



North Carolina Department of Health and Human Services
Division of Public Health

1931 Mail Service Center • Raleigh, North Carolina 27699-1931

Beverly Eaves Perdue, Governor
Lanter Cansler, Secretary

Jeffrey P. Engel, M.D.
State Health Director

August 30, 2011

MEMORANDUM:

TO: LHD Senior Vaccination Season Coordinators
LHD Nursing Directors
LHD Directors

FROM: Beth Rowe-West, R.N., B.S.N., Herd
Immunization Branch

RE: Adult Immunization and Influenza Season, 2011-2012

The purpose of this memorandum is to provide updated information to assist with your preparation for the upcoming influenza season. Updates to last year's recommendations from the CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of influenza vaccine was issued electronically, entitled "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011", *Morbidity and Mortality Weekly Report (MMWR)*, Early Release available at <http://www.cdc.gov/mmwr/>.

The first paragraph, which briefly lists information presented in the recommendations, is reprinted below.

"This document provides updated guidance for the use of influenza vaccines in the United States for the 2011-12 influenza season. In 2010, the Advisory Committee on Immunization Practices (ACIP) first recommended annual influenza vaccination for all persons aged 6 months and older in the United States. Vaccination of all persons aged 6 months and older continues to be recommended. Information is presented in this report regarding vaccine strains for the 2011-12 influenza season, the vaccination schedule for children aged 6 months through 8 years, and considerations regarding vaccination of persons with egg allergy. Availability of a new Food and Drug Administration (FDA)-approved intradermally administered influenza vaccine formulation for adults aged 18 through 64 years is also reported. For issues related to influenza vaccination that are not addressed in this update, refer to the 2010 ACIP statement on prevention and control of influenza with vaccines and associated updates."

CDC staff created key message points for the upcoming season based on the continuation of universal influenza recommendations begun last season and the potential confusion, by the public, because the vaccine composition remains unchanged from the previous season. Please



North Carolina Public Health
Working for a healthier and safer North Carolina
Everywhere. Everyday. Everybody.



Location: 5605 Six Forks Rd. • Raleigh, N.C. 27609-3811
An Equal Opportunity Employer

In this document:

- Influenza Vaccine Recommendations
- 2011-2012 Vaccine Formulation
- Vaccine Doses for Children Aged 6 Months through 8 Years
- Available Vaccine Products and Indications
- Intradermal Influenza Vaccination
- Egg Allergy and Influenza Vaccination
- MMWR— *Influenza Vaccination Coverage among Pregnant Women in the United States for the 2010-2011 Influenza Season*
- MMWR— *Influenza Vaccination Coverage Among Health Care Personnel-- United States, August 2010-April 2011*
- Waning Immunity
- Timing of Vaccination

Influenza Vaccine Recommendations

- On August 18, 2011, the Advisory Committee for Immunization Practices (ACIP) Recommendations on the "Prevention and Control of Influenza with Vaccines" for the 2011-2012 season were issued electronically in a *Morbidity and Mortality Weekly Report* (MMWR) Early Release available at <http://www.cdc.gov/mmwr/>.
- The recommendations will appear in the August 26 printed issue of the MMWR.
- The document provides updated guidance for the use of influenza vaccines in the United States for the 2011-2012 influenza season.
- This year's recommendations are issued in a shortened format because there are relatively few changes from the 2010-2011 recommendations.
- Vaccination of all persons aged ≥ 6 months (adopted in 2010) continues to be recommended.
- The abbreviated recommendations for 2011-2012 include information on:
 - Vaccine virus strains for 2011-2012,
 - The vaccination schedule for children aged 6 months through 8 years, and
 - Considerations regarding vaccination of persons with egg allergy.
 - A new formulation of trivalent inactivated vaccine that is given intradermally (into the skin).
- The 2010-2011 influenza vaccine recommendations (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s_cid=rr5908a1_w) should continue to be referenced for other information on influenza vaccines.
- Information about antiviral medications is available in "Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza — Recommendations of

Influenza Vaccination 2011-2012 Season

Key Points

August 18, 2011

the Advisory Committee on Immunization Practices (ACIP)" at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6001a1.htm?s_cid=rr6001a1_w

2011-2012 Vaccine Formulation

- All 2011-2012 vaccines are trivalent (three component) vaccines. There are trivalent inactivated vaccines (TIV) – most often called “flu shots” and a live attenuated influenza vaccine (LAIV) – most often called the nasal spray vaccine. (See section “Available Vaccine Products and Indications” for more information.)
- The 2011–2012 U.S. seasonal influenza vaccine virus strains are identical to those contained in the 2010–2011 vaccine.
- These include: A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens.
- The influenza A (H1N1) vaccine virus strain is derived from a 2009 pandemic influenza A (H1N1) virus.
- These vaccine virus strains were chosen by the U.S. Food and Drug Administration (FDA) in February 2011.
- At that time, international surveillance indicated that these viruses continued to be the predominant circulating viruses, making them the ones most likely to cause illness during the upcoming 2011-2012 season.
- CDC recommends an annual flu vaccine for everyone 6 months and older as the first and best way to protect against influenza.
- This recommendation is the same even during years when the vaccine composition (the viruses the vaccine protects against) remains unchanged from the previous season.
- There are two reasons for getting a yearly flu vaccine.
- The first reason is that because flu viruses are constantly changing, flu vaccines may be updated from one season to the next to protect against the most recent and most commonly circulating viruses.
- The second reason that annual vaccination is recommended is that a person’s immune protection from vaccination declines over time and annual vaccination is needed for optimal protection. (For more information, see section “Waning Immunity.”)
- Therefore, annual vaccination is recommended even for those who received the vaccine for the previous season.

Vaccine Doses for Children Aged 6 Months through 8 Years

- Experts have known for some time that children aged 6 months through 8 years require 2 doses of influenza vaccine during their first season of

Influenza Vaccination 2011-2012 Season

Key Points

August 18, 2011

vaccination (administered a minimum of 4 weeks apart) to optimize immune response.

- Because the 2011–2012 vaccine strains are unchanged from the 2010–2011 season, children in this age group who received at least 1 dose of the 2010–2011 seasonal vaccine will require only 1 dose of the 2011–2012 seasonal vaccine.
- Children in this age group who did not receive at least one dose of the 2010–2011 vaccine, or whom it is not certain whether the 2010–2011 was received, should receive 2 doses of the 2011–2012 seasonal vaccine.
- Recommendations regarding the number of doses for this age group might change for the 2012–2013 season if vaccine antigens change.

Available Vaccine Products and Indications

- Manufacturers estimate that between 166 and 173 million doses of influenza vaccine will be produced for the U.S. market this season.
- Manufacturers are now shipping flu vaccines for the 2011–2012 season.
- Distribution will continue through the fall.
- While some vaccine will be available in August, ample supplies should be available in September and October. (For information about the recommended timing of influenza vaccination, see section “Timing of Vaccination.”)
- Multiple influenza vaccines are expected to be available during the 2011–12 season, including a new intradermally administered flu shot preparation, Fluzone Intradermal (sanofi pasteur), that was licensed in May 2011.
- There are two types of vaccines:
- The “flu shot” — an inactivated vaccine (containing killed virus) that is given with a needle, usually in the arm. There are three different flu shots available:
 - a regular flu shot approved for people ages 6 months and older
 - a high-dose flu shot approved for people 65 and older, and
 - the new intradermal flu shot approved for people 18 through 64 years of age.
 - The age indications for the different flu shots vary, but all may be given to people with chronic medical conditions.
- The nasal-spray flu vaccine — a vaccine made with live, weakened flu viruses that is given as a nasal spray (sometimes called LAIV for “Live Attenuated Influenza Vaccine”). The viruses in the nasal spray vaccine do not cause the flu. LAIV is approved for use in healthy* people 2 through 49 years of age who are not pregnant.

Influenza Vaccination 2011-2012 Season

Key Points

August 18, 2011

- All influenza vaccines contain the same antigenic composition.
- There is no preferential recommendation between any of the formulations of TIV or LAIV, but clinicians should note the recommended age groups and possible contraindications for each vaccine.

Intradermal Influenza Vaccination

- On Tuesday, May 10, 2011, the U.S. Food and Drug Administration (FDA) issued a press release announcing a new flu vaccine for the U.S. market for the 2011-2012 flu season: "Fluzone Intradermal[®]".
- The new vaccine is a type of flu shot that injects a small amount of antigen into the dermal layer of the skin (the layer of skin beneath the epidermis).
- This is different from the regular flu shot, which is injected into the muscle (an intramuscular vaccine). This vaccine uses less antigen than the regular flu shot, but produces a comparable immune response.
- Development of intradermal vaccines has had appeal because of their "dose-stretching" benefit (more doses of vaccine can be produced with the same amount of antigen).
- Fluzone Intradermal is only approved for use in adults aged 18 through 64 years of age.
- Like all flu vaccines, Fluzone Intradermal will protect against three influenza virus subtypes: an influenza A (H1N1), an influenza A (H3N2), and an influenza B virus.
- Fluzone Intradermal vaccine is given with a needle that is 90% smaller than the needles used for giving regular flu shots (and may be more appealing to needle-averse adults).
- The most common adverse reactions to Fluzone Intradermal include erythema (redness), induration (hardness), swelling, pain and pruritus (itching) at the vaccination site. Headache, myalgia (muscle ache) and malaise may also occur.
- Fluzone Intradermal vaccine should not be given to anyone with a **severe** allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein.
- Fluzone Intradermal will be available to health care providers this fall for influenza vaccine administration during the 2011-2012 influenza season.
- For more information on the intradermal vaccine, see "Questions & Answers: Intradermal Influenza Vaccine" at http://www.cdc.gov/flu/protect/vaccine/qa_intradermal-vaccine.htm.

Egg Allergy and Influenza Vaccination

- Serious allergic reactions can be caused by various components of influenza vaccine. Fortunately, the risk of such reactions is low.

Influenza Vaccination 2011-2012 Season

Key Points

August 18, 2011

- A severe allergic reaction (e.g., anaphylaxis or a reaction involving angioedema (similar to hives but swelling is under the skin), respiratory distress, lightheadedness, or recurrent vomiting; or which required emergency medical care or epinephrine), no matter what component may have caused the reaction, is a contraindication to future receipt of the vaccine.
- Because influenza vaccines are produced by inoculating influenza virus into eggs, the finished vaccine contains a trace amount of egg protein. This trace amount of egg protein could cause a reaction in susceptible people. In previous seasons, allergy to egg has been listed as a contraindication to receipt of vaccine on package inserts (e.g., people with egg allergy have been told NOT to get an influenza vaccine.)
- However, several recent studies have documented safe receipt of TIV (flu shot) in people with egg allergy, particularly those with a history of less severe reactions to egg. Recent revisions of some TIV package inserts list only **severe allergic reaction** (e.g., anaphylaxis) to egg protein as a contraindication.
- Some of these studies used skin testing with vaccine, but in general this testing was not predictive of the likelihood of allergic reactions. Vaccine was generally well tolerated whether it was administered in two doses or given as a single dose. For these reasons, skin testing with vaccine and splitting of the vaccine dose are not necessary for persons with mild reactions (hives) to eggs.
- Egg allergic people who experience mild reactions to egg —specifically, those who have only experienced hives — can and should receive the influenza vaccine with some additional safety measures: vaccine should be given by a health care provider who is familiar with the subject of egg allergy; TIV should be used rather than LAIV because studies published to date involved TIV; and the recipient should be observed for at least 30 minutes (after the last dose, if vaccine is divided) by their health care provider to monitor for possible reactions.
- Persons who have reactions to egg that involve symptoms other than hives, such as angioedema (similar to hives but swelling is under the skin), respiratory distress, lightheadedness, or recurrent vomiting; or who required emergency medical care, particularly those that occurred immediately or within a short time following egg exposure (minutes to hours) are more likely to experience serious side effects to egg proteins. Prior to receiving vaccine, these people should be referred to a health care professional with expertise in the management of allergic conditions for further risk assessment.
- All vaccines should be given in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available. Providers should be familiar with the office emergency plan.
- Some people who report allergy to eggs may not be egg-allergic. Those who are able to eat lightly cooked eggs (e.g., scrambled eggs) without reaction

Influenza Vaccination 2011-2012 Season

Key Points

August 18, 2011

are unlikely to be allergic. Egg allergic persons may tolerate eggs in baked products (e.g. bread and cake).

- Tolerance to such egg-containing foods does not exclude the possibility of egg allergy. Egg allergy may be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, in addition to a skin or blood test.

MMWR— *Influenza Vaccination Coverage among Pregnant Women in the United States for the 2010-11 Influenza Season*

- On August 18, 2011, an MMWR article entitled *Influenza Vaccination Coverage among Pregnant Women in the United States for the 2010-11 Influenza Season* was issued electronically and is available at <http://www.cdc.gov/mmwr/>.
- The study estimated influenza vaccination coverage among pregnant women for the 2010-11 season.
- To do this, CDC analyzed data from an internet panel survey conducted in April 2011 among women pregnant any time during October 2010 through January 2011. The results of this panel survey are summarized in this report.
- This report found that for the 2010-11 season, 49% of pregnant women had received influenza vaccination: 32% during pregnancy and 17% before pregnancy or after delivery.
- One very interesting finding of the survey was that women whose providers offered them a flu shot were five times more likely to get vaccinated than women who didn't receive a provider offer. However, four out of 10 women in this survey did not receive a provider offer, though they visited a provider at least one time.
- These results indicate the uncharacteristically higher vaccination level achieved among pregnant women during the previous season (2009-2010) was sustained during the 2010-11 influenza season and emphasizes the critical role of health care providers in promoting influenza vaccination.
- However, vaccination levels still remain below the Healthy People 2020 objective for influenza vaccination coverage of 80% for pregnant women.
- The survey also looked at why pregnant women chose not to get vaccinated. The top two reasons that pregnant women gave for not getting vaccinated were: "I am concerned about possible safety risks to my baby if I got vaccinated" and "I am concerned that the vaccination would give me the flu."
- Women who received a provider offer for influenza vaccination were more likely to have positive attitudes about vaccination effectiveness and safety.
- The study underscores that fact that continued efforts are needed to encourage providers to 1.) get vaccinated themselves **and** 2.) to not only strongly recommend vaccination of their pregnant patients but to offer

Influenza Vaccination 2011-2012 Season
Key Points
August 18, 2011

influenza vaccine on site so both pregnant patients and their infants are protected.

MMWR— *Influenza Vaccination Coverage among Health Care Personnel--United States, August 2010-April 2011*

- On August 18, 2011, an MMWR article entitled *Influenza Vaccination Coverage among Health Care Personnel--United States, August 2010-April 2011* was issued electronically and is available at <http://www.cdc.gov/mmwr/>.
- The Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommend that all health care personnel (HCP) be vaccinated annually for influenza.
- Influenza vaccination among HCP has increased slowly over the past decade, and reached 63.5% in the 2010-2011 influenza season; however, coverage is still well below the Healthy People 2020 target of 90%.
- Coverage was highest among physicians, HCP working in hospital settings, and older HCP.
- Near universal coverage (98.1%) was achieved among HCP who reported being subject to an employment requirement for vaccination; however, a small percentage of U.S. HCP (13%) reported being subject to such a requirement.
- In the absence of employer requirements, increased vaccination coverage was associated with vaccination being offered free of charge onsite at the workplace for more than one day.
- Influenza vaccination coverage among HCP is important for patient safety, and health care facilities should make vaccine readily accessible to all HCP as part of a comprehensive infection control program.

Findings

- An estimated 63.5% of HCP reported receiving influenza vaccination in the 2010-11 influenza season. Coverage in 2010-2011 was similar to seasonal influenza vaccination coverage among HCP in the 2009-2010 season (62%).
- Coverage was highest among physicians (84.2%), HCP working in hospital settings (71.1%), and HCP 60 years of age or older (74.2%).
- Most HCP believed that influenza vaccination is safe. A higher percentage of those vaccinated believed that the vaccine is safe (94.8%) compared to those unvaccinated (66.2%).
- The largest differences in beliefs between those vaccinated and unvaccinated were: believing influenza to be a threat to the respondent's own health (70.1% among those vaccinated compared to 34.2% among those not vaccinated), believing that the influenza vaccine is efficacious in protecting

Influenza Vaccination 2011-2012 Season
Key Points
August 18, 2011

the respondent from influenza (92.7% among those vaccinated compared to 54.2% among those not vaccinated), believing that if the respondent gets vaccinated, people around him/her will be better protected against influenza (89.1% among those vaccinated compared to 44.6% among those not vaccinated), and believing that getting vaccinated is worth the time and expense (94.7% among those vaccinated compared to 45.8% among those not vaccinated).

- Thirteen percent of HCP reported being required by their employer to be vaccinated for influenza. Self-reported vaccination coverage among those required to be vaccinated was 98.1%, compared with 58.3% among those not subject to a requirement.
- Among those not subject to a vaccination requirement, coverage among HCP who were offered vaccination at their place of employment was 66.1%, compared to 38.5% among HCP who were not offered onsite vaccination.
- Among HCP who were offered onsite vaccination, additional increases in coverage were seen when vaccination was offered free of charge for more than one day and when the respondent was personally reminded by his/her employer to be vaccinated.
- None of the workplace interventions evaluated were associated with increased vaccination coverage among HCP who were not offered onsite vaccination.
- The methodology of this study was similar to a CDC-sponsored internet panel survey of HCP in the 2009-2010 season, which found that seasonal influenza vaccination coverage among HCP in 2009-2010 was 62%.

Waning Immunity

- Several studies conducted over different flu seasons and involving different influenza viruses and types of flu vaccine have shown that a person's protective antibody against influenza viruses declines over the course of a year after vaccination, particularly in the elderly.
- So, a flu shot given during one season may not provide adequate protection through later seasons (see reference section below).
- The decline in protective antibody may be influenced by several factors, including a person's age, the antigen used in the vaccine, and the person's health situation (for example, chronic health conditions that weaken the immune system may have an impact).
- This decline in protective antibody has the potential to leave some people more vulnerable to infection, illness and possibly serious complications from the same influenza viruses a year after being vaccinated.
- So, for optimal protection against influenza, annual vaccination is recommended regardless of whether the vaccine virus strains have changed since the previous season.

Influenza Vaccination 2011-2012 Season

Key Points

August 18, 2011

- More information about waning immunity can be found at [2011-12 Influenza Vaccine and Vaccination Information](#).

Timing of Vaccination

- CDC recommends that influenza vaccination begin as soon as 2011-2012 flu vaccine becomes available and continue throughout the flu season. People should begin getting vaccinated as soon as vaccine becomes available in their community.
- It takes about two weeks after vaccination for antibodies to develop in the body and provide protection against influenza virus infection. Influenza season can begin as early as October. Therefore, CDC recommends early vaccination to ensure that as many people as possible are protected before flu season begins.