



Department of Health and Social Services
William H. Hogan, MSW, Commissioner

Division of Public Health
Ward Hurlburt, MD, MPH, CMO/Director

Editor:
Joe McLaughlin, MD, MPH

3601 C Street, Suite 540
Anchorage, Alaska 99503

<http://www.epi.alaska.gov>

Local (907) 269-8000
24 Hour Emergency (800) 478-0084

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Recommendations for Influenza A (H1N1) 2009 Monovalent Vaccine

Background

Influenza activity attributed to 2009 H1N1 viruses has increased during September 2009 and is expected to continue through the fall and winter influenza season. On September 15, 2009, four influenza vaccine manufacturers received approval from the Food and Drug Administration for use of H1N1 vaccine. Both live, attenuated and inactivated H1N1 vaccine formulations are available, and each contains the strain *A/California/7/2009(H1N1)pdm*.

H1N1 vaccine is being manufactured in an identical process to seasonal influenza vaccines and is undergoing the same product quality testing and lot release procedures. Over the past several decades, millions of Americans have safely received seasonal influenza vaccines. The age groups, precautions, and contraindications approved for H1N1 vaccine are identical to those approved for seasonal vaccines.^{1,2} All influenza vaccines available in the United States for the 2009–10 influenza season are produced using embryonated chicken eggs and contain residual egg protein. All formulations of influenza vaccine are contraindicated for persons with a severe allergy to chicken eggs or any component of influenza vaccine, or those persons with a history of severe reaction to a previous influenza vaccination.

Recommendations

Initially, when vaccine supplies are limited, administration of H1N1 vaccine should be prioritized for the following groups:

- Pregnant women;
- Household and caregiver contacts (e.g., parents, siblings, and child care providers) of children younger than 6 months of age;
- Health care and emergency medical services personnel;
- Persons aged 6 months through 24 years;
- Persons aged 25 through 64 years who have medical conditions associated with a higher risk of influenza complications.

The results of clinical trials have indicated that one dose of H1N1 vaccine is sufficient for all persons aged 10 years and above. All children aged 6 months through 9 years should receive a second dose of H1N1 vaccine separated by approximately 4 weeks; however, if the second dose is separated from the first dose by at least 21 days, the second dose can be considered valid.

Persons who have experienced symptoms of an influenza-like illness since the spring of 2009 should be vaccinated with H1N1 vaccine unless their illness was confirmed by a real-time reverse transcriptase-polymerase chain reaction (rRT-PCR) test.

The approved age groups for use of H1N1 vaccines differ by manufacturer (Table).

Coadministration with Other Vaccines and Tuberculosis Testing

Providers can administer both seasonal and H1N1 vaccines during the same visit if at least one of the vaccines is inactivated. However, live attenuated versions of both seasonal and H1N1 vaccine should NOT be administered concurrently. If a person prefers to use live attenuated vaccine for both seasonal and H1N1, the doses should be separated by approximately 4 weeks. A similar 4-week interval is recommended between a live vaccine and receipt of another live vaccine (e.g., MMR or varicella) or tuberculosis skin testing. Because providers may be administering one or more doses of live, attenuated influenza vaccine to children this season, the Alaska Division of Public Health is issuing a grace period until April 1, 2010 for compliance with LIVE vaccine requirements (i.e., for MMR and varicella only) and completion of required annual tuberculosis reporting for school and/or child care attendance. Additional information will be posted shortly on the Section of Epidemiology website www.epi.alaska.gov.

Registration and Billing Information

Alaska providers wishing to receive and administer H1N1 vaccine must register with the Alaska Division of Public Health at <https://www.vactrak.alaska.gov>. During registration, providers must agree that they will not charge patients for the vaccine itself. However, providers may charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third party payer. The administration fee cannot exceed the regional Medicare vaccine administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed the state Medicaid administration fee. On October 8, the Alaska Department of Health and Social Services adopted emergency regulations that allow the Department to pay for H1N1 administration for adult Medicaid enrollees age 21 years and older.

Vaccine Adverse Event Reporting

Health care providers can help monitor the safety of vaccines by promptly and accurately reporting any clinically significant adverse event that occurs following vaccination to the Vaccine Adverse Event Reporting System (VAERS).³ VAERS reports may be submitted via a secure website, faxed or mailed.

References

1. Alaska Section of Epidemiology. Seasonal Influenza Vaccine Indications and Administration for 2009-10. *Bulletin* No. 21, September 14, 2009. Available at: http://www.epi.alaska.gov/bulletins/docs/b2009_21.pdf
2. Alaska Section of Epidemiology. TIV and LAIV Seasonal Influenza Vaccines for 2009-10. *Bulletin* No. 22, September 14, 2009. Available at: http://www.epi.alaska.gov/bulletins/docs/b2009_22.pdf
3. Vaccine Adverse Events Reporting System (VAERS). Available at: <http://vaers.hhs.gov/esub/index>

Table. Influenza A (H1N1) 2009 monovalent vaccines approved for use in the United States, October 6, 2009

Vaccine*	Manufacturer	Presentation	Age Group	Mercury Content (µg Hg/0.5 mL dose)	# of Doses	Route
Inactivated*	Sanofi Pasteur	0.25 mL prefilled syringe	6–35 mos	0	2 [†]	Intramuscular [§]
		0.5 mL prefilled syringe	≥36 mos	0	1 or 2 [†]	
		5.0 mL multidose vial	≥6 mos	25.0	1 or 2 [†]	
Inactivated*	Novartis Vaccines and Diagnostics Limited	5.0 mL multidose vial	≥4 yrs	25.0	1 or 2 [†]	Intramuscular [§]
		0.5 mL prefilled syringe	≥4 yrs	<1.0		
Inactivated*	CSL Limited	0.5 mL prefilled syringe	≥18 yrs	0	1	Intramuscular [§]
		5.0 mL multidose vial	≥18 yrs	24.5		
LAIV [¶]	MedImmune LLC	0.2 mL sprayer**	2–49 yrs	0	1 or 2 ^{††}	Intranasal

* A 0.5 mL dose contains 15 µg hemagglutinin of *A/California/7/2009 (H1N1)pdm*.

† Two doses administered approximately 4 weeks apart (≥21 days acceptable) are recommended for children aged 6 months–9 years.

§ 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 10^{6.5–7.5} fluorescent focal units of live attenuated influenza virus reassortants of *A/California/7/2009 (H1N1)pdm*.

** Influenza A (H1N1) 2009 LAIV is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°C) after arrival in the immunization clinic. The dose is 0.2 mL divided equally between each nostril. LAIV 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 LAIV, 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 LAIV.

†† Two doses administered approximately 4 weeks apart are recommended for children aged 2–9 years.