

PREVENTION AND CONTROL OF SEASONAL INFLUENZA WITH VACCINES

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides the policy for the prevention and control of seasonal influenza through the use of influenza vaccines.

2. SUMMARY OF MAJOR CHANGES:

This amendment dated October 16, 2018 updates the following:

a. Paragraph 2. e. (1): Deleted statement regarding use of LAIV in 2017-2018 influenza season. The use of live attenuated influenza vaccine (LAIV) is an option for whom it is appropriate in the 2018-2019 season.

b. Paragraph 4. d. (2) (c) 1. and 2: Updated links for healthcare provider influenza vaccination documentation.

c. Paragraph 4. e: Updated link for VA Adverse Drug Event Reporting System (VA ADERS).

d. Paragraph 5: Updated references to include CDC, Prevention and Control of Seasonal Influenza with Vaccines Recommendations of the Advisory Committee on Immunization Practices, and deleted reference to CDC Summary Recommendations: Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP).

e. Appendix A: Updated influenza vaccines available for 2018-2019.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Assistant Deputy Under Secretary for Health for Patient Care Services (10P4), is responsible for the contents of this directive. Questions relating to this directive may be referred to the National Infectious Diseases Service at 513-246-0270.

5. RESCISSIONS: VHA Directive 2013-004, dated February 22, 2013, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of February 2020. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Executive in Charge

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VHA DIRECTIVE 1013(2)

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NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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PREVENTION AND CONTROL OF SEASONAL INFLUENZA WITH VACCINES

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy for the prevention and control of seasonal influenza through the use of influenza vaccines.

AUTHORITY: Title 38 United States Code (U.S.C.) 1701(6)(D), (9)(F), and (K), 1704, and 1712(e).

2. BACKGROUND

a. The influenza vaccination program is an essential component of the Department of Veterans Affairs (VA) health promotion and disease prevention programs. Influenza is a cause of substantial morbidity and mortality in the United States (U.S.). Influenza 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, visitors, other patients, coworkers, and to health care personnel. The Veterans Health Administration (VHA) has made influenza vaccination a priority. The influenza vaccine for seasonal influenza is a safe and cost-effective means for preventing and controlling influenza.

NOTE: *The term health care personnel (HCP) is broadly defined as all paid and unpaid persons working in healthcare settings who have the potential for exposure to infectious materials. This definition of HCP includes a range of those directly, indirectly, or not involved in patient care who have the potential for transmitting influenza to patients, other HCP, and others. Influenza vaccination rates of Veteran patients are monitored in the VA performance measurement system.*

b. Since influenza viruses are always changing, each year's influenza vaccine is formulated to protect from the influenza viruses most likely to cause disease that year. Influenza A and B are the two types of influenza viruses that cause seasonal influenza, typically during the fall or winter months. The trivalent influenza vaccine formulations contain two influenza A virus strains and one influenza B virus strain, while quadrivalent influenza vaccine formulations contain the same strains as trivalent vaccines, also contain a second B virus strain.

c. Each year the National Center for Health Promotion and Disease Prevention (NCP), VHA Office of Patient Care Services collaborates with appropriate offices and programs within VA Central Office as described in VHA Handbook 1120.05, Coordination and Development of Clinical Preventive Services, to produce and post a VHA Clinical Preventive Services Guidance Statement on Seasonal Influenza Immunization. This Guidance Statement is a clinical resource to VHA staff for the care of adult Veteran patients. It is available from the Guidance Statement home page which can be found at

http://vaww.prevention.va.gov/Guidance_on_Clinical_Preventive_Services.asp

(navigate to current year's Influenza Immunization Guidance Statement from this page).

NOTE: *This is an internal VA Web site that is not available to the public.*

d. Influenza vaccine abbreviations were revised in 2013 by the Advisory Committee on Immunization Practices (ACIP) based on the additional available vaccines. The revisions are as follows: The former abbreviation TIV (Trivalent Inactivated Influenza Vaccine, previously used for inactivated influenza vaccines) has been replaced with the abbreviation IIV (Inactivated Influenza Vaccine). IIVs as a class will include egg-based and cell culture-based trivalent inactivated influenza vaccines (IIV3) and egg-based quadrivalent inactivated influenza vaccine (IIV4). Recombinant hemagglutinin influenza vaccine (RIV) is available as a trivalent formulation (RIV3). Live-attenuated influenza vaccine (LAIV) is available as a quadrivalent formulation (LAIV4). LAIV, IIV and RIV denote vaccine categories; numeric suffix specifies the number of antigens in the vaccine. When necessary to refer specifically to cell culture-based vaccine, the prefix "cc" is used (e.g., "ccIIV3").

e. Effective November 12, 2013, all vaccines against seasonal influenza (except trivalent influenza vaccines, which are already covered) 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 (codified at 42 U.S.C. 300aa-1 to 300aa-34), 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.

(1) VISs are developed by the Centers for Disease Control and Prevention (CDC). The VIS for IIV, which covers influenza vaccines given by injection with a needle, and the VIS for LAIV are available in several languages. The VIS, in English, for IIV is available from the CDC Web site at <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.html> and the VIS, in English, for LAIV is available at <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/flulive.html>.

(2) 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 or legal representative of any adult to whom the provider intends to administer such vaccine.

(3) The materials must be supplemented with visual presentations or oral explanations, as appropriate. **NOTE:** *If the Food and Drug Administration (FDA) approves any updated licensing for any of the influenza vaccine products, any new or interim VIS need to be used as soon as available from the CDC.*

f. 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. 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.

(1) 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 electronic health record. If further clarification is needed regarding informed consent for clinical treatments and procedures, see VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, located at http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2055. **NOTE:** *This is an internal VA Web site that is not available to the public.*

(2) Documentation must show that specific education was provided, that the resident either received influenza vaccine or did not receive the vaccine, and whether a refusal was due to medical contraindications.

g. For hospital and long-term care programs, The Joint Commission has revised and expanded the elements of performance for Infection Control Standard IC.02.04.01 pertaining to influenza vaccination for independent practitioners and staff effective July 1, 2012. The standard continues to call for an annual influenza vaccination program that is offered to licensed independent practitioners; education of these individuals concerning influenza vaccine, non-vaccine control and prevention measures, diagnosis, transmission, and impact of influenza; and providing influenza vaccination at sites accessible to these individuals. The revisions and new elements of performance are:

(1) Infection control plan to include goal of improving influenza vaccination rates.

(2) Set incremental influenza vaccination goals, consistent with achieving the 90 percent rate established in the national influenza initiative for 2020 and the 90 percent target for influenza vaccination goals established in the U.S. Department of Health and Human Services Healthy People 2010 initiative.

(3) Have a written description of the methodology to determine influenza vaccination rates.

(4) Annually evaluate reasons given for declining the influenza vaccination.

(5) Improve vaccination rates toward the established 2020 goal of 90 percent at least annually.

(6) Provide influenza vaccination rate data to key stakeholders.

NOTE: *VA recognizes the importance of HCP influenza vaccination as part of a multifaceted strategy to mitigate the impact of influenza on Veterans, VA HCP, visitors, and family members, and strongly encourages VA HCP to get vaccinated for influenza.*

3. POLICY

It is Veterans Health Administration (VHA) policy to have an annual influenza vaccination program for the prevention and control of seasonal influenza. **NOTE:** Though this program is based on annual influenza vaccination recommendations of the CDC Advisory Committee on Immunization Practices (ACIP) as published in the

Morbidity and Mortality Weekly Report (MMWR), it is necessary to comply with The Joint Commission Standard IC.02.04.01 and VHA National Center for Health Promotion and Disease Prevention Guidance Statements on Clinical Preventive Services-Immunizations.

4. RESPONSIBILITIES

The VA medical facility Director is responsible for ensuring that the:

a. **Influenza Vaccination Program is Implemented.** An influenza vaccination program is implemented in accordance with this directive, applicable updates from Centers for Disease Control (CDC), and any Seasonal Influenza Vaccine Advisories from the Office of the Under Secretary for Health.

b. **Targeted Populations are Covered.** The influenza vaccination program must cover all persons aged 6 months or greater in the patient population served by the VA medical facility, and must cover Health Care Personnel (HCP) covered by the VA medical facility.

NOTE: *An annual influenza vaccination program must be developed and implemented at each VA medical facility for HCP. The definition of HCP includes a range of those directly, indirectly, or not involved in patient care who have the potential for transmitting influenza to patients, other HCP, and others.*

c. **Appropriate Influenza Vaccines are Used.** Appropriate influenza vaccines and **antiviral** medications with activity against influenza viruses are to be used for those covered by the facility's influenza vaccination program (see Appendix A).

d. **Documentation is Ensured.** Documentation requirements must be met, to **include:**

(1) **Patient Consent and Documentation.**

(a) All persons receiving influenza vaccines must receive information about the vaccine and be given a copy of the most current and appropriate Vaccine Information Statements (VIS), either the VIS for Inactivated Influenza Vaccine (IIV) or VIS for live-attenuated influenza vaccine (LAIV), prior to administration of the vaccine.

(b) The practitioner who has primary responsibility for the patient, or the person who will perform the procedure must:

Explain in a language that is understandable to the patient, or personal representative:

1. The nature of the procedure.
2. Expected benefits.
3. Reasonably foreseeable associated risks.

4. Complications or side effects.
5. Reasonable and available alternatives.
6. Anticipated results if influenza vaccine is not given.
7. Ensure the patient has no allergies to the vaccine or components of the vaccine.
8. Document the non-signature informed consent process in the electronic health record. Documentation must include all the following:
 - a. Date of administration of the vaccine.
 - b. Lot number.
 - c. Manufacturer.
 - d. Dose, route and site of vaccine administration.
 - e. Name and title of the individual administering the vaccine.
 - f. Specific CDC VIS provided, indicating the edition date of the material and the date the VIS was provided.
 - g. Type of vaccine given (e.g. inactivated influenza vaccine-trivalent, inactivated influenza vaccine-quadrivalent, live attenuated influenza vaccine, etc.).

(c) In order to obtain accurate data, it is critical that administration of influenza vaccine to patients be recorded correctly into the electronic health record. For recording the administration of influenza vaccine, use the Current Procedural Terminology (CPT) codes that are specified by CDC in their code set tables located at <http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt>.

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

(1) HCP Consent and Documentation.

(a) Any HCP who receives an influenza vaccine from VA must receive information about the vaccine (i.e., CDC's VIS). The information, explained in terms the HCP understands, is to include:

1. The nature of the procedure.
2. Expected benefit.
3. Reasonably foreseeable associated risks.
4. Complications or side effects.

5. Reasonable and available alternatives.
6. Anticipated results if influenza vaccine is not given.
7. Information for HCP regarding allergies to the vaccine or components of the vaccine.

(b) Documentation must include the:

1. Type of vaccine given (e.g. inactivated influenza vaccine-trivalent, inactivated influenza vaccine-quadrivalent, live attenuated influenza vaccine, etc.).
2. Date of administration of the vaccine.
3. Lot number and expiration date.
4. Manufacturer.
5. Dose (volume and units), route and site of vaccine administration.
6. Non-signature informed consent process.
7. Name and title of the individual administering the vaccine.
8. Specific CDC VIS provided, indicating the edition date of the material and date the VIS was provided.

(c) Occupational Health staff and other VHA staff administering the influenza vaccine on behalf of Occupational Health to VA HCP must document vaccination in the Occupational Health Record System (OHRs). Documentation and maintenance of HCP health records concerning influenza vaccine must be in accordance with:

1. VA Handbook 5019, Employee Occupational Health Services, located at https://vaww.va.gov/vapubs/viewPublication.asp?Pub_ID=874&FType=2

NOTE: This is an internal VA Web site that is not available to the public.

2. VHA Directive 7716 Occupational Health Record-Keeping System, located at https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=5466

NOTE: This is an internal VA Web site that is not available to the public. Provision of influenza vaccine to HCP will be at no expense to these individuals.

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

e. **Adverse Events are Reported.** Adverse events related to drug products and vaccines must be reported appropriately to the VA Adverse Drug Event Reporting

System (VA ADERS) at https://vaww.cmop.med.va.gov/MedSafe_Portal **NOTE:** This is an internal VA Web site that is not available to the public.

(1) All adverse events related to vaccines must be reported to the FDA and CDC Vaccine Adverse Event Reporting System (VAERS) program through VA ADERS. The Vaccine Adverse Event Report submitted in VA ADERS will then be faxed directly to the FDA and CDC from VA ADERS.

(2) An adverse event, related to voluntary participation, in an employee annual 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.

f. **Necessary Procedures are in Place if There is an Influenza Vaccine Delay or Shortage.** If an influenza vaccine delay or a shortage occurs, prioritization plans for influenza vaccine must be developed at the local facility level. Vaccination efforts are to focus on targeted groups as identified in Appendix B. If there is a continued national influenza vaccine delay or shortage, the prioritization plans developed at the local facility level may need to be altered to be in alignment with applicable CDC updates and VHA communications from the Under Secretary for Health (10), Principal Deputy Under Secretary for Health (10A), or Deputy Under Secretary for Health for Operations and Management (10N) through Influenza Vaccine Advisories.

5. REFERENCES:

a. 42 United States Code, Chapter 6A, Subchapter XIX, Part I (National Vaccine Program), and Part II (National Vaccine Injury Compensation Program), <http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf>.

b. 42 CFR part 483 (Centers for Medicare and Medicaid Services, Department of Health and Human Services, Requirements for States and Long Term Care Facilities)

c. VA Influenza Manual at <http://vaww.publichealth.va.gov/flu>. **NOTE:** This is an internal VA Web site that is not available to the public.

d. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, at http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2055. **NOTE:** This is an internal VA Web site that is not available to the public.

e. VHA Clinical Preventive Services Guidance Statements available at http://vaww.prevention.va.gov/Guidance_on_Clinical_Preventive_Services.asp. (navigate to current year's Influenza Immunization Guidance Statement from this page). **NOTE:** This is an internal VA Web site that is not available to the public.

f. CDC. "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2018–19 Influenza Season," MMWR. Vol. 67(3);1–20; August 24, 2018. <https://www.cdc.gov/mmwr/volumes/67/rr/rr6703a1.htm>

- g. CDC. "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) – United States, 2017-2018 Influenza Season," MMWR. Vol. 66(2); August 25, 2017. <https://www.cdc.gov/mmwr/volumes/66/rr/rr6602a1.htm>.
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- k. CDC. "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years and Older — United States, 2017", MMWR/February 10, 2017/66(5); 136-138. <https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e2.htm>.
- l. CDC. "General Recommendations on Immunization Recommendations of the Advisory Committee on Immunization Practices (ACIP)," MMWR. Vol. 60 RR-2; 1-64; January 28, 2011. <http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>.
- m. CDC. "Influenza Vaccination of Healthcare Personnel," MMWR. Vol. 55 RR-2; 1-16; February 24, 2006. <http://www.cdc.gov/mmwr/PDF/rr/rr5502.pdf>.
- n. CDC. "Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP)". MMWR. Vol.60 RR-1; 1-28; January 21, 2011. <http://www.cdc.gov/mmwr/pdf/rr/rr6001.pdf> or CDC Influenza Antiviral Medications Summary for Clinicians at <https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>.
- o. CDC. Inactivated Influenza Vaccine, Vaccine Information Statement at <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.html>.
- p. CDC. Live Intranasal Influenza Vaccine, Vaccine Information Statement at <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/flulive.html>.
- q. CDC. Influenza (Flu) at <http://www.cdc.gov/flu/>.

r. Public Health Information from VA. Influenza (Flu) at https://www.index.va.gov/search/va/va_search.jsp?NQ=URL%3Ahttps%3A%2F%2Fwww.publichealth.va.gov%2Findex.asp&QT=Influenza&submit.x=37&submit.y=13

s. U.S. Department of Labor, OSHA, Regulations (Title 29 Code of Federal Regulations (CFR) 1904.5(Determination of Work-relatedness,) at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9636.

**INFLUENZA VACCINE AND ANTIVIRAL MEDICATIONS WITH ACTIVITY AGAINST
SEASONAL INFLUENZA VIRUSES****1. ANNUAL INFLUENZA VACCINATION**

Annual influenza vaccination is recommended for all persons aged 6 months or older. For the 2018-19 season, quadrivalent and trivalent influenza vaccines will be available. Inactivated influenza vaccines (IIVs) will be available in trivalent (IIV3) and quadrivalent (IIV4) formulations. Recombinant influenza vaccine (RIV) will be available in trivalent (RIV3) and quadrivalent (RIV) formulations. Live attenuated influenza vaccine (LAIV) may be used for healthy, non-pregnant persons 2 years to 49 years of age. These influenza vaccines are to be given in alignment with the package inserts provided by manufacturers, Center for Disease Control and Prevention (CDC) recommendations, and any Veterans Health Administration (VHA) communications from the Under Secretary for Health pertinent to influenza vaccines for the current influenza season. **NOTE:** Information pertinent to influenza vaccines can be found in Department of Veterans Affairs (VA) Influenza Manual at <http://vawww.publichealth.va.gov/flu/>. This is an internal VA Web site that is not available to the public. Health care providers must give the most current and appropriate Vaccine Information Statements (VIS), developed by CDC, to patients, parents, legal representatives, health care personnel, and volunteers prior to administration of either vaccine.

2. INACTIVATED INFLUENZA VACCINE (IIV)

a. IIVs as a class include trivalent inactivated influenza vaccines and quadrivalent inactivated influenza vaccine. Trivalent influenza vaccine formulations contain two influenza A virus strains and one influenza B virus strain. Quadrivalent influenza vaccine formulations contain the same strains as trivalent vaccines, but also contain a second B virus strain. Each annual seasonal influenza vaccine is formulated to protect against influenza viruses most likely to cause disease during the season. 2018-2019 U.S. trivalent influenza vaccines will contain an A/Michigan/45/2015 (H1N1) pdm09–like virus, an A/Singapore/INFIMH-16-0019/2016 (H3N2)–like virus; and a B/Colorado/06/2017–like virus (Victoria lineage). Quadrivalent vaccines will contain the same three HA antigens as trivalent vaccines, plus a B/Phuket/3073/2013–like virus (Yamagata lineage).

b. For the 2018-19 annual vaccination program, there is no preference expressed for one influenza vaccine product over another for persons whom more than one licensed recommendation product is available. **NOTE:** Each influenza season there are multiple manufacturers of influenza vaccine available in the U.S. The CDC maintains a list of all currently FDA approved influenza vaccines (with brand name, type of vaccine, presentation, age indications, and presence of latex or mercury (from thimerosal) at <https://www.cdc.gov/flu/protect/vaccine/vaccines.htm>.

- c. IIV is administered annually.
- d. IIV has vaccine virus strains updated annually.
- e. IIV contains noninfectious virus (i.e., inactivated, killed).
- f. IIV is given by injection with a needle.

(1) An intradermally administered IIV preparation, Fluzone® Intradermal (Sanofi Pasteur) was licensed in May 2011. This vaccine is indicated for persons 18 years through 64 years of age and contains less antigens than intramuscular IIV preparations and is in a smaller volume. The vaccine is administered intradermally via a single-dose, prefilled microinjection syringe. **NOTE:** *The preferred site for administration is over the deltoid muscle. Currently, there is no preferential recommendation to use this vaccine as opposed to other FDA-approved inactivated vaccines for this age group.*

(2) All other IIV formulations are to be administered intramuscularly. **NOTE:** *Adults and older children need to be vaccinated in the deltoid muscle. Consideration needs to be given to using a needle length of at least 1 inch, because shorter needles may not penetrate muscle tissue in certain adults and older children. Infants and young children less than 12 months should be vaccinated in the anterolateral aspect of the thigh using a needle length of 7/8 – 1 inch.*

- g. IIV cannot cause influenza.
- h. IIV can be co-administered with influenza antivirals.
- i. IIV can be administered in the presence of minor illnesses with or without fever.

NOTE: *Influenza vaccine can be administered in this situation. This is and has been so stated in CDC recommendations for administration of influenza vaccine.*

j. IIV usage for those who have experienced Guillian-Barré Syndrome (GBS) is an issue.

(1) Whether influenza vaccination specifically might increase the risk for recurrence of GBS is unknown. However, as a precaution, persons who are not at high risk for severe influenza complications and who are known to have experienced GBS within 6 weeks of receipt of an influenza vaccine generally should not be vaccinated. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these persons.

(2) 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.

k. CDC recommendations indicate that IIV can be simultaneously administered with other vaccines; however, co-administration with other vaccines has been evaluated

systematically only among adults who received pneumococcal polysaccharide vaccine or zoster vaccine. Vaccines administered simultaneously should not be mixed together in the same syringe and different administration sites should be used.

l. Moderate or severe acute illness with or without fever is a precaution for IIV. This precaution avoids causing diagnostic confusion between manifestations of the underlying illness and possible adverse effects of superimposing adverse effects of the vaccine on the underlying illness. **NOTE:** *If there is more than minor illness, then usually people are not vaccinated until their symptoms abate. However, individuals experiencing moderate or severe illness, need to be clinically evaluated to consider what effect the potential harms of not being vaccinated and potentially becoming ill with influenza would have on the individual. Concerns that the vaccine may not be effective in the presence of moderate or severe illness depends also on what the illness is and must be evaluated in light of any potential harms of not vaccinating. Therefore, it makes administration of influenza vaccine a precaution in these individuals calling for a clinical evaluation and decision making. This is and has been so stated in CDC recommendations.*

m. While IIV can be used for any person aged 6 months or older, including those who are healthy and those with chronic medical conditions, live attenuated influenza vaccine (LAIV) currently is recommended only for healthy, non-pregnant persons aged 2 years to 49 years of age. Because of this difference, persons who should be vaccinated with IIV include:

(1) Children aged 6 months to less than 2 years of age.

(2) Persons aged 50 years and older. For the subset of persons 65 years of age or older, the FDA has approved an IIV with a higher hemagglutinin (HA) antigen concentration (Fluzone® High-Dose [Sanofi Pasteur]). Currently, there is no preferential recommendation to use this vaccine as opposed to other FDA-approved inactivated influenza vaccines for this age group. The decision to use this vaccine should be as the result of a discussion between the health care provider and vaccine recipient. For the subset of persons 50 years to 64 years of age, the newly approved intradermally administered IIV preparation can be given (it is licensed for ages 19-64); again, there is no preferential recommendation to use this vaccine as opposed to other FDA-approved vaccines used in this age group.

(3) Children and adolescents (aged 6 months to 18 years) who are receiving long-term aspirin therapy and who, therefore, might be at risk for experiencing Reye's syndrome after influenza virus infection. **NOTE:** *The goal is to keep children and adolescents who are on long term aspirin therapy from getting influenza because if they do get influenza they run the risk of developing Reye Syndrome. This is and has been so stated in CDC recommendations for administration of influenza vaccine.*

(4) Women who are pregnant during the influenza season.

(5) Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological or neuromuscular conditions, 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) Residents of Community Living Centers, nursing homes and other long-term care facilities.

(8) Family members, health care personnel, and others who have close contact with immunosuppressed persons requiring a protected environment (e.g., hematopoietic stem cell transplant recipients).

n. Persons who should not be vaccinated with IIV include:

(1) Children less than 6 months of age.

(2) Persons with a previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction. **NOTE:** *Hypersensitivity to eggs and egg proteins has been listed as a contraindication to receipt of influenza vaccine on many manufacturer's package inserts. However, several recent studies have documented safe receipt of IIV in persons with egg allergy and recent revisions of some IIV package inserts note that only a severe allergic reaction (e.g., anaphylaxis) to egg protein is a contraindication. With the exceptions of recombinant IIV and cell culture trivalent IIV, currently available influenza vaccines are prepared by propagation of virus in embryonated eggs, however only RIV is considered totally egg-free. For the 2018-2019 season CDC has provided specific, detailed guidance and additional safety precautions on the administration of influenza vaccine to individuals who have egg allergies of various levels of severity. See <https://www.cdc.gov/mmwr/volumes/67/rr/rr6703a1.htm> and <http://www.cdc.gov/flu/professionals/acip/index.htm>*

3. LIVE, ATTENUATED INFLUENZA VACCINE (LAIV)

a. LAIV may be used for healthy non-pregnant persons 2 years to 49 years of age. NOTE: Since safety or effectiveness has not been established in persons with underlying medical conditions that confer a higher risk of influenza complications, it is generally stated for use in healthy, non-pregnant persons aged 2 years to 49 years of age (use of the term healthy in this recommendation refers to persons who do not have any of the underlying medical conditions that confer high risk for severe complications). As of the 2014-2015 influenza season, there is currently one LAIV available in the U.S.: FluMist®.

b. LAIV is administered annually.

c. LAIV is updated annually with vaccine virus strains.

- d. LAIV is administered intranasally by sprayer.
- e. LAIV contains live attenuated influenza viruses that have the potential to cause mild signs or symptoms related to mild virus infection from the attenuated virus (e.g., rhinorrhea, nasal congestion, fever, or sore throat).
- f. LAIV can be administered to appropriate persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration needs to be considered until resolution of the illness, or TIV should be administered instead.
- g. If the LAIV recipient sneezes after administration, the dose should not be repeated.
- h. If influenza antiviral therapy has been taken, 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.
- i. Persons receiving antivirals within the period 2 days before to 14 days after vaccination with LAIV should be revaccinated at a later date.
- j. CDC recommendations indicate that LAIV can be simultaneously administered (on the same day) with other vaccines; however, co-administration has been evaluated systematically only among children aged 12 months to 15 months of age who received measles, mumps, and rubella or varicella vaccine. CDC further suggests that it may be prudent to space non-simultaneous vaccinations of LAIV and other live vaccines at least 4 weeks apart.
- k. As a precautionary measure, health care personnel who receive LAIV need to avoid providing care to severely immunosuppressed patients requiring a protective environment (e.g., hematopoietic stem cell transplant recipients) for 7 days after vaccination.
- l. Hospital visitors who received LAIV need to avoid contact with severely immunosuppressed persons requiring a protective environment (e.g., hematopoietic stem cell transplant recipients) for 7 days after vaccination.
- m. Medical personnel at higher risk for influenza complications (including persons with underlying medical conditions placing them at higher risk or who are likely to be at risk, including pregnant women, persons with asthma, and persons aged 50 years or older) can administer LAIV.
- n. LAIV should not be administered by severely immunosuppressed persons.
- o. LAIV is an option for vaccination of healthy, non-pregnant persons aged 2 years to 49 years, including health care personnel and other close contacts of high-risk persons.

p. A moderate or severe illness with or without fever is a precaution for use of LAIV.

q. Development of GBS within 6 weeks following a previous dose of influenza vaccine is considered to be a precaution for the use of influenza vaccines.

r. Persons who should not be vaccinated with LAIV include:

(1) Children less than 2 years of age.

(2) Persons aged 50 years or older.

(3) Persons with a previous severe allergic reaction to influenza vaccine, regardless of the component suspected for being responsible for the reaction.

(4) Persons with asthma.

(5) Adults and children who have chronic pulmonary, cardiovascular (except hypertension) renal, hepatic, neurological or neuromuscular conditions, hematological, or metabolic disorders (including diabetes mellitus).

(6) Adults and children who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus (HIV)).

(7) Children 2 years to 4 years of age whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma, or whose health record indicates a wheezing episode has occurred during the preceding 12 months.

(8) Children or adolescents aged 6 months to 18 years receiving aspirin or other salicylates (because of the association of Reye's syndrome with wild-type influenza virus infection).

(9) Pregnant women.

(10) Close contacts of immunosuppressed persons who require a protected environment.

4. RECOMBINANT INFLUENZA VACCINE (RIV)

a. As of the 2014-2015 influenza season, FluBlok® is the only RIV available for use in the U.S. RIV is manufactured without the use of eggs, and does not carry a contraindication for egg allergy.

b. RIV can be administered to persons with egg allergy of any severity who are aged 18 years and older and do not have other contraindications.

- c. RIV is administered by intramuscular injection.
- d. Moderate or severe acute illness with or without fever is a general precaution for vaccination.
- e. GBS within 6 weeks following a previous dose of influenza vaccine is considered a precaution for use of influenza vaccines.
- f. RIV is currently not licensed for use in children younger than 18 years of age.

5. ANTIVIRAL MEDICATIONS WITH ACTIVITY AGAINST INFLUENZA VIRUSES

a. Antiviral medications with activity against influenza viruses are useful adjuncts in the prevention of influenza and effective when used early in the course of illness for treatment and for chemoprophylaxis after an exposure to the influenza virus. These agents are not a substitute for vaccination, although they are critical adjuncts in preventing and controlling influenza.

b. In January 21, 2011, CDC published Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza recommendations of the Advisory Committee on Immunization Practices (ACIP) (see <http://www.cdc.gov/flu/professionals/antivirals/index.htm>) that included the following recommendations for use of antivirals for the prevention and control of influenza:

(1) Antiviral treatment is recommended as soon as possible for patients with confirmed or suspected influenza who have severe, complicated or progressive illness or who require hospitalization.

(2) Antiviral treatment is recommended as soon as possible for outpatients with confirmed or suspected influenza who are at higher risk for influenza complications on the basis of their age or underlying medical conditions; clinical judgment should be an important component of outpatient treatment decisions.

(3) Currently, recommended antiviral medications include oseltamivir and zanamivir, on the basis of the most recent data indicating that greater than 99 percent of currently circulating influenza virus strains are sensitive to these medications. Amantadine and rimantadine should not be used because of the high levels of resistance to these drugs among circulating influenza A viruses. Because antiviral resistance patterns can change over time, clinicians should monitor local antiviral resistance surveillance data.

(4) Oseltamivir may be used for treatment or chemoprophylaxis of influenza among infants less than 1 year of age when indicated.

(5) Antiviral treatment may be considered on the basis of clinical judgment for any outpatient with confirmed or suspected influenza who does not have known risk factors for severe illness if treatment can be initiated within 48 hours of illness onset

(6) Antiviral treatment is recommended as early as possible for pregnant women or women who are up to 2 weeks postpartum (including following pregnancy loss) with suspected or confirmed influenza.

DELAY OR SHORTAGE OF SEASONAL INFLUENZA VACCINE

If there is a delay or shortage of seasonal influenza vaccine, focus vaccination efforts on the following groups:

1. Children aged 6 months to 4 years of age.
2. Persons aged 50 years and older.
3. Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological or neuromuscular conditions (include any condition such as 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, and hematological or metabolic disorders (including diabetes mellitus).
4. Persons who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus).
5. Women who are or will be pregnant during the influenza season.
6. Children and adolescents (aged 6 months – 18 years of age) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection.
7. Residents of Community Living Centers, nursing homes, other long-term care facilities, and any other chronic-care facilities.
8. American Indians and Alaska Natives.
9. Persons who are morbidly obese (body-mass index of 40 or greater).
10. Health care personnel.
11. Household contacts and caregivers of children less than 5 years of age and adults aged 50 years and older, with particular emphasis on vaccinating contacts of children aged less than 6 months.
12. Household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

NOTE: *If there is a continued limited supply of seasonal influenza vaccine nationally, it may become necessary for a national tiered timing of vaccination of different groups as announced by the Centers for Disease Control and Prevention and the Under Secretary for Health.*