an egg-free recombinant vaccine (RIV) for people age 18 years and older with severe egg allergy (see next question).

A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to future receipt of the vaccine. For a complete list of vaccine components (i.e., excipients and culture media) used in the production of the vaccine, check the package insert (at www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

For more details about giving influenza vaccine to people with a history of egg allergy, see www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6505.pdf, pages 29–30. You also may find the IAC handout "Influenza Vaccination of People with a History of Egg Allergy" helpful (see www.immunize.org/catg.d/p3094.pdf).

Does the ACIP prefer that healthcare personnel administer high-dose or adjuvanted influenza vaccine to people age 65 years and older, or is standard-dose influenza vaccine acceptable?

ACIP has no preference. CDC stresses that vaccination is the first and most important step in protecting against influenza.

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May Fluzone High-Dose or Fludac be administered to patients younger than age 65 years?

No. Fluzone High-Dose (Sanofi) and Fludac (Seqirus) are licensed only for people age 65 years and older and are not recommended for younger people.

Some of our patients believe that they have had reactions to influenza vaccine in the past, and request the dose to be split into 2 doses administered on different days. Is this an acceptable practice?

This is definitely not an acceptable practice. Doses of influenza vaccine (or any other vaccine) should never be split into “half doses.” If a “half dose” is given, it should not be accepted as a valid dose and should be repeated as soon as possible with an age-appropriate full dose.

The pneumococcal conjugate vaccine (PCV13, Prevnar, Pfizer) package insert says that in adults, antibody responses to PCV13 were diminished when given with inactivated influenza vaccine. Does this mean we should not give PCV13 and influenza vaccine at the same visit?

The available data have been interpreted that any changes in antibody response to either of the vaccines' components were clinically insignificant. If PCV13 and influenza vaccine are both indicated and recommended, they should be administered at the same visit. See the PCV13 ACIP recommendations at www.cdc.gov/mmwr/pdf/wk/mm6337.pdf, page 824.

How should influenza vaccines (IIV and LAIV) be stored?

Both IIV and LAIV should be refrigerated at temperatures between 2°C (36°F) and 8°C (46°F).

To submit an “Ask the Experts” question...

You can email your questions about immunization to us at admin@immunize.org. IAC will respond to your inquiry. Because we receive hundreds of emails each month, we cannot guarantee that we will use your question in “Ask the Experts.” IAC works with CDC to compile new Q&As for our publications based on commonly asked questions. Most of the questions are thus a composite of several inquiries.

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What are the ACIP recommendations for influenza vaccination of healthcare personnel (HCP)?

Because HCP provide care to patients at high risk for complications of influenza, they should be considered a high-priority group for receiving vaccination. Achieving high rates of vaccination among HCP will protect staff and their patients, and reduce disease burden and healthcare costs. Vaccination rates of HCP are still too low; overall only 79% of HCP report influenza vaccination during the 2015–16 season.

Influenza vaccination of HCP is summarized in the following points:

- All HCP should be educated regarding the benefits of influenza vaccination.
- Influenza vaccine should be administered annually to all eligible HCP.
- A signed declination should be obtained from HCP who decline influenza vaccination.
- Healthcare facilities should monitor HCP influenza vaccination coverage and declination at regular intervals.
- HCP vaccination coverage should be used as one measure of a patient-safety quality program.

In 2011, ACIP published “Immunization of Health Care Personnel,” which includes information about all recommended vaccines for HCP (see www.cdc.gov/mmwr/pdf/rr/rr6007.pdf).

Is it okay to draw up vaccine into syringes at the beginning of the day? If it isn't, how much in advance can this be done?

CDC discourages the practice of prefilling vaccine into syringes for several reasons, including

- the increased possibility of administration and dosing errors;
- the increased risk of inappropriate storage;
- the probability of bacterial contamination since the syringe will not contain a bacteriostatic agent; and
- the probability of reducing the vaccine's potency over time because of its interaction with the plastic syringe components.

Prefilling vaccine into syringes also violates basic medication administration guidelines, which state that an individual should administer only those medications he or she has prepared and drawn up.

Although pre-drawing vaccine is discouraged, a limited amount of vaccine may be pre-drawn in a mass-immunization clinic setting under the following conditions:

- Only a single type of vaccine (for example, influenza) is administered at the mass-immunization clinic setting.
- Vaccine is not drawn up in advance of its arrival at the mass-vaccination clinic site.
- These pre-drawn syringes are stored at temperatures appropriate for the vaccine they hold.
- No more than 1 vial or 10 doses (whichever is greater) is drawn into syringes.
- Clinic staff monitor patient flow carefully and avoid drawing up unnecessary doses or delaying administration of pre-drawn doses.

At the end of the clinic day, any remaining vaccine in syringes prefilled by staff should be discarded. ♦

Ask the Experts

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