

# IMMUNIZATION PROTOCOL FOR PHARMACISTS

## INFLUENZA TRIVALENT INACTIVATED VACCINE\*

2006–2007 Season updates based on ACIP recommendations issued July 28, 2006:

- All healthy children aged 24–59 months and their household contacts and out-of-home caregivers should be vaccinated against influenza.
- Children  $\geq 6$  months but  $< 9$  years of age who have not previously received any influenza vaccine should be given two doses this season. The second dose for inactivated vaccine should be given  $\geq 4$  weeks after the first dose and, if possible, before the start of the influenza season.
- Neither amantadine nor rimantadine should be used for treatment or chemoprophylaxis of influenza A in the U.S. because of recent data indicating widespread resistance of influenza virus to these medications.

### **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.

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Pharmacist signature

\_\_\_\_\_  
Date

<b>II. Licensed Inactivated Trivalent Influenza Vaccines (Types A and B) 2006-2007</b>			
<b>Product Name</b>	<b>Vaccine Components</b>	<b>Acceptable Age Ranges</b>	<b>Thimerosal as Preservative</b>
Fluzone® (Aventis)	A/Wisconsin/67/2005 (H3N2)-like A/New Caledonia/20/99 (H1N1)-like B/Malaysia/2506/2004- like antigens	≥6 months	Yes (Multi-dose vial) 25mcg/0.5ml mercury
Fluzone® (Sanofi)	As above	≥36 months	No (0.5 ml pre-filled syringe or vial)
Fluvirin™ (Novartis)	As above	≥4 years	No (0.5 ml pre-filled syringe)
Fluvirin™ (Chiron)	As above	≥4 years	Yes (Multi-dose vial) < 1mcg Hg/0.5ml)
Fluarix™ (GSK)	As above	≥18 years	No (0.5 ml pre-filled syringe)

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

- 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****A. Trivalent Influenza Vaccine (TIV) Schedule for the 2006-207 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 OF INFLUENZA VACCINE

### ACIP's phased distribution recommendations for the 2006–2007 Season

#### 1. If the supply of TIV is adequate<sup>1</sup>:

- a. Vaccination before October
  - Non-institutionalized children and adults at high risk for serious influenza complications<sup>2</sup>
  - Household contacts and out-of-home caregivers of children 0–59 months of age
  - Children  $\geq 6$  months but  $<9$  years of age who have not previously been vaccinated and need 2 doses of vaccine  $\geq 4$  weeks apart.
- b. Vaccination in October and November
  - All patients—both high-risk and healthy
  - Children  $\geq 6$  months but  $<9$  years of age who are receiving vaccine for the first time and didn't receive their first vaccine dose in September
  - Residents of chronic-care facilities<sup>2</sup>
- c. Vaccination in December 2006 through March 2007
  - Providers should continue to offer influenza vaccine throughout the season even after influenza activity has been documented in the community.<sup>3</sup>

#### 2. If the supply of TIV is delayed or inadequate<sup>1</sup>:

- a. Vaccination in October and November should focus on
  - Persons  $\geq 50$  years of age
  - Persons  $<50$  years of age who are at increased risk for influenza-related complications
  - Household contacts of persons at high risk
  - Healthcare workers
- b. Vaccination in December 2006 through March 2007
  - Providers should continue to offer influenza vaccine throughout the season even after influenza activity has been documented in the community.<sup>3</sup>

<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.

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

<b>A. Side Effects and Adverse Reactions</b>			
<b>Event</b>	<b>Frequency</b>	<b>Duration</b>	<b>Time until onset</b>
Soreness at site	frequent	up to 2 days	1-2 days
Fever <sup>1</sup>	infrequent	1-2 days	6-12 hours
Malaise <sup>1</sup>	infrequent	1-2 days	6-12 hours
Myalgia <sup>1</sup>	infrequent	1-2 days	6-12 hours
Hives	rare	----- -	immediate
Angioedema	rare	----- -	immediate
Allergic asthma	rare	-----	immediate
Anaphylaxis	rare	----- -	immediate - one half hour

<sup>1</sup> Most often affects persons with no prior exposure to the virus.

**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. Persons in high priority groups should be especially encouraged to receive the most current vaccines.
- 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 2006, 55(RR-10). Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm>
2. Influenza. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases*, ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 9<sup>th</sup> ed. Washington, DC: Public Health Foundation, 2006: 233–53. Available at: <http://www.cdc.gov/nip/publications/pink/flu.pdf>.
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.**