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INFLUENZA VACCINE – RECOMMENDATIONS FOR 2002-2003

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides guidance on the use of the influenza vaccine for 2002-2003.

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. 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 2002-2003 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). These guidelines provide information on the use of influenza vaccine for the 2002-2003 season, high priority groups to be targeted for vaccination, information on contraindications and potential side effects associated with vaccination, and the use of antivirals as an adjunct to vaccination.

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 reviewing the annual recommendations regarding the use of the influenza vaccine as published in MMWR, April 12, 2002; and that all employees receiving the vaccine sign VA Form 10-5549, Influenza Vaccine Consent Form.

NOTE: An abridged excerpted version of the CDC guidelines is included in Attachment A of this Directive.

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 workers in September and October, as soon as vaccine is available. Vaccination of other groups needs to begin in November. Plan major vaccination campaigns after mid-October to ensure adequate availability of vaccine supply. Vaccination should continue to be offered in December

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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 has not reached peak levels in the majority of recent 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 2002-2003 flu season; however, if an influenza vaccine delay and/or shortage should occur, VHA facilities at the local level need to develop a prioritization plan that will maximize protection of patients most likely to develop serious and life-threatening complications from influenza.

d. **Patient Consent.** All persons receiving influenza vaccinations need to receive information about the vaccine and its benefits and risks (e.g., CDC's Vaccine Information Statement). The consent form may be used for patients as a local option, but written informed consent is not required for patients when the vaccine is administered in the context of a regular "practitioner-patient" relationship. VA Form 10-5549, Influenza Vaccine Consent Form (see Att. B) is to be completed by all employees receiving the influenza vaccine. **NOTE:** *These forms are to be locally reproduced.*

5. REFERENCES

a. CDC. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," MMWR, April 12, 2002/51; 1-31. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5103a1.htm> (web version) and <http://www.cdc.gov/mmwr/PDF/rr/rr5103.pdf> (PDF file)

b. CDC. Influenza Vaccine Bulletin #1 Flu Season 2002-2003. February 26, 2002. <http://www.cdc.gov/nip/flu/>

c. CDC. The Advisory Committee on Immunization Practices Makes New Influenza Vaccine Recommendations for 2002-03. February 20, 2002-03. <http://www.cdc.gov/nip/flu/>

d. CDC. Vaccine Supply for 2002-2003. March 18, 2002. <http://www.cdc.gov/nip/flu/>

e. CDC. Vaccine information statement (VIS). Atlanta, GA: US Department of Health and Human Services, CDC, 2001. <http://www.cdc.gov/nip/flu/>

f. CDC. General Recommendations on Immunizations. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). February 8, 2002/51;1-36.

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

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 (NCHPDP), telephones (919) 383-7874 ext. 234, 227, or 224. 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 2001-053 is rescinded. This Directive expires on July 31, 2007.

S/ Nevin M. Weaver for
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Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 7/30/2002
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 7/30/2002

ATTACHMENT A

INFORMATION ABOUT THE INFLUENZA VIRUS VACCINE FOR 2002-2003

1. TARGET GROUPS FOR VACCINATION

a. **Persons at High Risk.** Vaccination is recommended for the following groups of persons who are at increased risk for complications from influenza or who have a higher prevalence of chronic medical conditions that place them at risk for influenza-related complications:

- (1) Persons ages \geq 65 years.
- (2) Residents of nursing homes, 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)).
- (5) Women who will be in the second or third trimester of pregnancy during the influenza season.

b. **Persons Aged 50-64 Years.** Vaccination is recommended for persons age 50-64 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 workers and others in close contact with persons at high risk including household members 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.
- (5) Household members of high-risk persons.

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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' of gestation) during the influenza season need to 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 need to be vaccinated before the influenza season, regardless of the stage of pregnancy.

(b) Because currently available influenza vaccine is an inactivated vaccine, many experts consider influenza vaccination safe during any stage of pregnancy. 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 benefits HIV-infected patients, including HIV-infected pregnant women.

(4) **Spinal Cord Injury & 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, most influenza activity occurs from 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 for 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.
3. Travel to the Southern Hemisphere from 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 aged ≥ 50 years and others at high risk might wish to consult with their physicians, before embarking on travel during the summer to discuss the symptoms and risks of influenza and the advisability of carrying antiviral medications for either prophylaxis or treatment of influenza.

(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) need to be encouraged to receive the vaccine in order to minimize the disruption of routine activities during epidemics.

2. PERSONS WHO SHOULD NOT BE VACCINATED

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.*

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 FOR ANNUAL VACCINATION

a. Persons planning substantial organized vaccination campaigns need to 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 will minimize 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. 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.

4. VACCINE DOSAGE

Adult patients (> 12 yrs.) should receive one intramuscular dose in the deltoid muscle per dosage information on package insert from manufacturer.

5. SIDE EFFECTS AND ADVERSE REACTIONS

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 6-12 hours after vaccination and can persist for 1-2 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 some vaccine component; most reactions likely are caused by residual egg protein. Although current influenza vaccines contain only a small quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy. Persons who have developed hives, have had swelling of the lips or tongue, or have experienced acute respiratory distress or collapse after eating eggs need to 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, most patients do not develop 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.

d. **Special Cases. Guillain-Barre' 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 greatly outweigh the possible risks for developing 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 developing GBS than persons without such a history. Thus, the likelihood of coincidentally developing GBS after the 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, it would seem prudent to avoid the influenza vaccination of persons who are not at high risk for severe influenza complications and who are known to have developed GBS within 6 weeks after a previous influenza vaccination. Although data are limited, for most 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.

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6. SIMULTANEOUS ADMINISTRATION OF OTHER VACCINES

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

7. ANTIVIRAL DRUGS FOR INFLUENZA

a. Antiviral drugs for influenza are an important adjunct to influenza vaccine for the control and prevention of influenza. However, they are not a substitute for vaccination. Four currently licensed agents are available in the United States: amantadine, rimantadine, zanamivir, and oseltamivir.

b. Amantadine and rimantadine are chemically related antiviral drugs with activity against influenza A viruses, but not influenza B viruses. Amantadine was approved in 1966 for prophylaxis of influenza A (H2N2) infection and was later approved in 1976 for the treatment and prophylaxis of influenza type A virus infections in adults and children aged ≥ 1 year. Rimantadine was approved in 1993 for treatment and prophylaxis of infection among adults.

c. Zanamivir and oseltamivir are neuraminidase inhibitors with activity against both influenza A and B viruses. Both zanamivir and oseltamivir were approved in 1999 for the treatment of uncomplicated influenza infections. Zanamivir is approved for treating persons aged ≥ 7 years, and oseltamivir is approved for treating persons aged ≥ 1 years. In 2000, oseltamivir was approved for chemoprophylaxis of influenza among persons aged ≥ 13 years.

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 Employee Health Program, because employees may transmit influenza to patients. Influenza vaccine needs to be offered to employees through the Employee Health Unit.

(2) Immunization records must be maintained in the Employee Health Unit.

(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.** 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 12, 2002.

ATTACHMENT B

VA FORM 10-5549, INFLUENZA VACCINE CONSENT FORM

The Disease. Influenza (flu) is caused by viruses. When people get the flu they may have fever, chills, headache, dry cough or muscle aches. Illness may last several days or a week or more, and complete recovery is usual. However, complications may lead to pneumonia or death in some people. For the elderly and people with diabetes or heart, lung, or kidney diseases, flu may be especially serious.

The Vaccine. Today's flu vaccines cause fewer side effects than those used in the past. In contrast with some other vaccines, flu vaccine can be taken safely during pregnancy; however, flu vaccine should be given to pregnant women according to the chronic illness criteria applied to other persons. One shot will protect most people from influenza during the next flu season.

Possible Vaccine Side Effects. Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people will also have fever, chills, headache, or muscle aches within the first 48 hours.

Special Precautions. As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated with severe or fatal reactions. An uncommon illness characterized by ascending paralysis (Guillain-Barre' Syndrome) has been reported following other flu vaccines but not in association with this flu vaccine; however, it must be assumed that the risk is present. Hypersensitivity reactions to any vaccine component can occur. Exposure to vaccines containing thimerosal can lead to induction of hypersensitivity. When reported, hypersensitivity to thimerosal has usually consisted of local, delayed-type hypersensitivity reactions (localized swelling and redness). In some instances people receiving vaccine have had allergic reactions. The following precautions should be carefully noted:

People with known allergy to eggs should receive the vaccine only for specific indications and under special medical supervision.

People with fever should delay getting vaccinated until the fever is gone.

People who have received another type of vaccine in the past 14 days should consult a physician before taking the flu vaccine.

NOTE: Please ask if you have any questions about flu or flu vaccine.

I have read the above statement about influenza (flu), the vaccine, and the special precautions. I have had an opportunity to ask questions, and understand the benefits and risks of flu vaccination. I request that it be given to me or to the person named below of whom I am the parent or guardian.

(Print Name of Person to Receive Vaccine)

(Date Vaccinated)

(Signature of Person Receiving Vaccine or Parent or Guardian)

(Date Signed)

(Manufacturer & Lot)