

**MODEL STANDING ORDERS**

**Inactivated 2009 H1N1 Influenza Vaccine (Revised 11/23/09)**

These model standing orders are current as of November 23, 2009. They should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Changes to the Inactivated 2009 H1N1 Influenza Vaccine Standing Orders:

- For children 9 years of age and younger who are receiving 2 doses of H1N1 vaccine, and one or both of the 2 doses is inactivated H1N1 vaccine, if the interval separating the 2 doses is less than 21 days, the second dose should be repeated at least 21 days after the invalid (second) dose.
- The approval of the CSL H1N1 vaccine formulation in 0.5 prefilled syringes for children and adults 3 years of age and older, and in multidose vials for everyone 6 months of age and older.
- The addition of a GSK formulation of H1N1 vaccine in multidose vials approved for adults 18 years of age and older.

Initially, H1N1 vaccine should be targeted to:

- Pregnant women
- Household contacts and caregivers of infants younger than 6 months old
- Health care and emergency medical services personnel
- Infants, children, and young adults 6 months – 24 years old
- Adults 25 - 64 years old with the following conditions:
  - Pulmonary (including asthma)
  - Cardiovascular (except hypertension)
  - Renal, hepatic, hematologic, , or metabolic disorders (incl. diabetes mellitus)
  - Cognitive, neurologic or neuromuscular disorders, such as cerebral palsy, muscular dystrophy and developmental delays
  - Immunosuppression (incl. that caused by medications or by HIV)

When H1N1 vaccine becomes more available, MDPH will provide guidance about expanding H1N1 vaccination to:

- Everyone 6 months - 64 years of age

When the demand for H1N1 vaccine in the target groups listed above, MDPH will provide guidance about expanding H1N1 vaccination to:

- Everyone 65 years of age and older

**ORDER:**

1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement

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(VIS) and answer any questions. VIS's in English and other languages are available from the MIP and online at <http://www.immunize.org/vis>.

2. Screen for contraindications according to Table 1.
3. Administer inactivated H1N1 vaccine intramuscularly (IM), according to the recommended age-specific dose and schedule (Table 2). Administer IM vaccines at a 90° angle with 22-25-gauge needle. The needle length for IM injections depends upon the age, gender, and/or weight of the vaccine recipient (see Table 1 below). **Always check the package insert prior to administration of any vaccine.**

**Table 1. Needle Length and Injection Site for IM Injection**

<b>6 month – 18 Years of Age</b>		
<b>Age</b>	<b>Needle Length</b>	<b>Injection Site</b>
Infants 6 - 12 months)	1”	Anterolateral thigh
Toddlers (12 months – 24 months)	1” – 1¼”	Anterolateral thigh (preferred)
	5/8” – 1”	Deltoid
Children (3 – 18 y/o )	5/8”* – 1”	Deltoid (preferred)
	1” – 1¼”	Anterolateral thigh
<b>Adults 19 Years of Age and Older</b>		
<b>Sex/Weight</b>	<b>Needle Length</b>	<b>Injection Site</b>
Male and female < 130 lbs (< 60 kg)	1”	Deltoid
Female 130 – 200 lbs (60-90 kg)	1” – 1 ½”	Deltoid
Male 130 – 260 lbs (60 – 118 kg)	1½”	Deltoid
Female > 200 lbs (>90 kg)	1½”	Deltoid
Male > 260 lbs (> 118 kg)	1½”	Deltoid

\* A 5/8” needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

4. Shake the vial well before withdrawing and shake the prefilled syringe well before administering.
5. Administer inactivated H1N1 influenza vaccine simultaneously with all other vaccines indicated, including inactivated or live, attenuated seasonal influenza vaccine.

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6. If possible, observe patient for an allergic reaction for 15 - 20 minutes after administering vaccine.
7. Facilities and personnel should be available for treating immediate hypersensitivity reactions.
8. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <http://www.vaers.hhs.gov/>.
9. See the MDPH document *General Protocols for Standing Orders* for further recommendations and requirements regarding vaccine administration, documentation and consent.

**Table 2. Contraindications and Precautions to Inactivated Influenza Vaccine**

Valid Contraindications for Inactivated Influenza Vaccine	Invalid Contraindications (Give Inactivated Influenza Vaccine)
<p>Anaphylactic reaction to a previous dose of influenza vaccine; chicken eggs<sup>1</sup> or any other component of the vaccine (see package insert for specific components)<sup>2</sup></p> <hr/> <p><b>Precaution to influenza vaccine:</b></p> <p>Moderate to severe acute febrile illness (temporary precaution).</p> <p>Guillain-Barré syndrome (GBS) <math>\leq</math> 6 weeks of receiving a dose of influenza vaccine.<sup>3</sup></p>	Mild illness with or without fever
	Non-anaphylactic allergy to any component of the vaccine
	HIV infection <sup>4</sup>
	Pregnancy <sup>5</sup> or breast feeding
	Treatment with warfarin (Coumadin), theophylline, phenytoin, or aminophylline <sup>6</sup>
	Anticoagulation or bleeding disorder <sup>7</sup>

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> Pregnant women have an increased risk for hospitalization due to complications from influenza. No adverse fetal effects have been associated with influenza vaccine. **Inactivated H1N1 vaccine can be administered in any trimester.**

<sup>6</sup> Although flu vaccine can inhibit the clearance of warfarin, theophylline, phenytoin, and aminophylline,

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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  $\geq 2$  minutes.

**Table 3. Inactivated H1N1 Influenza Vaccine Dosage, by Age Group**

Age Group	Dose	No. of Doses
6 – 35 months	0.25 mL	2 <sup>1</sup>
3 – 9 years <sup>1</sup>	0.5 mL	2 <sup>1</sup>
$\geq 10$ years	0.5 mL	1

<sup>1</sup>Children  $< 10$  years of age should receive 2 doses,  $\geq 4$  weeks apart, regardless of the number of doses of seasonal influenza vaccine they have ever received. If the second dose of inactivated H1N1 vaccine is separated from the first dose by at least 21 days, the second dose can be considered valid. If the interval separating the 2 doses is less than 21 days, the second dose should be repeated at least 21 days after the invalid (second) dose.

Note: When feasible, the same type of vaccine (live attenuated or inactivated) should be used in a 2-dose schedule, but mixed schedules are preferable to not completing the series. A 28-day interval is recommended, but 21 days is acceptable. If the second dose in a mixed schedule are given less than 21 days apart, repeat the second dose at least 21 days (preferably 28 days) from the invalid (second dose).

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**Table 4. Approved Inactivated H1N1 Influenza Vaccines for Different Age Groups**

<b>Manufacturer</b>	<b>Dose/ Presentation</b>	<b>Age Group</b>	<b>Thimerosal Content (mcg Hg/0.5 mL dose)</b>
sanofi pasteur	0.25 mL prefilled syringe	6 - 35 mos	0
	0.5 mL prefilled syringe	≥ 36 mos	0
	0.5 mL single dose vial	≥ 36 mos	0
	5.0 mL multidose vial	≥ 6 mos	25
Novartis	0.5 mL prefilled syringe	≥ 4 yrs	≤ 1
	5.0 mL multidose vial	≥ 4 yrs	25
GSK	0.5 mL multidose vial	≥ 18 yrs	25
CSL Biotherapies	0.5 mL prefilled syringe	≥ 3 yrs	0
	5.0 mL multidose vial	≥ 6 mos	24.5

**Resources**

CDC. Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009 2009;58(No. RR-10):[1-9].

<http://www.cdc.gov/mmwr/PDF/rr/rr5810.pdf>

CDC. Update on Influenza A (H1N1) 2009 Monovalent Vaccines. MMWR 2009. Vol. 58 / No. 39:[1100-1101] <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5839a3.htm>

CDC. Frequently asked questions on use of influenza A (H1N1) 2009 monovalent vaccines (2009 H1N1 vaccines): Practical considerations for immunization programs and providers. Revised 11/10/09 [http://www.cdc.gov/H1N1flu/vaccination/top10\\_faq.htm](http://www.cdc.gov/H1N1flu/vaccination/top10_faq.htm)

CSL Limited Influenza A (H1N1) 2009 Monovalent Vaccine Prescribing Information <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182401.pdf>

IDB Influenza A (H1N1) 2009 Monovalent Vaccine Prescribing Information (Distributed by GlaxoSmithKline) <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM190377.pdf>

Novartis Influenza A (H1N1) 2009 Monovalent Vaccine Prescribing Information <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182242.pdf>

sanofi pasteur Influenza A (H1N1) 2009 Monovalent Vaccine Prescribing Information <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182404.pdf>

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