



## Recommendations for Management of Influenza and other Community Viral Respiratory Diseases Winter 2009-2010 (October 14, 2009)

### **Influenza Vaccine Recommendations for Providers**

The use of the seasonal and novel 2009 H1N1 influenza vaccines can provide significant benefit not only to individual patients who receive the vaccine, but also to the general public by decreasing the possibility that they will become infected with influenza and transmit infection to others. Mathematical models indicate that immunizing 30 to 70% of target populations could markedly diminish the number of individuals who become ill with influenza this season.

The seasonal and novel 2009 H1N1 vaccines were created using identical manufacturing processes used in previous years. Both involve viruses grown in chicken eggs, and should not be given to individuals with severe egg allergy (asking if someone can eat eggs without adverse effects is a reasonable way to screen for severe egg allergy). Both are available as an inactivated “killed” vaccine given by intramuscular injection as well as in a live attenuated nasal spray flu vaccine. Each of these four vaccines, seasonal inactivated, seasonal live attenuated nasal spray, the novel H1N1 inactivated, and the novel H1N1 live attenuated nasal spray, requires a separate vaccine information sheet (VIS). Versions of each on OurNet.

The FDA approved seasonal and H1N1 vaccines prepared by multiple manufacturers and tables below provide detailed information on the specific influenza vaccines preparations currently available for the 2009-2010 flu season. Select vaccine preparations as listed below contain trace amounts of latex, neomycin or polymyxin; patients with severe hypersensitivity reactions to these compounds can receive alternative preparations.

The nasal-spray vaccines are options for healthy people 2 to 49 years of age who are not pregnant, do not have asthma, and if under age 19 years are not taking long-term salicylates or have severe allergies to eggs or other vaccine components (as detailed in tables below). In addition, individuals who receive the nasal spray vaccines should not be in contact with hematopoietic stem cell transplant (e.g., bone marrow transplant) recipients during the seven days after receiving the vaccine.

There are differences in the target groups for the seasonal and novel 2009 H1N1 influenza vaccines based on the groups at highest risk of infection and complications from the different viruses.

**The seasonal influenza vaccine** is recommended for any adult who wants to reduce the risk of becoming ill with influenza or of transmitting it to others.

It is also recommended for:

- All children aged 6 months--18 years should be vaccinated annually
- Persons aged 50 years and older
- Women who will be pregnant during the influenza season
- Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematological or metabolic disorders (including diabetes mellitus)
- Persons who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus)
- Residents of nursing homes and other long-term care facilities
- Health-care personnel
- Household contacts and caregivers of children aged <5 years and adults aged 50 years and older, with particular emphasis on vaccinating contacts of children aged <6 months
- Household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza

**The 2009 H1N1 influenza vaccine** is currently recommended for:

- Pregnant women
- Household contacts and caregivers for children younger than 6 months of age
- Healthcare and emergency medical services personnel
- All people from 6 months through 24 years of age
- Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza (chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematological or metabolic disorders (including diabetes mellitus); persons who have immunosuppression

## **ADVERSE REACTIONS**

Adverse reactions linked to the seasonal influenza vaccines are usually mild. The predominant side effect is soreness at the vaccination site that generally lasts less than two days. They are not associated with higher rates of fever, malaise, myalgias or headaches. The seasonal nasal spray vaccine is associated with a slight increase in mild self-limited symptoms of runny nose or nasal congestion, cough, headache, sore throat, tiredness and chills. Detailed information on adverse reactions linked to the H1N1 vaccines are not yet available but at present appear to be comparable to the seasonal flu vaccines.

There has been concern raised about a possible association between the Guillain-Barré syndrome and influenza immunization. In general, there are about one to two cases of Guillain-Barré syndrome per 100,000 persons each year. However, in 1976 there was a slight increase in the number of Guillain-Barré syndrome cases noted in individuals who received a swine influenza vaccine. This was an increase of approximately one additional case per 100,000 persons. In no other year since then has there been a substantial increase in the number of Guillain-Barré syndrome cases linked to the flu vaccine. Notably, a recent study from France has found that the risk of Guillain-Barré syndrome after having influenza is four- to seven-fold greater than that for the general population. Consequently, the risk of Guillain-Barré syndrome

is significantly greater for individuals who become sick with the flu than for those who receive the flu vaccine.

If a serious adverse event is identified in patients following receipt of a vaccine, the events should be reported to the national Vaccine Adverse Event Reporting (VAERS). Please report clinically significant adverse events after vaccination, even if you are not sure if the vaccine caused the adverse event. There are three ways to report to VAERS:

- 1) Submit online via a secure website at <https://secure.vaers.org/VaersDataEntryintro.htm>
- 2) Fax a completed VAERS form to 877-721-0366, or
- 3) Mail a completed VAERS form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

A VAERS form may be downloaded from the VAERS web site at [www.vaers.hhs.gov/pdf/vaers\\_form.pdf](http://www.vaers.hhs.gov/pdf/vaers_form.pdf). Alternatively, you may request a VAERS form by sending an email to [info@vaers.org](mailto:info@vaers.org), by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366. For additional information on VAERS or vaccine safety, visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call 800-822-7967.

Additional details on these vaccines are available in:

CDC. Prevention and Control of Seasonal Influenza with Vaccines. Recommendations of the advisory committee on immunization practices. Morbid Mortal Weekly Report 2009;58:No. RR-8.

CDC. Use of influenza A (H1N1) 2009 monovalent vaccine. Recommendations of the advisory committee on immunization practices, 2009. Morbid Mortal Weekly Report 2009;58:No. RR-10.

### **Attached Below**

TABLE 1. Approved Seasonal influenza vaccines for different age groups --- United States, 2009 - 2010 season

TABLE 2. Approved H1N1 influenza vaccines for different age groups --- United States, 2009 - 2010 season

**TABLE 1. Approved Seasonal influenza vaccines for different age groups --- United States, 2009- 2010 season**

Vaccine	Trade name	Manufacturer	Presentation	Mercury content (mcg Hg/0.5 mL dose)	Age group	No. of doses	Route
TIV*	Fluzone**	Sanofi Pasteur	0.25mL prefilled syringe	0	6--35 mos	1 or 2†	Intramuscular§
			0.5 mL prefilled syringe	0	≥36 mos	1 or 2	Intramuscular
			0.5 mL vial	0	≥36 mos	1 or 2	Intramuscular
			5.0 mL multidose vial	25	≥6 mos	1 or 2	Intramuscular
TIV	Fluvirin	Novartis Vaccine	5.0 mL multidose vial 0.5 mL prefilled syringe	25 <1.0	≥4 yrs	1 or 2	Intramuscular
TIV	Fluarix**	GlaxoSmithKline	0.5 mL prefilled syringe (contains trace latex)	0	≥18 yrs	1	Intramuscular
TIV	FluLaval	GlaxoSmithKline	5.0 mL multidose vial	25	≥18 yrs	1	Intramuscular
TIV	Afluria**	CSL Biotherapies	0.5 mL prefilled syringe; 5.0 mL multidose vial (contains trace polymyxin/neomycin)	0	≥18 yrs	1	Intramuscular
				25			
LAIV¶	FluMist***	MedImmune	0.2 mL sprayer (contains trace gentamicin, gelatin, and arginine)	0	2--49 yrs	1 or 2††	Intranasal

\* Trivalent inactivated vaccine. A 0.5-mL dose contains 15 mcg each of A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007

(H3N2)-like, and B/Brisbane/ 60/2008-like antigens.

\*\* Vaccines in use at UMass Memorial Medical Center

† Two doses administered at least 1 month apart are recommended for children aged 6 months--8 years who are receiving TIV for the first time and those who only received 1 dose in their first year of vaccination should receive 2 doses in the following year.

§ For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

¶ Live attenuated influenza vaccine. A 0.2-mL dose contains 106.5--7.5 fluorescent focal units of live attenuated influenza virus reassortants of each of the three strains for the 2008--09 influenza season: A/Brisbane/59/2007(H1N1), A/Brisbane/10/2007(H3N2), and B/Brisbane/60/2008.

\*\*\* FluMist is shipped refrigerated and stored in the refrigerator at 2°C--8°C (36°F to 46°F) after arrival in the immunization clinic. The dose is 0.2 mL divided equally between each nostril. FluMist should not be administered to persons with asthma. Health-care providers should consult the medical record, when available, to identify children aged 2--4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving FluMist, parents or caregivers of children aged 2--4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record during the preceding 12 months should not receive FluMist.

†† Two doses administered at least 4 weeks apart are recommended for children aged 2--8 years who are receiving LAIV for the first time, and those who only received 1 dose in their first year of vaccination should receive 2 doses in the following year.

<b>TABLE 2. Approved H1N1 influenza vaccines for different age groups --- United States, 2009 - 2010 season</b>						
<b>Manufacturer</b>	<b>Type and route of admin</b>	<b>Available dosage forms</b>	<b>Age group FDA approved</b>	<b>Dose by age</b>	<b>Contraindications*</b>	<b>Contain latex?</b>
Medimmune	Live attenuated, intranasal	0.2 ml prefilled single-dose intranasal sprayer	2-49	<ul style="list-style-type: none"> <li>• Age 2-9: 0.2 ml x 2 doses 1 month apart</li> <li>• Age 10-49: 0.2 ml x 1 dose</li> </ul>	<ul style="list-style-type: none"> <li>• Hypersensitivity to eggs, egg protein, <b>gentamicin, gelatin, or arginine</b></li> <li>• <b>Concomitant aspirin therapy in children and adolescents</b></li> </ul>	No
Sanofi	Inactivated, IM	<ul style="list-style-type: none"> <li>• Prefilled 0.25ml (thim free)</li> <li>• Prefilled 0.5ml (thim free)</li> <li>• SDV 0.5 ml (thim free)</li> <li>• MDV 5 ml (contains thim)</li> </ul>	6 mos and above	<ul style="list-style-type: none"> <li>• 6 mos-35 mos: 0.25 ml x 2 doses 1 month apart</li> <li>• 36 mos – 9 yrs: 0.5 ml x 2 doses 1 month apart</li> <li>• ≥ 10 yrs: 0.5 ml x 1 dose</li> </ul>	Hypersensitivity to egg protein	No
Novartis	Inactivated, IM	<ul style="list-style-type: none"> <li>• Prefilled 0.5 ml (contains trace thim)</li> <li>• MDV 5 ml (contains thim)</li> </ul>	4 years and above	<ul style="list-style-type: none"> <li>• 4-9 yrs: 0.5 ml x 2 doses 1 month apart</li> <li>• ≥ 10 yrs: 0.5 ml x 1 dose</li> </ul>	Hypersensitivity to egg protein. Not listed as CI but also contains <b>neomycin and polymixin</b>	No
CSL	Inactivated, IM	<ul style="list-style-type: none"> <li>• Prefilled 0.5 ml (thim free)</li> <li>• MDV 5 ml (contains thim)</li> </ul>	18 years and above	≥ 18 yrs: 0.5 ml x 1 dose	Hypersensitivity to egg or chicken protein, <b>neomycin, or polymixin</b>	No

Thim= thimerosal, a derivative of mercury; trace = ≤1 mcg mercury/ 0.5 ml dose; contains thim = 25 mcg/0.5 ml dose

SDV= single dose vial

MDV= multi dose vial

\*Please review additional warnings and precautions in individual package inserts and VIS