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INFLUENZA VACCINE – RECOMMENDATIONS FOR 2003-2004

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides guidance on the use of the influenza vaccine for 2003-2004.

2. BACKGROUND

a. The influenza vaccine immunization program is an integral component of the Department of Veterans Affairs (VA) Preventive Medicine Program. Influenza is a cause of substantial morbidity and mortality in the United States. Considering that epidemics of respiratory disease typically occur during the winter months, there is concern that there may be an increase in cases of Severe Acute Respiratory Syndrome (SARS). Because symptoms of SARS and influenza are similar, the potential for clinical and operational impact on the VA health care system this winter could be substantial. Therefore, active participation in the influenza vaccine program is strongly encouraged to reduce cases of respiratory disease caused by influenza. The influenza vaccine is the most effective way to protect against influenza disease. Vaccination is a safe and cost effective means for preventing and controlling influenza. For several years VA has provided the influenza vaccine to high-risk veterans and persons who can transmit influenza to veterans at high-risk. Influenza vaccination rates are monitored in the VHA performance measurement system.

b. The trivalent influenza vaccine recommended for the 2003-2004 season includes: A/Moscow/10/99 (H3N2)-like, A/New Caledonia/20/99 (H1N1)-like, and B/HongKong/330/2001-like antigens.

c. VHA bases the vaccination immunization program on the annual recommendations of the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) Influenza Vaccine Recommendations as published in Morbidity and Mortality Weekly Report (MMWR). Information is provided on the use of inactivated influenza vaccine for the 2003-2004 season, high-priority groups to be targeted for vaccination, information on contraindications, potential side effects associated with vaccination, and the use of antivirals as an adjunct to vaccination. Recently the Food and Drug Administration (FDA) approved live, attenuated intranasal influenza vaccine (see Att. A).

3. POLICY: It is the VHA policy to publish annual recommendations on the use of the influenza vaccine.

4. ACTION: VHA facility Directors are responsible for implementing the influenza vaccination program outlined by the Advisory Committee on Immunization Practices and published in MMWR, Vol. 52: No. RR-8: April 25, 2003.

a. **Timing of Vaccinations.** The optimal time to vaccinate is during October and November. Begin vaccinating persons at greatest risk for influenza-like complications and health care

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workers in September and October, as soon as vaccine is available. Vaccination of other groups needs to begin in November. Major vaccination campaigns need to be planned for after mid-October to ensure adequate availability of vaccine supply. Vaccinations need to continue to be offered in December, and throughout the influenza season as long as vaccine supplies are available, even after influenza activity has been documented in the community. In the United States, seasonal influenza activity can increase as early as November, but does not reach peak levels in the majority of recent influenza seasons until late December through early March. Adults develop peak antibody protection against influenza infection 2 weeks after vaccination.

b. **Program Planning.** Successful vaccination programs combine publicity and education for health care workers and other potential vaccine recipients, a plan for identifying persons at high-risk, use of reminder and/or recall systems, standing orders programs, and other strategies to remove barriers that prevent persons from receiving vaccine.

c. **Vaccine Shortage.** Shortfalls of vaccines are not expected during the 2003-2004 flu season; however, only two companies are producing influenza vaccine this year, down from three companies in 2002. If an influenza vaccine delay and/or shortage occur, VHA facilities at the local level need to develop a prioritization plan that maximizes protection of the patients most likely to develop serious and life-threatening complications from influenza.

d. **Patient Consent and Documentation.** All persons receiving influenza vaccinations need to receive information about the vaccine (e.g., CDC's Vaccine Information Statement on Inactivated Influenza Vaccine). 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 procedure, the expected benefits, reasonably foreseeable associated risks, complications or side effects, and anticipated results if influenza vaccine is not given, and document the non-signature informed consent process in the medical record. Documentation must include the date the vaccine was administered, the lot number, the manufacturer, and the name and the title of individual administering the vaccine.

e. **Employee Consent and Documentation.** All employees receiving influenza vaccinations need to receive information about the vaccine (e.g., CDC's Vaccine Information Statement on Inactivated Influenza Vaccine). Documentation must include the date the vaccine was administered, the lot number, the manufacturer, and the name and the title of individual administering the vaccine. *NOTE: Documentation concerning influenza vaccine must be in accordance with VA Handbook 5019, Part V.*

5. REFERENCES

a. CDC. "Prevention and Control of Influenza: Recommendations of ACIP," MMWR. 52 (No. RR-8):1-34. April 25, 2003. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5208a1.htm> (web version) and <http://www.cdc.gov/mmwr/PDF/rr/rr5208.pdf> (PDF file)

b. CDC. Influenza Vaccine Information for Health Care Providers, Including the Vaccine Information Statement (VIS). <http://www.cdc.gov/nip/flu/>

c. CDC. "General Recommendations on Immunizations. Recommendations of ACIP and the American Academy of Family Physicians (AAFP)," MMWR. 51:1-36: February 8, 2002.

d. "Maximizing Vaccination Rates for Veterans with SCI&D," VA QUERI Quarterly Newsletter. Vol. 3:No 4; March 2002.

e. VHA Handbook 1004.1, VHA Informed Consent for Clinical Treatments and Procedures, January 29, 2003.

f. VA Handbook 5019, Occupational Health Services, April 15, 2002.

g. FDA News P03-45, "First Nasal Mist Flu Vaccine Approved," June 17, 2003.

h. Package insert (Circular) Influenza Virus Vaccine Live, Intranasal (FluMist) June 16, 2003.

6. FOLLOW-UP RESPONSIBILITY: The Chief Officer, Patient Care Services (11), is responsible for the contents of this Directive. Questions relating to implementation of the influenza immunization program are referred to the National Center for Health Promotion and Disease Prevention (NCP), telephone (919) 383-7874, extension 234, or extension 222. Questions relating to influenza and/or influenza vaccine are referred to the Infectious Diseases Program Office, telephone number (513) 475-6398.

7. RECISSION: VHA Directive 2002-044 is rescinded. This VHA Directive expires on November 30, 2004.

S/ Nevin M. Weaver for
Robert H. Roswell, M.D.
Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 10/7/03
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ATTACHMENT A

INFORMATION ABOUT THE INFLUENZA VIRUS VACCINE FOR 2003-2004

1. TARGET GROUPS FOR INACTIVATED INFLUENZA VACCINE

a. **Persons at High-risk.** Vaccination is recommended for the following groups of persons who are at increased risk for complications from influenza:

- (1) Persons ages 65 years or older;
- (2) Residents of nursing homes, and residents of other chronic-care facilities that house persons of any age who have chronic medical conditions, and residents of domiciliaries;
- (3) Adults who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;
- (4) Adults who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus (HIV)); and
- (5) Women who will be in the second or third trimester of pregnancy during the influenza season.

b. **Persons Ages 50 to 64 Years.** Vaccination is recommended for persons ages 50 to 64 years because this group has an increased prevalence of persons with high-risk conditions.

c. **Persons Who Can Transmit Influenza to Those at High-risk.** Vaccination of health care personnel and others in close contact with persons at high-risk including household contacts, is recommended. The following groups need to be vaccinated:

- (1) Physicians, nurses, and other personnel in both hospital and outpatient-care settings, including medical emergency response workers (e.g., paramedics and emergency medical technicians);
- (2) Employees of nursing homes and chronic-care facilities who have contact with patients or residents;
- (3) Employees of assisted living and other residences for persons in groups at high-risk;
- (4) Persons who provide home care to persons in groups at high-risk; and
- (5) Household contacts of persons in groups at high-risk.

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d. **Vaccination of Specific Populations**

(1) **Pregnant Women**

(a) Women who will be beyond the first trimester of pregnancy (greater than 14 weeks gestation) during the influenza season should be vaccinated because of the increased risk for influenza-related complications. Pregnant women who have medical conditions that increase their risk for complications from influenza should be vaccinated before the influenza season, regardless of the stage of pregnancy.

(b) Certain providers prefer to administer influenza vaccine during the second trimester to avoid a coincidental association with spontaneous abortion, which is common in the first trimester, and because exposures to vaccines traditionally have been avoided during the first trimester.

(2) **Breastfeeding Mothers**

(a) Influenza vaccine does not affect the safety of mothers who are breastfeeding or their infants.

(b) Breastfeeding does not adversely affect the immune response and is not a contraindication for vaccination.

(3) **Persons Infected with HIV**

(a) Limited information is available regarding the frequency and severity of influenza illness or the benefits of influenza vaccination among persons with HIV infection.

(b) Because influenza can result in serious illness and because influenza vaccination can result in the production of protective antibody titers, vaccination will benefit HIV-infected persons, including HIV-infected pregnant women.

(4) **Spinal Cord Injury and Disease (SCI&D).** Persons living with SCI&D are at risk of developing pulmonary complications and are more likely to die as a result of influenza or pneumonia than persons in the general population; therefore, vaccination needs to be emphasized for this high-risk group.

(5) **Travelers**

(a) The risk of exposure to influenza during travel depends on the time of year and destination. In the tropics, influenza can occur throughout the year. In the temperate regions of the Southern Hemisphere, the majority of influenza activity is during April through September. In temperate climate zones of the Northern and Southern Hemispheres, travelers also can be exposed to influenza during the summer, especially when traveling as part of large organized

tourist groups that include persons from areas of the world where influenza viruses are circulating.

(b) Persons at high-risk for complications of influenza who were not vaccinated with influenza vaccine during the preceding fall or winter need to consider receiving influenza vaccine before travel, if they plan to:

1. Travel to the tropics;
2. Travel with large organized tourist groups at any time of year; or
3. Travel to the Southern Hemisphere during April through September.

(c) No information is available regarding the benefits of revaccinating persons before summer travel who were already vaccinated in the preceding fall. Persons at high-risk who received the previous season's vaccine before travel need to be revaccinated with the current vaccine in the following fall or winter. Persons ages 50 years and older and others at high-risk might want to consult with their physicians to discuss the symptoms and risks for influenza and the advisability of carrying antiviral medications for either prophylaxis or treatment of influenza, before embarking on travel during the summer.

(6) General Population

(a) Depending on availability of vaccine, physicians need to administer influenza vaccine to any person who wishes to reduce the likelihood of becoming ill with influenza.

(b) Persons who provide essential community services need to be considered for vaccination to minimize disruption of essential activities during influenza outbreaks.

(c) Students or other persons in institutional settings (e.g., those who reside in dormitories) should be encouraged to receive the vaccine in order to minimize the disruption of routine activities during epidemics.

2. PERSONS WHO SHOULD NOT RECEIVE INACTIVATED INFLUENZA VACCINE

a. Inactivated influenza vaccine should not be administered to persons known to have anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine without first consulting a physician (see par. 5, Effects and Adverse Reactions). Prophylactic use of the antiviral agents is an option for preventing influenza among such persons. However, persons who have a history of anaphylactic hypersensitivity to vaccine components but who are also at high-risk for complications from influenza can benefit from vaccine after appropriate allergy evaluation and desensitization. **NOTE:** *Information about vaccine components can be found in package inserts from each manufacturer.*

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b. Persons with acute febrile illness usually should not be vaccinated until their symptoms have abated. However, minor illnesses with or without fever do not contraindicate the use of influenza vaccine.

3. TIMING OF ANNUAL VACCINATION WITH INACTIVATED INFLUENZA VACCINE

a. Persons planning substantial organized vaccination campaigns should consider scheduling these events after mid-October because the availability of vaccine in any location cannot be ensured consistently in the early Fall. Scheduling campaigns after mid-October minimizes the need for cancellations because the vaccine is unavailable. To the extent feasible, campaigns conducted before November need to focus efforts on vaccination of persons at high-risk, health care workers, and household contacts of persons at high-risk.

b. While the optimal time to vaccinate is usually during October-November, it is recommended that vaccine providers focus their vaccination efforts in October and earlier primarily on persons age 50 and older, persons younger than age 50 who are at increased risk of influenza-related complications, household contacts of persons at high-risk (including out-of-home caregivers), and health care workers.

c. To avoid missed opportunities for vaccination of persons at high-risk for serious complications, such persons should be offered vaccine beginning in September during routine health care visits or during hospitalizations, if vaccine is available.

d. Efforts to vaccinate other persons who wish to decrease their risk for influenza infection should begin in November.

e. In facilities housing elderly persons (e.g., nursing homes), vaccination before October generally is to be avoided, because antibody levels in such individuals can begin to decline within a few months after vaccination. All residents within a nursing home need to be vaccinated at one time, preceding the influenza season. Residents admitted through the winter months, after completion of the vaccination program, need to be vaccinated at the time of admission, if not previously vaccinated during current season.

f. To improve vaccine coverage, influenza vaccine should continue to be offered in December and throughout the influenza season as long as vaccine supplies are available, even after influenza activity has been documented in the community. **NOTE:** *In the United States, seasonal influenza activity can begin to increase as early as November or December, but influenza activity has not reached peak levels until late December-early March, in the majority of recent influenza seasons.*

4. VACCINE DOSAGE OF INACTIVATED INFLUENZA VACCINE. Adult patients (those 9 years old and older) need to receive one intramuscular dose in the deltoid muscle per dosage information on package insert from manufacturer.

5. SIDE EFFECTS AND ADVERSE REACTIONS OF INACTIVATED INFLUENZA VACCINE

a. Inactivated Influenza Vaccine

(1) Inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza.

(2) Coincidental respiratory disease unrelated to influenza vaccination can occur after vaccination.

b. Local Reactions

(1) The most frequent side effect of vaccination is soreness at the vaccination site that lasts less than 2 days.

(2) These local reactions generally are mild and rarely interfere with the person's ability to conduct usual daily activities.

c. Systemic Reactions

(1) Fever, malaise, myalgia, and other systemic symptoms can occur following vaccination and most often affect persons who have had no prior exposure to the influenza virus antigens in the vaccine (e.g., young children). These reactions begin 6 to 12 hours after vaccination and can persist for 1 or 2 days.

(2) Immediate, presumably allergic, reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) rarely occur after influenza vaccination. These reactions probably result from hypersensitivity to certain vaccine components; most reactions likely are caused by residual egg protein. Although current influenza vaccines contain only a limited quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy. Persons who have had hives or swelling of the lips or tongue, or have experienced acute respiratory distress or collapse after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons with documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma or other allergic responses to egg protein, might also be at increased-risk for allergic reactions to influenza vaccine, and consultation with a physician is to be considered.

(3) Hypersensitivity reactions to any vaccine component can occur. Although exposure to vaccines containing thimerosal can lead to induction of hypersensitivity, the majority of patients do not have reactions to thimerosal when it is administered as a component of vaccines, even when patch or intradermal tests for thimerosal indicate hypersensitivity. When reported, hypersensitivity to thimerosal usually has consisted of local, delayed-type hypersensitivity reactions.

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d. **Special Cases as in Guillain-Barré Syndrome (GBS)**

(1) Investigations to date suggest no substantial increase in GBS associated with influenza vaccines (other than the swine influenza vaccine in 1976) and that, if influenza vaccine does pose a risk, it is probably slightly more than one additional case per million persons vaccinated.

(2) The potential benefits of influenza vaccination in preventing serious illness, hospitalization, and death substantially outweigh the possible risks for experiencing vaccine-associated GBS. The average case fatality ratio for GBS is 6 percent, increasing with age. However, no evidence indicates that the case fatality ratio for GBS differs among vaccinated persons and those not vaccinated.

(3) The incidence of GBS among the general population is low, but persons with a history of GBS have a substantially greater likelihood of subsequently experiencing GBS than persons without such a history. Thus, the likelihood of coincidentally experiencing GBS after influenza vaccination is expected to be greater among persons with a history of GBS than among persons with no history of this syndrome. Whether influenza vaccination specifically might increase the risk for recurrence of GBS is unknown; therefore, 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, for the majority of persons who have a history of GBS and who are at high-risk for severe complications from influenza, the established benefits of influenza vaccination justify yearly vaccination.

6. SIMULTANEOUS ADMINISTRATION OF OTHER VACCINES WITH INACTIVATED INFLUENZA VACCINE.

Adult target groups for influenza and pneumococcal polysaccharide vaccination overlap considerably. For persons at high-risk who have not previously been vaccinated with pneumococcal vaccine, health care providers should strongly consider administering pneumococcal polysaccharide and inactivated influenza vaccines concurrently. Both vaccines can be administered at the same time at different sites without increasing side effects. **NOTE:** *Influenza vaccine is administered each year, whereas pneumococcal vaccine is not.*

7. ANTIVIRAL DRUGS FOR INFLUENZA

a. Antiviral drugs for influenza are an adjunct to influenza vaccine for controlling and preventing influenza. However, these agents are not a substitute for vaccination. Four licensed influenza antiviral agents are available in the United States: amantadine, rimantadine, zanamivir, and oseltamivir.

b. Amantadine and rimantadine are chemically related antiviral drugs known as adamantanes with activity against influenza A viruses, but not influenza B viruses. Amantadine was approved in 1966, for chemoprophylaxis of influenza A (H2N2) infection and was later approved in 1976, for the treatment and chemoprophylaxis of influenza type A virus infections among adults and

children 1 year old and older. Rimantadine was approved in 1993, for treatment and chemoprophylaxis of influenza A infection among adults and prophylaxis among children.

c. Zanamivir and oseltamivir are chemically related antiviral drugs known as neuraminidase inhibitors and that have activity against both influenza A and B viruses. Both zanamivir and oseltamivir were approved in 1999 for treating uncomplicated influenza infections. Zanamivir is approved for treating persons age 7 years old and older, and oseltamivir is approved for treatment for persons age 1 year old and older. In 2000, oseltamivir was approved for chemoprophylaxis of influenza among persons age 13 years old and older.

d. The four drugs differ in terms of their pharmacokinetics, side effects, routes of administration, approved age groups, dosages, and costs. **NOTE:** *Consult the package inserts for more information.*

8. STRATEGIES FOR IMPLEMENTING RECOMMENDATIONS IN HEALTH CARE SETTINGS

a. Department of Veterans Affairs (VA) Medical Center Employees

(1) Measures need to be taken to provide all health care workers convenient access to influenza vaccination at the work site, free of charge, as part of the VA Occupational Health Services Program, because employees may transmit influenza to patients. Influenza vaccine needs to be offered to employees through the Employee Health Unit.

(2) Vaccination records must be maintained in the Occupational Health Unit or in a separate locked area controlled by Human Resources Management Office in accordance with VA Handbook 5019, Part V.

(3) Expenses involved in this program need to be kept at a minimum; therefore, the use of centrally-procured vaccine vials is recommended instead of unit dose vaccine.

b. **Additional Strategies.** The VA National Center for Health Promotion and Disease Prevention (NCP) has updated the Influenza-Pneumococcal Resource Toolkit; it is available at website <http://www.vaprevention.com> or at <http://vaww.nchpdp.med.va.gov>. For additional strategies for implementing recommendations in health care settings, see "Recommendations of the Advisory Committee on Immunization Practices (ACIP)," Morbidity and Mortality Weekly Report (MMWR), April 25, 2003, pages 14-16 (<http://www.cdc.gov/mmwr/PDF/rr/rr5208.pdf>).

9. LIVE, ATTENUATED INTRANASAL INFLUENZA VACCINE

a. On June 17, 2003, the Food and Drug Administration (FDA) approved a nasally-administered live, attenuated influenza vaccine to be marketed in the United States. The vaccine is approved to prevent influenza illness due to influenza A and B viruses in healthy children and adolescents, ages 5 to 17 years old, and healthy adults, ages 18 to 49 years old. As with other live virus vaccines, it should not be given for any reason to people with immune suppression, including those with immune deficiency diseases, such as Acquired Immune Deficiency

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Syndrome (AIDS) or cancer, and people who are being treated with drugs that cause immunosuppression. The safety of this vaccine, in individuals with underlying medical conditions that may predispose them to severe disease following wild-type influenza infection, has not been established and is therefore not indicated for these individuals.

(1) Such individuals include, but are not limited to: adults and children with chronic disorders of the cardiovascular and pulmonary systems, including asthma; pregnant women who will be in their second or third trimesters during influenza season; adults and children who required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes), renal dysfunction, or hemoglobinopathies; and adults and children with congenital or acquired immunosuppression caused by underlying disease or immunosuppressive therapy.

(2) For these high-risk individuals, intramuscularly-administered inactivated influenza vaccines are available. Individuals with a history of hypersensitivity, especially anaphylactic reactions to any component of this product, including eggs or egg products, should not receive this vaccine. It is also contraindicated in children and adolescents (ages 5 through 17 years old) receiving aspirin therapy or aspirin-containing therapy, because of the association of Reye syndrome with aspirin and wild-type influenza infection, and it should not be administered to individuals who have a history of GBS.

b. Data related to shedding of the vaccine in children and adults are limited. Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to 3 weeks. Due to the possible transmission of vaccine virus, vaccine recipients or their parents or guardians should be advised to avoid close contact (e.g., within the same household) with immunocompromised individuals for at least 21 days.

c. The vaccine has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility. The safety and immunogenicity of this vaccine when administered concurrently with other vaccines have not been determined. Therefore, the vaccine should not be administered concurrently with other vaccines.