

# IMMUNIZATION PROTOCOL FOR PHARMACISTS

## INFLUENZA TRIVALENT INACTIVATED VACCINE (TIV)\*

Revision in November 2007

- Adding Afluria® influenza virus vaccine to this protocol in Section II. pg. 2. Afluria® was FDA approved for use in the US on 9/28/07.

### **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 pneumococcal vaccine and all other routine adolescent and adult immunizations according to age and immunization status of recipient.

\*This order does not include FluMist (live attenuated influenza vaccine), which is under a separate standing order.

\_\_\_\_\_  
Pharmacist signature

\_\_\_\_\_  
Date

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

November 2007

| <b>II. Licensed Inactivated Trivalent Influenza Vaccines (Types A and B)<br/>2007-2008</b> |   |                              |   |
|--|---|------------------------------|---|
| <b>Product Name</b>  | <b>Vaccine Components</b>   | <b>Acceptable Age Ranges</b> | <b>Thimerosal as Preservative</b>   |
| Fluzone®<br>(Aventis)  | A/Wisconsin/67/2005 (H3N2)-like<br>A/Solomon Islands/3/2006 (H1N1), and<br>B/Malaysia/2506/2004-like antigens | ≥6 months                    | Yes<br>(Multi-dose vial)<br>25mcg/0.5ml<br>mercury                                  |
| Fluzone®<br>(Sanofi)   | As above  | ≥36 months                   | No<br>(0.5 ml pre-filled<br>syringe or vial)  |
| Fluvirin™<br>(Novartis)  | As above  | ≥4 years                     | No<br>(0.5 ml pre-filled<br>syringe)  |
| Fluvirin™<br>(Chiron)  | As above  | ≥4 years                     | Yes<br>(Multi-dose vial)<br>< 1mcg Hg/0.5ml)  |
| Fluarix™<br>(GSK)  | As above  | ≥18 years                    | No<br>(0.5 ml pre-filled<br>syringe)  |
| FluLaval™<br>(GSK)   | As above  | ≥18 years                    | Yes<br>(multi-dose vial;<br>25 µg Hg/0.5 ml)  |
| Afluria® <sup>1</sup><br>(CSL Biotherapies)  | As above  | ≥18 years                    | Yes<br>(multi-dose vial;<br>25 µg Hg/0.5 ml<br>No<br>(0.5 ml pre-filled<br>Syringe) |

<sup>1</sup>Shake the vial or syringe thoroughly before withdrawing each dose, and administer the dose immediately.

**RECOMMENDATIONS FOR USE****Persons for whom annual vaccination is recommended**

- All persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting it to others.
- Children aged 6-59 months<sup>1</sup>;
- Women who will be pregnant during the influenza season<sup>2</sup>;
- Persons aged ≥50 years<sup>3</sup>;
- Children and adolescents (aged 6 months–18 years) receiving long-term aspirin therapy<sup>4</sup>;
- Persons with chronic disorders of the pulmonary or cardiovascular systems, including asthma (hypertension is not considered a high-risk condition);
- Persons with chronic metabolic diseases such as diabetes, renal dysfunction, or hemoglobinopathies;
- Persons with immunodeficiency (including immunodeficiency caused by medications or HIV);
- 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;
- Residents of nursing homes and other chronic-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 0–59 months of age<sup>5</sup>; and
- Healthcare workers<sup>5</sup>

<sup>1</sup> 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.

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

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

<sup>4</sup> Might be at risk for experiencing Reye syndrome if they contract influenza.

<sup>5</sup> 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 2007-2008 Season:<sup>1, 2</sup>

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

<sup>1</sup> Contains 3 strains of influenza viruses. Specific strains change yearly.

<sup>2</sup> Recommended site of intramuscular injection is the deltoid for adults and older children.

<sup>3</sup> 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.

#### 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, and if possible by October.<sup>1, 2, 3</sup>
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

<sup>1</sup> **Do not defer vaccination of any person who requests influenza vaccine unless vaccine supplies dictate otherwise.**

<sup>2</sup> Vaccination before October should typically be avoided for elderly patients in chronic-care facilities, because antibody levels in such persons can begin to decline more rapidly after vaccination

<sup>3</sup> 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, or to other components of the influenza vaccine, without first consulting a physician.

**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:**

| <b>Inactivated Influenza Vaccine<br/>Adverse Reactions</b> |                   |
|--|-------------------|
| <b>Local reactions</b>                                     | <b>15% – 20%</b>  |
| <b>Fever, Malaise</b>                                      | <b>Not Common</b> |
| <b>Allergic reactions</b>                                  | <b>rare</b>       |
| <b>Neurological reactions</b>                              | <b>very rare</b>  |

Source: 10<sup>th</sup> Edition "Pink Book" January 2007 p. 247

**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. Zanamivir is approved for chemoprophylaxis of children aged  $\geq 5$  years. Oseltamivir is approved for treatment for persons aged  $\geq 1$  year, and for chemoprophylaxis in persons aged  $\geq 13$  years. For more information consult package inserts or MMWR 2006; 55(RR-10):26-9.
  3. Although the antiviral agents amantadine and rimantadine are available in the U.S., the ACIP recommended in 2006 that neither be used for treatment or chemoprophylaxis of influenza A until susceptibility to these antiviral medications has been re-established among circulating influenza A viruses.
- B. Foreign travelers: Indications for influenza vaccination should be reviewed before travel. Any person, especially those at high risk for flu complications, who wants to reduce the risk for influenza infection should be vaccinated at least 2 weeks before departure.
- 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.
- D. Persons infected with HIV: Since influenza can result in serious illness and complications, vaccination is a prudent precaution 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.
- 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.org](http://www.vaers.org). 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. CDC. Prevention and Control of Influenza, MMWR 2007; 56(RR-6). Available at: <http://www.cdc.gov/mmwr/PDF/rr5606.pdf>.
2. Influenza. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 10<sup>th</sup> ed. Washington, DC: Public Health Foundation, 2007:235–54. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm>
3. Influenza. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27<sup>th</sup> ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006: 401-10.
4. Vaccine product inserts.

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.**