

IMMUNIZATION PROTOCOL FOR PHARMACISTS

INFLUENZA TRIVALENT INACTIVATED VACCINE (TIV)*

UPDATE as of 11-17-2009

- On 11/12/09 FDA approved the expanded use of the CSL Limited (Afluria®) 2009 inactivated seasonal influenza vaccine to include persons ≥ 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)

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. Administer one 0.5 ml dose of inactivated influenza vaccine **intramuscularly** (IM) to all eligible persons ≥ 15 years of age.
5. May be given simultaneously with pneumococcal vaccine and all other routine adolescent and adult immunizations according to age and immunization status of recipient.

*FluMist under separate order. Standing orders for H1N1 will be provided in a separate document.

Pharmacist signature

Date

Original provided courtesy of the Oregon State Public Health Division Immunization Program

(November 17, 2009)

II. U.S. Licensed Inactivated Trivalent Influenza Vaccines (Types A and B) 2009–2010¹			
Product Name	Acceptable Age Range	Formulation	Thimerosal as a Preservative
Fluzone® (Sanofi)	≥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
Fluvirin™ (Novartis)	≥4 years	0.5-ml pre-filled syringe	No
		multi-dose vial	24.5 µg Hg/0.5 ml
Fluarix® (GSK)	≥36 months	0.5-ml pre-filled syringe	No
FluLaval™ (GSK)	≥18 years	multi-dose vial	25 µg Hg/0.5 ml
Afluria® (CSL Limited)	≥6 months	multi-dose vial	24.5 µg Hg/0.5 ml
	6–35 months	0.25 ml pre-filled syringe	No
	≥36 months	0.5 ml pre-filled syringe	No

¹ Vaccine components: A/Brisbane/59/2007 (H1N1)-like; A/Brisbane/10/2007; (H3N2)-like; and B/Brisbane/60/2008-like influenza viruses.

III. RECOMMENDATIONS FOR USE

Persons for whom annual vaccination is recommended

- All persons \geq 6 months of age who want to reduce the risk of becoming ill with influenza or of transmitting it to others,
- All children 6 months–18 years of age¹; continue to focus on children and adolescents at high risk for influenza complications.
- Persons aged \geq 50 years³;
- Children and adolescents (aged 6 months–18 years) receiving long-term aspirin therapy⁴;
- Persons with chronic disorders of:
 - 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;
- Healthcare workers⁵
- Will be pregnant during the influenza season²
- Are residents of long-term care facilities
- Persons who live with or care for persons at high risk for influenza-related complications, including healthy household contacts and caregivers of children <6 months of age⁵

¹ Children aged 6–23 months are at increased risk for influenza-related hospitalizations, and children aged 24–59 months are at increased risk for influenza-related clinic and emergency department visits.

² Case reports and limited studies indicate that pregnancy can increase the risk for serious medical complications of influenza.

³ 50–64 year-olds have an increased prevalence of high-risk conditions.

⁴ Might be at risk for experiencing Reye syndrome if they contract influenza.

⁵ Persons clinically or asymptotically infected can transmit influenza virus to persons at high risk for complications from this disease.

IV. VACCINE SCHEDULE

Trivalent Influenza Vaccine (TIV) Schedule for the 2009-2010 Season:^{1, 2}

<u>Age</u>	<u>Number of Doses in Series</u>	<u>Product Type</u>	<u>Amount of Vaccine⁴</u>
≥15 years	1	split virus ³	0.5 ml

¹ Contains 3 strains of influenza viruses. Specific strains change yearly.

² Recommended site of intramuscular injection is the deltoid for adults and older children.

³ Although, it is acceptable to use either formulation of vaccine, whole or split, in persons older than 12 years of age, whole-virus vaccine is not available in the United States.

⁴ 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 influenza vaccine for person's ≥3 years of age.

V. SUPPLY AND TIMING RECOMMENDATIONS OF TIV VACCINE

1. Healthcare providers should begin offering vaccination to all patients, both high-risk and healthy, as soon after vaccine becomes available.^{1, 2,}
2. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health-care visits or during hospitalizations whenever vaccine is available.
3. Children aged 6 months–8 years who are recommended to receive two influenza vaccine doses this season should receive their first dose as soon after vaccine becomes available as is feasible, so both doses can be administered before the onset of influenza activity.
4. Vaccination efforts should continue throughout the season, because the duration of the influenza season varies, and influenza might not appear in certain communities until February or March

¹ **Do not defer vaccination of any person who requests influenza vaccine.**

² Adults have peak antibody protection against influenza virus 2 weeks after vaccination.

VI. CONTRAINDICATIONS

- 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.
- C. Delay the immunization of FluLaval™ in a person with an acute evolving, neurologic disorder until stabilized.

VII. 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.
- C. Individuals with bleeding disorders at risk of hematoma following IM injection of FluLaval™

VIII. SIDE EFFECTS AND ADVERSE REACTIONS:

Inactivated Influenza Vaccine Adverse Reactions	
Local reactions Soreness, erythema, induration at injection site	15% – 20%
Fever, malaise, chills	not common
Allergic reactions	rare
Neurological reactions	very rare

Source: 11th Edition "Pink Book" January 2009 p. 148

IX. OTHER CONSIDERATIONS

A. Antiviral agents for Influenza:

1. Chemoprophylaxis is not a substitute for vaccination.
2. Zanamivir and oseltamivir are neuraminidase inhibitors that have activity against both influenza A and B viruses. Both are approved for the treatment of uncomplicated influenza infection.
3. Zanamivir is provided as a dry powder for inhalation, and approved for prophylaxis of influenza in persons aged ≥ 7 years and for **treatment** of persons aged ≥ 5 years who have been symptomatic for no more than 48 hours.
4. Oseltamivir is provided as an oral capsule, for prophylaxis of influenza in persons aged ≥ 1 year and approved for **treatment** for persons aged ≥ 1 year who have been symptomatic for no more than 48 hours. For more information, consult FluMist® package insert section 7.2 or:
MMWR 2008; 57(RR-7): 1:60. Available at:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5707a1.htm>

5. Due to high levels of resistance seen among influenza A strains in recent years, amantadine and rimantadine are not recommended.

Source: 11th Edition "Pink Book" January 2009 p. 152

- ### B. Foreign travelers: Influenza occurs throughout the year in the tropics. Indications for influenza vaccination should be reviewed before travel. Any person traveling to the tropics, with organized tour groups at any time of the year or to the Southern Hemisphere April–September, especially those at high risk for flu complications, who want to reduce the risk for influenza infection should be vaccinated at least 2 weeks before departure. (*MMWR*, July 2009, pg 31)
- ### C. Breast-feeding mothers: TIV is safe for mothers who are breastfeeding and their infants. Breastfeeding does not adversely affect the immune response and is not a contraindication for vaccination. (*MMWR*, July 2009, pg 12)
- ### D. Persons infected with HIV: Since influenza can result in serious illness and complications, vaccination is prudent and will result in protective antibody levels in many recipients. However, the antibody response to vaccine may be low in persons with advanced HIV-related illnesses. (*MMWR*, July 2009, pg 12)
- ### E. For someone with a history of fainting with injections, a 15-minute observation period is recommended after vaccination.

X. 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 In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510.

XI. REFERENCES

1. 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>
2. 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
3. Influenza. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 11th ed. Washington, DC: Public Health Foundation, 2009:135–156. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/flu-508.pdf>
4. Influenza. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006: 401-10.
5. Fluzone package insert, 2009. Available at:
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123704.pdf>
6. Afluria package insert, 2009. Available at:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094043.htm>
7. FluLaval package insert, 2009. Available at:
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM112904.pdf>
8. Fluarix® package insert, 10-2009. Available at:
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM112920.pdf>

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider, a consulting physician, or contact Health Services, Immunization Program at (971) 673-0300.

Electronic copy of this protocol available at:

<http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml>

**To request this material in an alternate format (e.g., Braille),
Please call (971) 673-0300.**