



State of Louisiana

Department of Health and Hospitals
Office of the Secretary

Office of Public Health

STANDING ORDERS

Influenza A (H1N1) 2009 Monovalent Vaccine (MIV)

These standing orders are current as of September 2009. They should be reviewed carefully against the most current recommendations and may be revised by the Medical Director of the Louisiana Office of Public Health Immunization Program.

Influenza A (H1N1) 2009 Monovalent Vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons against influenza disease caused by the pandemic (H1N1) 2009 virus. Administer Influenza A (H1N1) 2009 Monovalent Vaccine to any person without contraindications who wishes to reduce the likelihood of becoming ill with influenza or of transmitting influenza to others should they become infected.

Influenza A (H1N1) 2009 Monovalent Vaccine is especially recommended for persons in the following groups:

I. Target Group for H1N1 Influenza Vaccine:

1. Persons aged 6 months - 24 years;
2. Pregnant women;
3. Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
4. Healthcare and emergency medical services personnel;
5. Persons aged 25-64 years who have medical conditions that put them at higher risk for influenza-related complications

ORDER:

1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions. VIS's in English and other languages are available from the Louisiana Immunization Program (LIP) and online at <http://www.immunize.org/vis>.
2. Screen for contraindications according to Table 1.
3. Inspect Influenza A (H1N1) 2009 Monovalent Vaccine syringes and vials for particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

4. Shake the syringe and single-dose vials well before administering the vaccine. Shake the multi-dose vial each time before withdrawing a dose of vaccine.
5. Administer MIV intramuscularly (IM), according to the recommended age-specific dose and schedule (Table 2). Administer IM vaccines at a 90° angle with a 22-25 gauge needle. The needle length for IM injections depends upon the age, gender, and/or weight of the vaccine recipient (see Table 2 below). **Always check the package insert prior to administration of any vaccine.**
6. Influenza A (H1N1) 2009 Monovalent Vaccine should not be mixed with any other vaccine in the same syringe or vial. If Influenza A (H1N1) 2009 Monovalent Vaccine is to be given at the same time as another injectable vaccine(s), the vaccine(s) should always be administered at different injection sites.
7. If possible, observe patient for an allergic reaction for 15 - 20 minutes after administering vaccine.
8. Appropriate facilities and medical personnel must be available to manage possible anaphylactic reactions following administration of the vaccine.
9. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <http://www.vaers.hhs.gov/>.
10. See the document *General Protocols for Standing Orders* for further recommendations and requirements regarding vaccine administration, documentation and consent.

Table 1. Contraindications and Precautions to Inactivated Influenza Vaccine

Valid Contraindications for Inactivated Influenza Vaccine	Invalid Contraindications (Give Inactivated Influenza Vaccine)
Known severe hypersensitivity to eggs ¹ or chicken proteins or any component of the vaccine or life-threatening reactions after previous administration of any influenza vaccine (see package insert for specific components) ²	Mild illness with or without fever
	Non-anaphylactic allergy to any component of the vaccine
	HIV infection ⁴
	Pregnancy ³ or breast feeding
Precaution to influenza vaccine: The immune response of immunocompromised persons may be decreased after receiving Influenza A (H1N1) 2009 Monovalent Vaccine Guillain-Barré Syndrome (GBS) ≤ 6 weeks of receiving dose of influenza vaccine. ³	Treatment with warfarin (Coumadin), theophylline, phenytoin, or aminophylline ⁶
	Anticoagulation or bleeding disorder ⁷

Table 2. Needle Length and Injection Site for IM Injection

Gender and Weight	Needle Length	Injection Site	Injection Technique
Infants (< 12 months)	1”	Anterolateral thigh	Bunch subcutaneous and muscle tissue
Toddlers (12 months – 24months)	≥ 1”	Anterolateral thigh (preferred)	Depends on body mass
	5/8”	Deltoid	Stretch skin flat between thumb and forefinger
Children (3 – 18 y/o)	5/8” – 1”	Deltoid	Depends on body mass
Male and female < 60 kg (< 130 lbs)	5/8”	Deltoid	Do not bunch subcutaneous and muscle tissue
Male and female (130 – 152 lbs)	1”		
Female 70 – 90 kg (152 - 200 lbs)	1” – 1½”		
Male 70 – 118 kg (152 – 260 lbs)			
Female > 90 kg (200 lbs)	1½”		
Male > 118 kg (260 lbs)			

- 1 Asking persons if they can eat eggs without adverse effects is a reasonable way to determine who might be at risk for an allergic reaction.
- 2 Refer persons with a history of anaphylaxis to a vaccine component, but who are at risk for complications from influenza, to their health care provider for evaluation, desensitization and possible administration of influenza vaccine. Protocols have been developed for safely administering influenza vaccine to persons with egg allergies.
- 3 It may be prudent to avoid influenza vaccination of persons who are not at high risk of complications from influenza and who have experienced GBS within 6 weeks of a previous dose of influenza vaccine. As an alternative, consider antiviral chemoprophylaxis for these persons.
- 4 Because influenza can result in serious illness, *vaccination will benefit many HIV-infected patients, including HIV-infected pregnant women.* Vaccine may not induce protective antibodies in patients with advanced disease. A second dose during the same flu season *does not* improve immune response in these patients.
- 5 Pregnant women have an increased risk for hospitalization due to complications from influenza.
- 6 Although flu vaccine can inhibit the clearance of warfarin, theophylline, phenytoin, and aminophylline, studies show no adverse clinical effects. High-risk patients who take these medications *should* receive flu vaccine.
- 7 Minimize the risk of bleeding after an IM injection in these patients by administering the vaccine immediately after the patient’s receipt of replacement factor. Use a 23-gauge (or smaller) needle and immediately apply direct pressure to the vaccination site for ≥2 minutes.

Table 2. Inactivated influenza vaccine dosage, by age group - United States

Age Group	Dose	No. of Doses	Preservative (Thimerosal)
6 – 35 months	0.25 mL	2 ¹	Thimerosal- Free ²
3 – 9 years	0.5 mL	2 ^{1, 3}	
≥ 10 years	0.5 mL	1	

¹ Children < 10 years of age should receive 2 doses, ≥1 month apart. Administer the 2nd dose before the onset of flu season, if possible.

² If available, pregnant women and children under 10 yrs should receive Thimerosal-free vaccine.

³ Existing recommendations are that two inactivated vaccines can be administered at any time before, after, or at the same visit as each other. Existing recommendations also state that an inactivated and live vaccine may be administered at any time before, after or at the same visit as each other. Consequently, providers can administer seasonal and 2009 H1N1 inactivated vaccines, seasonal inactivated vaccine and 2009 H1N1 LAIV, or seasonal LAIV and inactivated 2009 H1N1 at the same visit, or at any time before or after each other.

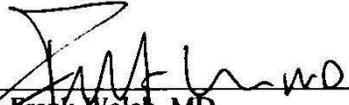
Patient Counseling Information

- Inform vaccine recipient or guardian that Influenza A (H1N1) 2009 Monovalent Vaccine contains killed viruses and cannot cause influenza.
- Inform vaccine recipient or guardian that there are two influenza vaccine formulations for this influenza season, the monovalent vaccine against H1N1 pandemic virus and seasonal trivalent influenza vaccine.
- Instruct vaccine recipient or guardian to report any severe or unusual adverse reactions to their health care provider.

Table 3. Approved Influenza A (H1N1) 2009 Monovalent Vaccines

Proper Name / Type	Manufacturer	Dose/ Presentation	Dosage	Age Group
Influenza A (2009) H1N1 Monovalent Vaccine Inactivated virus; Intramuscular injection	CSL Limited 1-888-435-8633	- 0.5 mL prefilled single-dose syringe - 5.0 mL multi-dose vial containing 10 doses (with thimerosal)	- Single 0.5 mL dose	Adult 18 years of age and older
Influenza A (2009) H1N1 Monovalent Vaccine Inactivated virus; Intramuscular injection	Novartis 1-800-244-7668	- 0.5 mL prefilled single-dose syringe (trace thimerosal) - 5.0 mL multi-dose vial (with thimerosal)	- Two 0.5 mL doses approx. 1 month apart for children 4 to 9 - Single 0.5 mL dose for children 10 – 17 - Single 0.5 mL dose for adults 18 and older	Persons 4 yrs of age and older

Proper Name / Type	Manufacturer	Dose/ Presentation	Dosage	Age Group
Influenza A (2009) H1N1 Monovalent Vaccine Inactivated virus; Intramuscular injection	Sanofi Pasteur Inc. 1-800-822-2463	- 0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod - 0.5 mL prefilled single-dose syringe (thimerosal free) - 0.5 mL single-dose vial (thimerosal free) - 5.0 mL multi-dose vial (with thimerosal)	- 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	Persons 6 months and older
Influenza A (2009) H1N1 Monovalent Vaccine	GlaxoSmithKline	Awaiting FDA licensure		



 Dr. Frank Welch, MD
 Medical Director
 Immunization Program

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 Date