



## This is an official DHEC Health Update

Distributed via Health Alert Network  
October 5, 2009 5:00 pm  
10185-DHU-10-05-09-H1N1

### Novel Influenza A H1N1 Vaccine

#### Background

Vaccination is the best way to prevent influenza and its complications. This year, full protection will require seasonal influenza vaccine and the novel H1N1 influenza A (2009 H1N1) vaccine. Although the 2009 H1N1 vaccine is new, it is not experimental and is being made using the same processes and facilities that are used to make seasonal influenza vaccines.

#### FDA Approval of 2009 H1N1 Vaccine: Summary

Manufacturer	Presentations	Age	Dosage <sup>1</sup>	Type	Package Insert
CSL Limited	-0.5 mL prefilled single-dose syringe (thimerosal free) -5 mL multi-dose vial containing 10 doses (with thimerosal)	Adults 18 years of age and older	-Single 0.5 mL dose	Inactivated virus; intramuscular injection	<a href="#">Link</a>
GlaxoSmithKline <sup>2</sup>	<i>Awaiting FDA licensure</i>				
Novartis Vaccines and Diagnostics Limited	-0.5 mL prefilled single-dose syringe (trace thimerosal) -5 mL multi-dose vial (with thimerosal)	Persons 4 years of age and older	-Two 0.5 mL doses approx. 1 month apart for children 4 to 9 years of age -Single 0.5 mL dose for children 10-17 years of age -Single 0.5 mL dose for adults 18 years and older	Inactivated virus; intramuscular injection	<a href="#">Link</a>
Sanofi Pasteur Inc.	-0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod -0.5 mL prefilled single-dose syringe (thimerosal free) -5 mL multi-dose vial (with thimerosal)	Persons 6 months and older	-Two 0.25 mL doses approx. 1 month apart for children 6-35 months of age -Two 0.5 mL doses approx. 1 month apart for children 36 months-9 years -Single 0.5 mL dose for children 10 years and older -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	<a href="#">Link</a>
MedImmune, LLC	-0.2 mL prefilled single-dose intranasal sprayer	Persons aged 2 to 49 years	-Two 0.2 mL doses approx. 1 month apart for children 2 to 9 years -Single 0.2 mL dose for persons 10-49 years	LAIV; Intranasal spray	<a href="#">Link</a>

<sup>1</sup> Based on currently available information, which suggests children 6 months to 9 years of age have little or no evidence of protective antibodies to the novel H1N1 virus. It is expected that children 9 years of age and younger should be administered two doses of the vaccine, and that children and adults 10 years of age and older will need one dose. Clinical studies are underway and will provide additional information about the optimal dosage for children.

<sup>2</sup> The GlaxoSmithKline H1N1 vaccine has not yet been approved. Based on their licensure for 2009-2010 seasonal influenza vaccine, their H1N1 vaccine can be expected to be an inactivated virus vaccine for adults 18 and older with presentations of 0.5 mL prefilled single-dose syringes (thimerosal free).

## Vaccine Approval and Formulations

On September 15, 2009, the FDA approved four 2009 H1N1 vaccines as a strain change to each manufacturer's seasonal influenza vaccine. One manufacturer is awaiting FDA licensure. Like seasonal influenza vaccines, the 2009 H1N1 vaccine is available as a live attenuated vaccine administered by intranasal sprayer or as an inactivated preparation delivered by intramuscular injection. **None of these vaccines contains an adjuvant.** Details for each manufacturer's product are listed in the chart above (Source: The Association of State and Territorial Health Officials, <http://www.astho.org/WorkArea/DownloadAsset.aspx?id=2721>).

## 2009 H1N1 Live Attenuated Influenza Vaccine (LAIV)

Nationally, the LAIV formulation of the 2009 H1N1 vaccine was the first H1N1 product available to states. It is expected that additional doses of LAIV as well as inactivated vaccine will be available in the coming weeks. The timing of this allocation is unclear. Therefore, it is important for providers to administer LAIV to as many approved population groups as possible.

- **LAIV is approved for use in healthy people 2-49 years of age who are not pregnant**
- The following people **should not receive LAIV**:
  - Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological/neuromuscular, hematological or metabolic disorders (including diabetes), immunosuppression (including immunosuppression caused by medications or by HIV)
  - Children 2-4 years of age with wheezing in the past 12 months
  - Children or adolescents receiving aspirin or other salicylate therapy
  - Pregnant women
  - People who have a severe allergy to chicken eggs or who are allergic to any LAIV components
  - Persons < 2 years or those  $\geq 50$  years
- The following are **precautions to receiving LAIV**:
  - Guillain-Barré Syndrome (GBS) within 6 weeks following a previous dose of an influenza vaccine
  - Moderate or severe illness with or without fever

## Use of LAIV in Healthcare Workers (HCW)

Healthy, nonpregnant HCWs under 49 years of age may receive either inactivated vaccine or LAIV, with the exception of those HCWs caring for severely immunosuppressed patients. Inactivated vaccine is preferred for HCW who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) during those periods in which the immunosuppressed person requires care in a protective environment (typically defined as a specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes).

LAIV transmission from a recently vaccinated person causing clinically important illness in an immunocompromised contact has not been reported. The rationale for avoiding use of LAIV among HCW caring for severely immunocompromised patients is the theoretical risk that a live, attenuated vaccine virus could be transmitted to the severely immunosuppressed person. As a precautionary measure, HCW who receive LAIV should avoid providing care for severely immunosuppressed patients for 7 days after vaccination.

There is no preference for inactivated vaccine use by HCW caring for persons with lesser degrees of immunosuppression (e.g., persons with diabetes, persons with asthma who take corticosteroids, persons who have recently received chemotherapy or radiation but who are not being cared for in a protective environment as defined above, or persons infected with HIV) or by HCW in close contact with persons in all other groups at high risk for influenza.

## Safety of 2009 H1N1 Vaccine

In clinical studies, the 2009 H1N1 vaccine has been well tolerated. Each of the manufacturers is producing the vaccine using the well-established, licensed egg-based manufacturing process that is used for seasonal influenza vaccine. It is expected that the 2009 H1N1 vaccine will continue to have a safety profile similar to seasonal influenza vaccine.

Providers should report any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States, including the 2009 H1N1 vaccine, to the federal Vaccine Adverse Event Reporting System (VAERS: [www.vaers.hhs.gov](http://www.vaers.hhs.gov)). Of particular interest are cases of Guillain-Barré Syndrome (GBS) occurring after the 2009 H1N1 vaccine. However, there is no reason to suspect this will occur. The novel H1N1 virus is genetically different from the 1976 "Swine Flu" virus whose vaccine was associated with cases of GBS (approximately 1 additional case per 100,000 people who

received the swine flu vaccine). Since that time, studies have not consistently found a link between influenza vaccines and development of GBS. When a link was suggested, it was estimated at approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine.

FDA and CDC will closely monitor the safety of the 2009 H1N1 vaccine. FDA is collaborating with CDC, and other government agencies to enhance the capacity for vaccine safety monitoring during and after the 2009 H1N1 vaccination program. Some of these systems include: actively observing persons in defined geographic areas, collaborating with professional organizations for reports of any adverse events after vaccination, and conducting thorough investigations when severe adverse events occur to determine whether they may have been associated with the vaccine.

## 2009 H1N1 Vaccine Initial Target Populations

The initial supply of the Influenza A (H1N1) 2009 Monovalent vaccines might not be enough to meet the demand for these vaccines. For this reason, *CDC's Advisory Committee on Immunization Practices (ACIP) recommends that certain groups at highest risk for infection or influenza-related complications should be the initial targets for vaccination.* Additionally, current epidemiologic data indicate that the risk for infection among persons age 65 or older is less than the risk for younger age groups.

Therefore, the CDC has recommended 2009 H1N1 vaccine for the following 5 **initial target groups** (not listed in priority order):

- o pregnant women;
- o people who live with or care for children < 6 months (e.g. parents, siblings, daycare providers);
- o healthcare and emergency services personnel;
- o children and young adults 6 months-24 years;
- o Persons aged 25- 64 years who have health conditions that put them at higher risk for influenza-related medical complications.

SC DHEC will notify healthcare providers if vaccination efforts may be expanded to include population groups outside of these initial target groups.

## Links for Additional Information

- Prevention and Control of Seasonal Influenza with Vaccines --- Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. <http://www.cdc.gov/mmwr/PDF/rr/rr5808.pdf>
- Use of Influenza A (H1N1) 2009 Monovalent Vaccine --- Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. <http://www.cdc.gov/mmwr/PDF/rr/rr5810.pdf>
- Vaccine Information Statement (VIS) for Live, Intranasal 2009 H1N1 Influenza Vaccine. <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-laiv-h1n1.pdf>
- Vaccine Information Statement (VIS) for Inactivated 2009 H1N1 Influenza Vaccine. <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-inact-h1n1.pdf>
- CDC H1N1 Influenza Vaccine page. <http://www.cdc.gov/h1n1flu/vaccination/>

## DHEC Contact Information for Reportable Diseases and Reporting Requirements

Reporting of outbreaks/clusters of cases of influenza (both seasonal and novel H1N1), aggregate positive influenza rapid tests, positive virus cultures for influenza and influenza deaths are consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2009 List of Reportable Conditions available at: <http://www.scdhec.gov/administration/library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

## Regional Public Health Offices – 2009

Mail or call reports to the Epidemiology Office in each Public Health Region.

### Region 1

#### **Anderson, Oconee**

220 McGee Road  
Anderson, SC 29625  
Phone: (864) 260-4358  
Fax: (864) 260-5623  
Nights / Weekends: 1-866-298-4442

#### **Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda**

1736 S. Main Street  
Greenwood, SC 29646  
Phone: 1-888-218-5475  
Fax: (864) 942-3690  
Nights / Weekends: 1-800-420-1915

### Region 2

#### **Greenville, Pickens**

PO Box 2507  
200 University Ridge  
Greenville, SC 29602-2507  
Phone: (864) 282-4139  
Fax: (864) 282-4373  
Nights / Weekends: 1-800-993-1186

#### **Cherokee, Spartanburg, Union**

PO Box 4217  
151 E. Wood Street  
Spartanburg, SC 29305-4217  
Phone: (864) 596-2227, x- 210  
Fax: (864) 596-3443  
Nights / Weekends: 1-800-993-1186

### Region 3

#### **Chester, Lancaster, York**

PO Box 817  
1833 Pageland Highway  
Lancaster, SC 29720  
Phone: (803) 286-9948  
Fax: (803) 286-5418  
Nights / Weekends: 1-866-867-3886

### Region 3 (continued)

#### **Fairfield, Lexington, Newberry, Richland**

2000 Hampton Street  
Columbia, SC 29204  
Phone: (803) 576-2749  
Fax: (803) 576-2993  
Nights / Weekends: 1-888-554-9915

### Region 4

#### **Clarendon, Kershaw, Lee, Sumter**

PO Box 1628  
105 North Magnolia Street  
Sumter, SC 29150  
Phone: (803) 773-5511  
Fax: (803) 775-9941  
Nights/Weekends: 1-877-831-4647

#### **Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion**

145 E. Cheves Street  
Florence, SC 29506  
Phone: (843) 661-4830  
Fax: (843) 661-4859  
Nights / Weekends: (843) 660-8145

### Region 5

#### **Bamberg, Calhoun, Orangeburg**

PO Box 1126  
1550 Carolina Avenue  
Orangeburg, SC 29116  
Phone: (803) 533-7199  
Fax: (803) 533-7134  
Nights / Weekends: (803) 954-8513

#### **Aiken, Allendale, Barnwell**

1680 Richland Avenue, W. Suite 40  
Aiken, SC 29801  
Phone: (803) 642-1618  
Fax: (803) 643-8386  
Nights / Weekends: (803) 827-8668 or  
1-800-614-1519

### Region 6

#### **Georgetown, Horry, Williamsburg**

1931 Industrial Park Road  
Conway, SC 29526-5482  
Phone: (843) 915-8804  
Fax: (843) 365-0085  
Nights / Weekends: (843) 381-6710

### Region 7

#### **Berkeley, Charleston, Dorchester**

4050 Bridge View Drive, Suite 600  
N. Charleston, SC 29405  
Phone: (843) 953-0060  
Fax: (843) 953-0051  
Nights / Weekends: (843) 219-8470

### Region 8

#### **Beaufort, Colleton, Hampton, Jasper**

219 S. Lemacks Street  
Walterboro, SC 29488  
Phone: (843) 525-5910  
Fax: (843) 549-6845  
Nights / Weekends: 1-800-614-4698

#### **DHEC Bureau of Disease Control Division of Acute Disease Epidemiology**

1751 Calhoun Street  
Box 101106  
Columbia, SC 29211  
Phone: (803) 898-0861  
Fax: (803) 898-0897  
Nights / Weekends: 1-888-847-0902



[www.scdhec.gov](http://www.scdhec.gov)

### Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.