

**OREGON PUBLIC HEALTH DIVISION, DHS  
IMMUNIZATION PROGRAM**

**INFLUENZA A (H1N1)  
MONOVALENT INACTIVATED VACCINE (MIV)\***

**Update as of 11/17/09**

- On 11/12/09 FDA approved the expanded use of the CSL Limited 2009 H1N1 inactivated vaccine to include persons  $\geq 6$  months of age. The vaccine will be available in single-dose, preservative-free, pre-filled syringes and in multi-dose vials. (Section II p.2)
- On 11/10/09 FDA approved licensure of ID Biomedical 2009 H1N1 inactivated vaccine for persons  $\geq 18$  years of age. The vaccine will be available in 0.5 ml single-dose, preservative-free, pre-filled syringes and in multi-dose vials (Section II p.2)
- While vaccine is limited administration is to be targeted to the first five priority groups listed in Section III on p 3.

**I. ORDER:**

1. Screen for contraindications
2. Provide the current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Give the dosage of influenza vaccine recommended for the recipient's age **intramuscularly (IM)**.
5. May be given simultaneously with all other routine child, adolescent and adult immunizations according to age and immunization status of recipient.
6. **For Children 6 months through 9 years schedule return visit in 4 weeks for 2<sup>nd</sup> dose. However, if the 2<sup>nd</sup> dose is separated from the first dose by at least 21 days, the 2<sup>nd</sup> dose can be considered valid.**

\*H1N1/LAIV and Antivirals are under separate order.

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Health Officer or Medical Provider

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Date

11/17/09

<b>II. U.S. Licensed Monovalent Inactivated H1N1 Vaccines 2009–2010<sup>1</sup></b>			
<b>Product Name</b>	<b>Acceptable Age Range</b>	<b>Formulation</b>	<b>Thimerosal as a Preservative</b>
sanofi pasteur	≥6 months	multi-dose vial	25 µg Hg/0.5 ml
	6–35 months	0.25-ml pre-filled syringe	No
	≥36 months	0.5-ml pre-filled syringe or vial	No
Novartis	≥4 years	multi-dose vial	24.5 µg Hg/0.5 ml
		0.5-ml pre-filled syringe	No
CSL Limited	≥6 months	multi-dose vial	24.5 µg Hg/0.5 ml
	6–35 months <sup>2</sup>	0.25-ml pre-filled syringe	No
	≥36 months <sup>2</sup>	0.5 ml pre-filled syringe	No
ID Biomedical	≥18 years	multi-dose vial	25 µg Hg/0.5 ml
		0.5-ml pre-filled syringe	No

<sup>1</sup> Vaccine component: A/California/7/2009, 15 mcg HA per 0.5-mL dose.

<sup>2</sup> Approval based on a study of the company's seasonal flu vaccine in children showing the vaccine's safety and efficacy findings supported approval under FDA's accelerated approval regulation, which helps safe and effective medical products for serious or life-threatening diseases to become available sooner to the public.

### III. RECOMMENDATIONS FOR USE

#### Persons for whom Influenza A (H1N1) vaccination is recommended

1. **Pregnant Women:** At higher risk of complications and can potentially provide protection to infants who cannot be vaccinated.
  2. **Household contacts and caregivers for children younger than 6 months of age:** Younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants less than 6 months old might help protect infants by “cocooning” them from the virus
  3. **Healthcare and emergency medical services personnel:** Infections among healthcare workers have been reported and this can be a potential source of infection for vulnerable patients. Increased absenteeism in this population could reduce healthcare system capacity
  4. **All people from 6 months through 24 years of age:**
    - **Children from 6 months of age through 18 years of age** are in close contact with each other in school and day care settings which increases the likelihood of spreading disease. **Young adults 19 through 24** often live, work, and study in close proximity, and they are a frequently mobile population.
  5. **Persons aged 25 through 64 years** who have health conditions associated with higher risk of medical complications from influenza.
    - pulmonary (including asthma),
    - cardiovascular (except hypertension),
    - renal, hepatic,
    - cognitive, neurologic or neuromuscular,
    - hematological or metabolic disorders (including diabetes mellitus, renal dysfunction or hemoglobinopathies);
    - Immunocompromised (including immunosuppression caused by medications or by human immunodeficiency virus);
    - Persons with any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions, or that can increase the risk for aspiration.
- **All eligible persons  $\geq 6$  months of age, without contraindications, should receive vaccine to reduce the risk of H1N1 influenza disease or transmitting it to others.**

#### IV. VACCINE SCHEDULE

Influenza A H1N1 Schedule for the 2009–2010 Flu Season <sup>1</sup>			
Age	Dose	No. of Doses	Route <sup>2</sup>
6–35 months <sup>3</sup>	0.25 ml	2 <sup>4</sup>	Intramuscular
36 months–9 years	0.5 ml <sup>5</sup>	2 <sup>4</sup>	Intramuscular
≥10 years	0.5 ml <sup>5</sup>	1	Intramuscular

<sup>1</sup> Contains A/California/7/2009

<sup>2</sup> Recommended site of intramuscular injection is the deltoid for adults and older children and the anterolateral aspect of the thigh for infants and young children.

<sup>3</sup> DO NOT vaccinate infants who are less than 6 months of age.

<sup>4</sup> Two doses administered ≥28 days apart are recommended for children <10 years of age. However, if the 2nd dose is separated from the 1<sup>st</sup> dose by at least 21 days, the 2<sup>nd</sup> dose can be considered valid. If the interval separating the doses is less than 21 days, the 2nd dose should be repeated ≥21 days after the 1st dose. The dose volume is determined by the child's age at the time of each dose.

(reference: [www.cdc.gov/H1N1flu/vaccination/top10\\_faq.htm](http://www.cdc.gov/H1N1flu/vaccination/top10_faq.htm) )

<sup>5</sup> The 0.25-ml pre-filled syringe dose can be administered at two different anatomical sites to equal one 0.5-ml dose of inactivated H1N1 influenza vaccine for persons ≥3 years of age.

**V. CONTRAINDICATIONS for**

- A. Persons who have experienced a severe allergic reaction to a previous dose of influenza vaccine.
  
- B. Inactivated influenza vaccine should not be administered to persons known to have anaphylactic hypersensitivity to eggs, the preservative thimerosal (in multi-dose vials only), or to other components of the influenza vaccine, without first consulting a physician.

**VI. PRECAUTIONS**

- A. Persons with moderate or severe illnesses with or without fever should delay immunization until illness has resolved. However, minor illnesses with or without fever do not contraindicate use of influenza vaccine; e.g., children with mild URI or allergic rhinitis.
  
- B. Persons with a history of Guillain-Barré syndrome (GBS) following influenza vaccination have a substantially greater likelihood of subsequently developing GBS than persons without such a history. Whether influenza vaccination might be causally associated with this risk for recurrence is not known. Consult with an individual's health care provider and consider avoiding a subsequent influenza vaccination in persons known to have developed GBS within **6 weeks** of a previous influenza vaccination. Experts believe that the benefits of influenza vaccination justify yearly vaccination for most persons who have a history of GBS and who are at risk for severe complications from influenza.

**VII. SIDE EFFECTS AND ADVERSE REACTIONS:**

H1N1 Inactivated Influenza Vaccine Adverse Reactions Based on Seasonal TIV Experience	
Local reactions Soreness, erythema, induration at injection site	≥10%
Fever, malaise, chills	≥10%
Allergic reactions	rare
Neurological reactions	very rare

Source: Sanofi Pasteur Package insert of 10 September 2009 from <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182404.pdf>

**VIII. OTHER CONSIDERATIONS**

- A. **Breastfeeding mothers:** According to H1N1 Inactivated VIS breastfeeding is not a reason to avoid getting 2009 H1N1 flu vaccine.
- B. **Persons with Altered Immunocompetence:** If H1N1 monovalent vaccine is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.
- C. **For someone with a history of fainting** with injections, a 15-minute observation period is recommended after vaccination.

**IX. ADVERSE EVENTS REPORTING:**

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: [www.vaers.hhs.gov](http://www.vaers.hhs.gov) In addition, a copy of the completed VAERS form should be sent to the patient’s primary provider, per ORS 855-041-0510.

**X. REFERENCES**

1. CDC. Frequently asked questions on use of influenza A (H1N1) 2009 monovalent

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vaccines (2009 H1N1 vaccines): Practical considerations for immunization programs  
and providers. From: [www.cdc.gov/H1N1flu/vaccination/top10\\_faq.htm](http://www.cdc.gov/H1N1flu/vaccination/top10_faq.htm)

2. Use of Influenza A (H1N1) 2009 Monovalent Vaccine: MMWR: Early Release, August 21, 2009 / 58; 1-8. From:  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm>
3. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR, July 24, 2009.  
<http://www.cdc.gov/mmwr/pdf/rr/rr58e0724.pdf>
4. Sanofi Pasteur Package Insert for Influenza A (H1N1) Monovalent Vaccine; 10 September 2009 from:  
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182404.pdf>
5. CSL Package Insert for Influenza A (H1N1) Monovalent Vaccine, 2009; from:  
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182401.pdf>
6. ID Biomedical Package Insert for Influenza A (H1N1) Monovalent Vaccine, 2009; from:  
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM190377.pdf>
7. Novartis Package Insert for Influenza A (H1N1) Monovalent Vaccine; September 2009; from:  
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182242.pdf>
8. Prevention and Control of Influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008. MMWR 2008; 57(RR-7). Available at:  
[www.cdc.gov/mmwr/pdf/rr/rr5707.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5707.pdf)
9. Influenza. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 11<sup>th</sup> ed. Washington, DC: Public Health Foundation, 2009:135–156. Available at:  
<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/flu-508.pdf>

For more information or to clarify any part of the above order, consult with your health officer, or contact the Oregon State Public Health Division Immunization Program at 971-673-0300.

**Electronic copy of this protocol available at:**  
**<http://oregon.gov/dhs/ph/imm/provider/stdqordr.shtml>**  
**To request this material in an alternate format (e.g., Braille),**  
**Please call (971) 673-0300.**