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INFLUENZA VACCINE RECOMMENDATIONS FOR 2007-2008

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy for the implementation and use of influenza vaccine for 2007-2008.

2. BACKGROUND

a. The influenza vaccination program is an essential component of VHA's health promotion and disease prevention programs. Influenza is a cause of substantial morbidity and mortality in the United States (U.S.) and vaccination is the most effective way to primarily protect against the disease and resultant complications. Vaccination also reduces the risk of transmitting influenza to family members, other patients and to health-care personnel. Vaccination of health-care personnel can likewise reduce transmission of influenza to patients, co-workers, visitors, and family members. VHA has made influenza vaccination a priority. It is a safe and cost-effective means for preventing and controlling influenza. *NOTE: Influenza vaccination rates of veteran patients are monitored in the VHA performance measurement system.*

b. The 2007-2008 trivalent vaccine strains are A/Solomon Islands/3/2006 (H1N1)-like (new for this season), A/Wisconsin/67/2005 (H3N2)-like, and B/Malaysia/2506/2004-like antigens. Only the H1N1 strain was changed for the recommended vaccine for the 2007-2008 influenza season, compared with the 2006-2007 season.

c. Effective July 1, 2005, trivalent influenza vaccines became covered vaccines under the National Vaccine Injury Compensation Program (VICP) and have been added to the Vaccine Injury Table that lists the vaccines covered under VICP. As required by Federal law under the National Childhood Vaccine Injury Act, all health care providers who administer any vaccine covered by the VICP must provide a copy of the relevant current edition of vaccine information materials (specifically Vaccine Information Statements (VIS) prior to administration of each dose of the vaccine. VIS are developed by the Centers for Disease Control and Prevention (CDC). VIS for trivalent inactivated influenza vaccine (TIV) is available from the CDC website at: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flu.pdf> and the VIS for live, attenuated influenza vaccine (LAIV) is available at: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flulive.pdf>. The appropriate VIS must be provided to the parent or legal representative of any child to whom the provider intends to administer such vaccine, and to any adult to whom the provider intends to administer such vaccine. The materials must be supplemented with visual presentations or oral explanations, as appropriate. *NOTE: It is very possible that the U.S. Food and Drug Administration will approve updated licensing for FluMist™ during this flu season—possibly before any vaccine is shipped. If this happens, a new interim VIS for LAIV will be published. The available 2007-08 VIS for LAIV dated July 16, 2007, reflects the current licensing.*

d. The immunization standard for long-term care facilities from the Department of Health and Human Services, Centers for Medicare and Medicaid Services became effective October 7, 2005.

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participating Medicare and Medicaid long-term care facilities are required to offer each resident immunization against influenza annually, as well as lifetime immunization against pneumococcal disease. For the influenza vaccine, the standard requires education for the resident or legal representative regarding benefits and potential side effects prior to the annual offering of the vaccine, the right of the resident or legal guardian to refuse vaccination, and the pertinent documentation in the medical record. Documentation must include:

- (1) That specific education was provided;
- (2) The resident either received the influenza vaccine or did not receive the vaccine; and
- (3) Whether the refusal was due to medical contraindications.

e. The Joint Commission has approved an infection control standard that requires accredited organizations to offer influenza vaccination to staff, including volunteers, and licensed independent practitioners with close patient contact. **NOTE:** *The standard became an accreditation requirement beginning January 1, 2007.*

3. POLICY: It is VHA policy to base the influenza vaccination program on recommendations of the CDC Advisory Committee on Immunization Practices (ACIP) as published in the Morbidity and Mortality Weekly Report (MMWR), while focusing on VHA specific issues in accordance with statutes or other regulations, and policies governing vaccine administration to patients and employees.

4. ACTION: Each facility Director is responsible for implementing an influenza vaccination program in accordance with this Directive, updates from CDC, and any VHA Influenza Vaccine Advisories from the Under Secretary for Health to ensure alignment with the following:

a. **Target Groups for Annual Influenza Vaccination.** Target groups for the annual influenza vaccination include:

- (1) Persons who are at increased risk for severe complications from influenza, or who are more likely to require medical care, such as:
 - (a) Adults aged 50 years and older;
 - (b) Residents of nursing homes and other chronic-care facilities;
 - (c) Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
 - (d) Persons who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);

(e) Persons who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of their respiratory secretions or that can increase the risk of aspiration;

(f) Women who will be pregnant during the influenza season;

(g) Children and adolescents aged 6 months to 18 years who are receiving long-term aspirin therapy; and

(h) Children aged 6 months to 59 months.

(2) Persons who live with or provide care for persons at high risk for influenza related complications, such as:

(a) Health-care personnel;

(b) Employees of assisted living and other residences for persons in groups at high risk for influenza-related complications;

(c) Persons who provide home care to persons in groups at high risk for influenza-related complications; and

(d) Household contacts of persons in groups at high risk for influenza-related complications.

(3) Household contacts and caregivers of children aged 59 months or younger and adults aged 50 years or older.

(4) Travelers.

(a) For travelers the risk of exposure to influenza during travel depends on the time of year and destination. To reduce the risk for influenza infection, if traveling at a time and to an area of influenza activity, the traveler should consider influenza vaccination preferably at least 2 weeks before departure; and

(b) Persons at high risk for complications of influenza, and who were not vaccinated with influenza vaccine during the preceding fall or winter should consider receiving influenza vaccine before travel, if they plan to travel to the tropics or travel with organized tourist groups at any time of year, or travel to the Southern Hemisphere during April – September.

(5) General population, this includes any person who wishes to reduce the likelihood of becoming ill with influenza or transmitting influenza to others (depending on vaccine availability).

NOTE: Depending upon vaccination availability, it may be necessary for tiered timing of vaccination of different groups as announced by CDC and the Under Secretary for Health through Influenza Vaccine Advisories.

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b. **Influenza Vaccines.** There are two trivalent influenza vaccines available for use in the U.S., TIV and LAIV. Both vaccines are to be given in alignment with the package inserts provided by manufacturers, CDC recommendations, and VHA Influenza Vaccine Advisories. *NOTE: Information pertinent to influenza vaccines can be found in the VA Influenza Toolkit Manual 2007-2008 http://vaww.vhaco.va.gov/phshcg/Flu/flu_toolkit.htm.* Health care providers must give the most current and appropriate VIS developed by CDC to patients, parents, legal representatives, and/or health care personnel prior to administration of either TIV or LAIV.

(1) **Trivalent Inactivated Influenza Vaccine (TIV)**

(a) General Information

1. TIV:

a. Is approved for use among persons aged 6 months or older, including those who are healthy and those with chronic medical conditions.

b. Is administered annually.

c. Is updated annually with vaccine virus strains.

d. Contains killed viruses.

e. Is administered intramuscularly in the deltoid muscle by injection for adults and older children. *NOTE: Consideration should be given to using a needle length of at least 1 inch because shorter needles may not penetrate muscle tissue.*

f. Cannot produce signs or symptoms of influenza virus infection.

g. Is preferred for vaccinating household members, health care personnel, and others who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) during those periods in which the immunosuppressed person requires care in a protective environment.

h. Can be co-administered with influenza antivirals.

i. Can be administered in the presence of minor illnesses with or without fever.

2. Usage of TIV for those who have experienced Guillain-Barre´ Syndrome (GBS) is an issue. Avoiding vaccinating persons who are not at high risk for severe influenza complications and who are known to have experienced GBS within 6 weeks after a previous influenza vaccination is prudent. Although data are limited, the established benefits of influenza vaccination might outweigh the risks for many persons who have a history of GBS and who are also at high risk for severe complications from influenza.

3. CDC recommendations indicate that TIV can be simultaneously administered with other vaccines; however, co-administration with other vaccines has been evaluated systematically only among adults with pneumococcal polysaccharide vaccine.

(b) Persons Who Should be Vaccinated With TIV. Persons who should be vaccinated with TIV include:

1. Children aged 6 months to 59 months;
2. Persons aged 50 years of age or older;
3. Children and adolescents (aged 6 months to 18 years) who are receiving long-term aspirin therapy;
4. Women who will be pregnant during the influenza season;
5. Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
6. Adults and children who are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus);
7. Adults and children who have 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;
8. Residents of nursing homes and other chronic care facilities;
9. Household members and others who have close contact with severely immunosuppressed persons requiring a protective environment (e.g., hematopoietic stem cell transplant recipients); and
10. Health care personnel who provide care for severely immunosuppressed patients requiring a protective environment (e.g., hematopoietic stem cell transplant recipients).

(c) Persons Who Should Not be Vaccinated With TIV. Persons who should not be vaccinated with TIV include:

1. Children aged less than 6 months;
2. Persons known to have anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine; and
3. Usually, persons with moderate to severe acute febrile illness (wait until their symptoms have abated).

(2) **Live, Attenuated Influenza Vaccine (LAIV)**

(a) General Information

1. LAIV is:
 - a. Approved for use among healthy, non-pregnant persons aged 5 to 49 years of age;
 - b. Administered annually;
 - c. Updated annually with vaccine virus strains; and
 - d. Administered intranasally by sprayer.
2. LAIV contains live, attenuated viruses.
3. LAIV has a potential to produce mild signs or symptoms related to attenuated influenza virus infection.
4. LAIV can be administered to appropriate persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever).
5. Deferral of LAIV should be considered if clinical judgment indicates nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa until resolution of the illness.
6. If the LAIV recipient sneezes after administration, the dose should not be repeated.
7. LAIV should not be administered until 48 hours after cessation of influenza antiviral therapy, and influenza antiviral medications should not be administered for 2 weeks after receipt of LAIV.
8. CDC recommendations indicate that LAIV can be simultaneously administered with other vaccines; however, there is no available data regarding effect on safety or efficacy on simultaneous administration with other vaccines. CDC further suggests that it may be prudent to space vaccinations of LAIV and other live vaccines 4 weeks apart.
9. Health care personnel who receive LAIV should avoid providing care to severely immunosuppressed patients requiring a protective environment (e.g., hematopoietic stem cell transplant recipients) for 7 days after vaccination.
10. Hospital visitors who received LAIV should avoid contact with severely immunosuppressed persons requiring a protective environment (e.g., hematopoietic stem cell transplant recipients) for 7 days after vaccination.

(b) Administration of LAIV Vaccine. LAIV:

1. Can be administered by persons at high risk for influenza complications. These include persons with underlying medical conditions placing them at high risk or who are likely to be at risk, including pregnant women, persons with asthma, and persons aged 50 years or older; and
2. Should not be administered by severely immunosuppressed persons.

(c) LAIV is an Option For Vaccination of Some Persons. LAIV is an option for vaccination of healthy, non-pregnant persons aged 5 years to 49 years, including health care personnel and other close contacts of high-risk persons.

(d) Persons Who Should Not be Vaccinated With LAIV. Persons who should not be vaccinated with live attenuated influenza vaccine include:

1. Persons aged less than 5 years or those aged 50 years or older.
2. Persons with any medical conditions including: asthma, reactive airway disease, or other chronic disorders of the pulmonary or cardiovascular systems. Persons with other underlying medical conditions, including: metabolic diseases, such as diabetes, renal dysfunction, and hemoglobinopathies; or known or suspected immunodeficiency diseases or immunosuppressed states.
3. Family members or close contacts of immunosuppressed persons requiring a protective environment (e.g., hematopoietic stem cell transplant recipient).
4. Children or adolescents receiving aspirin or other salicylates.
5. Persons with a history of GBS.
6. Pregnant women.
7. Persons with a history of hypersensitivity, including anaphylaxis, to any components of LAIV or to eggs.

c. Documentation

(1) **Patient Consent and Documentation**

(a) All persons receiving trivalent influenza vaccines must receive information about the vaccine and be given a copy of the most current and appropriate VIS (VIS for trivalent inactivated influenza vaccine or VIS for live, attenuated influenza vaccine) prior to administration of the vaccine.

(b) The practitioner who has primary responsibility for the patient, or who will perform the procedure, must explain in language understandable to the patient or surrogate the nature of the

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procedure, expected benefits, reasonably foreseeable associated risks, complications or side effects, anticipated results if influenza vaccine is not given, and document the non-signature informed consent process in the medical record. Documentation must include the:

1. Date of administration of the vaccine,
2. Lot number,
3. Manufacturer,
4. Route and site of vaccine administration,
5. Name and title of the individual administering the vaccine, and
6. Specific CDC VIS provided, indicating the edition date of the material and the date the VIS was provided.

(c) Administration of influenza vaccine to veteran patients must be documented in the Computerized Patient Records System (CPRS) in the immunization section.

(d) A signed consent for administration of influenza vaccine to veteran patients is not required.

(2) **Employee Consent and Documentation.** Any employee who receives a trivalent influenza vaccine from VA must receive information about the vaccine (CDC's VIS). The information is to include the nature of the procedure; expected benefit; reasonably foreseeable associated risks, complications, or side effects, and anticipated results if influenza vaccine is not given.

(a) Documentation is to include employee receipt of the specific VIS provided indicating the edition date of the material and the date the VIS was given to the employee, lot number, manufacturer, route and site of vaccine administration, the non-signature informed consent process, and name and title of the individual administering the vaccine. Documentation and maintenance of employee health records concerning influenza vaccine must be in accordance with VA Handbook 5019, Part V. Provision of influenza vaccine to employees, will be at no expense to the employee.

(b) A signed consent for administration of influenza vaccine to employees is not required.

(c) An annual influenza vaccination program must be developed and implemented at each facility for staff, which includes volunteers and licensed independent practitioners with close patient contact. This program must be in alignment with The Joint Commission's new infection control standard that became effective January 1, 2007. **NOTE:** *Influenza Vaccine for employees is a performance monitor and the facility is expected to provide data to VA Central Office on the percent of employees who have received influenza vaccine.*

(d) Implement strategies to encourage healthcare personnel to get influenza vaccine.

(3) **Adverse Events Related to Drug Products and Vaccines.** Adverse Events related to drug products and vaccines must be reported.

(a) All adverse drug events relating to biologicals at the facility must be reported to the Food and Drug Administration (FDA) on a completed FDA form 3500, Med Watch. Reports of adverse events related to vaccine use need to be reported to FDA on completed FDA Form VAERS – 1, Vaccine Adverse Event Form. These forms are available at:
<http://www.fda.gov/cber/vaers/vaers.htm>

(b) An adverse event related to voluntary participation in an employee influenza vaccination program is not a work-related Occupational Safety and Health Administration (OSHA) recordable event. This exclusion does not affect eligibility for Office of Workers' Compensation Programs (OWCP) claims.

d. **Implementing Vaccination Recommendations.** Program planning must be undertaken for a successful vaccination program.

(1) Vaccination coverage can be increased by administering vaccine to persons during hospitalization as appropriate.

(2) Clinics should be scheduled for the influenza vaccine throughout the influenza season and the need to continue vaccination beyond the traditional months of October and November should be emphasized.

(3) See subparagraph 5k to assist with program planning. *NOTE: VA has published a VA Influenza Toolkit Manual for 2007-2008 influenza season that has been distributed to each VA Medical Center.*

(4) See subparagraph 5a for vaccination program strategies.

e. **Antiviral Medications for Influenza.** Antiviral medications for influenza are an adjunct to influenza vaccine for controlling and preventing influenza. They are effective when administered as treatment and when used for chemoprophylaxis after an exposure to the influenza virus. These agents are not a substitute for vaccination.

(1) Oseltamivir and zanamivir are the only antiviral medications for influenza currently recommended for use in the United States. Resistance to oseltamivir or zanamivir remains rare.

(a) Oseltamivir (available through the VA National Formulary restricted to specific criteria for use developed by the Pharmacy Benefits Management-Medical Advisory Panel) or zanamivir can be prescribed if antiviral treatment or chemoprophylaxis is indicated.

(b) Since the drugs differ in pharmacokinetics, side effects, routes of administration, approved age groups, dosages, and costs, administration of the medications needs to be in

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alignment with the package inserts provided by the manufacturers and the most recent CDC guidelines for usage.

(2) Amantadine or rimantidine should not be used for the treatment or prevention of influenza in the U.S. until evidence of susceptibility to these antiviral medications has been reestablished among circulating influenza A viruses.

f. **Vaccine Shortage.** The annual supply of influenza vaccine and the timing of its distribution cannot be guaranteed in any year because of the inherent critical time constraints in manufacturing the vaccine given the annual updating of the influenza vaccine strains.

(1) Depending upon vaccine availability, it may be necessary for tiered timing of vaccination of different groups as communicated by CDC and the Under Secretary for Health through Influenza Vaccine Advisories.

(2) If an influenza vaccine delay and/or a shortage occurs, prioritization plans for influenza vaccine must be developed at the local facility level and administered in accordance with the preceding guidance.

5. REFERENCES

a. CDC. "Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP) 2007," MMWR. Vol. 56 RR-6; 1-54: July 13, 2007. See at: <http://www.cdc.gov/mmwr/PDF/rr/rr5606.pdf>.

b. CDC. "Recommended Adult Immunization Schedule – United States", MMWR. Vol. 55(4); Q1-4: October 13, 2006. See at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5540a10.htm?s_cid=mm5540a10_e

c. CDC. "General Recommendations on Immunization," MMWR. Vol. 55 RR-15; 1-48: December 1, 2006. See at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm>

d. CDC. "Influenza Vaccination of Health-Care Personnel," MMWR. Vol. 55 RR-2; 1-16; February 24, 2006. See at: <http://www.cdc.gov/mmwr/PDF/rr/rr5502.pdf>

e. CDC. Inactivated Influenza Vaccine, Vaccine Information Statement at: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flu.pdf>

f. CDC. Live Intranasal Influenza Vaccine, Vaccine Information Statement at: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flulive.pdf>

g. CDC. Influenza (Flu) at: <http://www.cdc.gov/flu/>

h. CDC. News about Vaccine Information Statements. See at: <http://www.cdc.gov/vaccines/pubs/vis/vis-news.htm#flu>

- i. Public Health Information from VA. Influenza (Flu) at:
<http://www.publichealth.va.gov/flu/>
- j. VA Influenza Vaccine Advisories at: <http://www.publichealth.va.gov/flu/advisory.htm>
- k. VA Influenza Toolkit Manual 2007-2008 at:
http://www.publichealth.va.gov/flu/flu_toolkit.htm
- l. U.S. Department of Labor, OSHA, Regulations (Title 29 Code of Federal Regulations (CFR) – Standards) Determination of Work-relatedness, Standard 1904.5, at:
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9636
- m. Title 42 United States Code. Chapter 6A, Subchapter XIX Vaccines, at:
<http://www4.law.cornell.edu/uscode/42/ch6AschXIX.html>
- n. Federal Register. Title 42 CFR Part 483, Medicare and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities; Final Rule. Vol. 70, No. 194, 58834-58852: October 7, 2005.

6. FOLLOW-UP RESPONSIBILITY: The Chief Officer, Patient Care Services (11), is responsible for the contents of this Directive. Questions relating to influenza and/or the influenza vaccine may be referred to the Infectious Diseases Program Office at (513) 475-6398.

7. RECISSIONS: VHA Directive 2006-058 is rescinded. This VHA Directive expires on December 31, 2008.

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