



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 30 2015

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER
AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER
AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER
AND RESERVE AFFAIRS)
DIRECTOR OF THE JOINT CHIEFS OF STAFF
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH
SERVICES POLICY AND OVERSIGHT)
DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR
MILITARY COMMUNITY AND FAMILY POLICY
DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Guidance for the Use of Influenza Vaccine for the 2015–2016 Influenza Season

It is Department of Defense (DoD) policy that all Active Duty and Reserve Component personnel be immunized against influenza with vaccines approved for their intended use by the U.S. Food and Drug Administration, and according to the recommendations of the Centers for Disease Control and Prevention and its Advisory Committee on Immunization Practices (ACIP). This year's influenza vaccination program will be administered in accordance with Service-specific immunization regulations, ACIP guidance, and Defense Health Agency guidance (attached) (http://www.vaccines.mil/Influenza_-_Seasonal).

For the 2015–2016 influenza season, the Department has ordered approximately 3,600,000 doses of vaccine. As in the past, delivery of the vaccine is dependent on the priorities of the manufacturers and availability of approved lots. Military Medical Treatment Facilities should expect multiple deliveries, starting in August and continuing for several months. Immunization campaigns should begin immediately upon receipt of vaccine. Commanders are responsible for establishing policies and procedures to minimize loss of vaccine and to prevent unnecessary and avoidable waste of Government resources.

We applaud the efforts of the Services and the Combatant Commands in preparing for seasonal influenza. Our goal is to exceed 90 percent immunization of military Service members by December 15, 2015. The Military Departments should begin implementation of this policy immediately.


Jonathan Woodson, M.D.

Attachment:
As stated

cc:

Assistant Secretary of Defense (Reserve Affairs)
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Director, National Capital Region Medical Directorate, DHA
Director, Defense Supply Center Philadelphia
Director of Health, Safety and Work-Life, U.S. Coast Guard
Director, Marine Corps Staff

**Defense Health Agency
2015-2016 Seasonal Influenza Vaccination Program (IVP) Guidance**

1. References.

- a. Assistant Secretary of Defense (Health Affairs) Memorandum, Subject: "Department of Defense Influenza Pandemic Preparation and Response Health Policy Guidance," 25 January 2006.
- b. National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34)
- c. Department of Defense Joint Regulation (Army Regulation 40-562, BUMEDINST 6230.15B, AFI 48-110_IP, CG COMDTINST M6230.4G), Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases, 7 October 2013.
- d. HA Policy: 08-005, Policy for Mandatory Seasonal Influenza Immunization for Civilian Health Care Personnel Who Provide Direct Patient Care in Department of Defense Military Treatment Facilities, 4 April 2008.
- e. Centers for Disease Control and Prevention, MMWR, Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 25 November 2011, 60 (RR07);1-45.

2. Purpose. To provide guidance for the Department of Defense (DoD) 2015-2016 Influenza Vaccination Program. Please disseminate this message to all military treatment facility (MTF) commanders, immunization clinics, primary care clinics that administer immunizations, public health offices, pharmacy services, ships, aid stations, medical logistics/supply sections, and primary care managers.

3. Summary. Influenza is a highly contagious disease which has the potential to significantly degrade operational readiness. The most effective strategy to prevent an influenza infection is annual vaccination.

- a. Annual influenza vaccination is mandatory for uniformed personnel, and should be obtained through the service member's assigned medical facility or contract provider.
- b. Annual influenza vaccination is mandatory for civilian healthcare personnel who provide direct patient care and highly recommended for all other hospital employees who work in DoD MTFs. See section 12 for specific requirements.
- c. Annual influenza vaccination is recommended for all persons 6 months and older.
- d. The influenza virus strains used in this year's vaccine have changed from strains used in last year's vaccine.
- e. Influenza vaccination should begin as early in the season as is possible. Begin immunizing as soon as vaccine becomes available in order to ensure early protection from influenza. Although mass immunization programs can be efficient, withholding

immunizations until there is sufficient vaccine for such a campaign leads to delays in immunization and can lead to wasted vaccine at the end of the flu season.

4. Changes in vaccine recommendations for the 2015-2016 influenza season.

- a. For healthy children aged 2 through 8 years who have no contraindications or precautions, either Live Attenuated Influenza Vaccine (LAIV) or Inactivated Influenza Vaccine (IIV) is an appropriate option. No preference is expressed for LAIV or IIV for any person aged 2 through 49 years for whom either vaccine is appropriate.
- b. The influenza vaccine dosing flow diagram for children 6 months through 8 years has been updated for this season, and can be seen in Appendix 1.

5. 2015-2016 Seasonal influenza vaccines.

- a. The 2015-2016 trivalent influenza vaccine is made from the following three virus strains:
 - i. A/California/7/2009 (H1N1)pdm09-like virus
 - ii. A/Switzerland/9715293/2013 (H3N2)-like virus
 - iii. B/Phuket/3073/2013-like virus (Yamagata lineage)
- b. The quadrivalent influenza vaccine contains the following additional strain:
 - i. B/Brisbane/60/2008-like virus (Victoria lineage)
- c. The virus strains A/Switzerland and B/Phuket, used in this year's vaccine, are new this influenza season.
- d. For a table of DOD contracted influenza vaccines for the 2015-2016 season, see Appendix 2.

6. Ordering and Distribution.

- a. For the 2015-2016 influenza season, the Services requested 3.6 million doses of vaccine.
 - i. Defense Logistics Agency-Troop Support Medical (DLA-TSM) has contracted to receive shipments of influenza vaccine by the following projected dates:

Product	28 Aug	30 Sep	30 Oct	15 Nov
Injectable (6-36 months)	10%	40%	40%	10%
Injectable	83%	17%	n/a	n/a

Product	8 Sep	6 Oct	17 Nov
Intranasal	37%	37%	26%

- ii. These dates represent vaccine shipment to DLA-TSM and do not indicate when vaccine will be delivered to the MTF or operational units. Delivery to the MTF or operational units is based on logistics allocation strategy.
 - iii. Vaccine shipping schedule is Monday/Friday to OCONUS locations and Monday/Tuesday/Wednesday to CONUS locations to ensure receipt on the receiving end. DLA-TSM does not ship on holidays or weekends and will only ship on Thursdays on a case by case basis.
- b. Ensure logistic and immunization personnel are registered for DoD Medical Materiel Quality Control Messages (MMQCs) to receive influenza vaccine updates. MMQCs may include information on the Flumist® replacement program, recalls, and destruction instructions throughout the season. Personnel who have recently migrated to Defense Enterprise Email should ensure their new address is registered to receive MMQCs. Personnel can go to the following website to register:
www.usamma.amedd.army.mil/assets/apps/nala_qaweb/nala_index.cfm
- c. Receiving facilities will ensure that logistic and immunization staffs are on hand and properly trained to receive and store vaccine upon arrival. Received vaccine quantity shall promptly be posted in facilities' requisition processing system.
- d. The following vaccine products have been licensed for use in the U.S. but have not been contracted for by the DoD for the 2015-2016 influenza season. MTFs may order these products through the DLA-TSM Direct Vendor Delivery (DVD) program, via MILSTRIP if they choose to do so.
 - i. Fluzone High-Dose®: trivalent influenza vaccine licensed for persons 65 years of age and older. (NSN-6505016433903)
 - ii. Fluzone Intradermal®: quadravalent influenza vaccine for injection in the skin of the upper arm (and not the muscle), licensed for persons 18 years through 64 years. (NSN-6505016432917)
 - iii. FluBlok®: trivalent recombinant influenza vaccine, manufactured without using eggs, is licensed for persons 18 years and older. (NSN-6505016434300)

7. Operational considerations.

- a. It is DoD policy to generally follow ACIP recommendations, consistent with requirements and guidance of the Food and Drug Administration and with consideration for the unique needs of military populations. www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html
- b. Vaccination of all military members should be completed as soon as possible after receipt of sufficient vaccine supplies. The goal for vaccination coverage is >90% of all service members immunized by 15 December 2015.
- c. Prioritization plans. In the event of a severe influenza epidemic, extreme vaccine shortage, or unforeseen distribution delays, target populations will be prioritized in accordance with the 25 January 2006, Assistant Secretary of Defense, Health Affairs memo, Department of Defense Influenza Pandemic Preparation and Response Health Policy Guidance(reference a), and current ACIP recommendations.

8. Vaccine Administration.

- a. Only appropriately trained and qualified medical personnel working within their scope of practice, upon the order of an appropriately privileged health care provider, will administer the influenza vaccine. A major component of implementation is education and training. The Defense Health Agency Immunization Healthcare Branch (DHA-IHB) provides online training for management of the influenza vaccine program to include proper vaccine screening, administration and cold chain management procedures. This online training may be incorporated into local or regional training programs and is available at: <http://www.vaccines.mil/Training>
- b. Standing order programs authorize the administration of immunizations based on approved protocols without a written physician order or referral from a primary care provider. Standing orders are intended for use by properly trained healthcare personnel working within their scope of practice as determined by their license and each Service. Examples of a standing order for the administration of the influenza vaccine be found here: www.vaccines.mil/Standing_Orders
- c. An example of an influenza vaccination competency form can be found here:
 - i. Injectable influenza vaccination competency form:
http://www.vaccines.mil/documents/1828_InjectableFluCompetency2015-16.pdf
 - ii. Intranasal influenza vaccination competency form:
http://www.vaccines.mil/documents/1827_IntranasalFluCompetency2015-16.pdf
- d. See Appendix 1 for the pediatric dosing algorithm.
- e. See Appendix 3 for contraindications to influenza vaccination.
- f. See Appendix 4 for recommendations regarding influenza vaccination of persons who report allergy to eggs.

9. Documentation.

- a. IAW reference b, proper documentation of an immunization includes: patient identification; the date the vaccine was administered; the vaccine name or code; the manufacturer and lot number; the dose administered, route and anatomic site of vaccination; the date the Vaccine Information Statement (VIS) was provided, and the VIS version date.
- b. Accurate documentation of the seasonal influenza vaccine is critical for vaccine safety. There are multiple vaccine products available and staff should verify all product names and CVX codes before documentation. CVX codes 15 (influenza, split), 16 (influenza, whole), and 111 (influenza, live, intranasal) are NOT to be used to document vaccines administered in the 2015-16 season. Current products for the 2015-16 influenza season and CVX codes are located in Appendix 1 of this document.

- c. Documentation Systems.
 - i. Documentation of vaccination for uniformed members is required in the appropriate Service Immunization Tracking System (ITS) IAW reference c.
 - ii. When documenting vaccinations in Armed Forces Longitudinal Technology Application (AHLTA), the immunization module should be used. If the vaccination is not documented in the immunization module, the information will not appear on the AHLTA 2766C and will not transfer to the medical readiness systems.
- d. Service members who receive influenza vaccinations from non-military facilities will provide immunization data to their unit's ITS point of contact for transcription no later than close of business the next duty day following vaccination. All available information to include date administered, product, manufacturer and lot number should be transcribed. Contract providers will enter into ITS directly as applicable.
- e. Service members who receive care through TRICARE-Overseas Remote programs (e.g. DAO, embassy support/security staff, etc.), will provide their record of vaccination to their servicing military medical support staff for entry into their Service electronic medical record no later than the next duty day following vaccination.
- f. Beneficiaries who receive vaccination from civilian providers should provide documentation of vaccination to their servicing MTF as soon as is practical.
- g. Entities utilizing contracted support to administer and document vaccinations are responsible for ensuring that documentation of the immunization includes all required vaccine identifier information, as outlined in section 9a.
- h. Only appropriate medical exemptions for seasonal influenza vaccine should be utilized for uniformed personnel. Exemption codes "Medical, immune" (MI), "Medical, assumed (MA)", "Medical, declined (MD)", and "Not required" (NR) are not acceptable to defer annual influenza vaccination. Due to the wide variety of influenza vaccines available each year "Medical, permanent (MP)" exemptions should expire annually and be renewed each year.

10. Vaccine Information Statement (VIS) and Vaccine Adverse Event Reporting System (VAERS).

- a. VIS and Patient Information: IAW reference b, the current CDC published influenza VIS (Inactivated/Recombinant, Injectable or Live, Intranasal), shall be provided to any individual receiving a vaccine or, in the case of children, to the child's legal representative (i.e., parents or guardians). Additionally, reasonable effort to ensure the patient or legal representative understands the material presented is expected. All VISs are available at www.cdc.gov/vaccines/hcp/vis/current-vis.html and are also available in 40 languages on the CDC partner site, www.immunize.org/vis
- b. VAERS Reporting: All vaccine-related adverse events must be reported through VAERS. Additionally, healthcare professionals should promptly report all clinically significant adverse events after vaccination of children, even if the healthcare professional is not certain the vaccine caused the event. The VAERS form is available at: <http://vaers.hhs.gov/esub/index>

11. Vaccine cold chain management.

- a. All TempTales received in influenza vaccine shipments will be returned to DLA-TSM as soon as possible after receipt. This applies both to the green-labeled refrigerated TempTales that accompany injectable shipments, and to the blue frozen TempTales enclosed with FluMist shipments. The instructions provided with shipping containers should be completely filled out and returned with each TempTale. Use the POC information on the neon orange label on the shipping container to contact DLA-TSM if paperwork is not present in the container.
 - i. No Alarm TempTales - The material is released for immediate use. Disposition is not needed from DLA - TSM, but the TempTale must be returned for audit purposes.
 - ii. Alarmed TempTales - Facility will immediately suspend use of the vaccine and place in refrigeration, return TempTale to DLA-TSM, and await disposition instructions.
 - iii. Un-started or malfunctioning TempTales - Facility will treat the shipment as alarmed.
- b. Facilities with the TempTale hardware and software should send TempTale data and information from the instruction sheet to DLA-TSM via email. Facilities without this capability will use the pre-paid/pre-addressed FedEx materials provided with shipping containers to physically return the TempTales to DLA-TSM. In all cases, if TempTales appear to be malfunctioning, they should be physically returned.
- c. Vaccine Temperature Compromise. If influenza vaccine is not stored correctly within the temperature parameters of 2° - 8°C (36° - 46°F), the vaccine may lose potency. If temperature compromise is suspected after receipt:
 - i. Vaccine should be placed immediately in a working refrigerator and marked as "DO NOT USE".
 - ii. Notify your DHA-IHB Immunization Healthcare Specialist, and complete the Potentially Compromised Vaccine/Temperature Sensitive Medical Products (TSMP) response worksheet located on the DHA-IHB website. The worksheet must be submitted online, to DLA-TSM and USAMMA-DOC, and to your local medical logistics directorate.
 - iii. Do not assume the vaccine is unusable, and do not discard potentially compromised vaccine until directed to do so by DLA-TSM and/or USAMMA-DOC. The worksheet and submission information can be accessed here: <http://vaccines.mil/documents/PC-TSMPWorksheet.pdf>
 - iv. If required by Service policy, an EXSUM for all confirmed compromises will be submitted through Service headquarters.
- d. Vaccine waste reporting and destruction.
 - i. This guidance applies to waste due to vaccine expiration only. Destruction documents are required when reporting destruction of vaccine due to expiration for the USA and USCG. USAF is required to report via the Aeromedical Services Information Management System (ASIMS) inventory module. The Army, Air Force, and Coast Guard should report the product/CVX code and number of

- expired/wasted doses at the end of the 2015-16 season to their Service POC no later than Jul 8, 2016 via the email addresses listed below.
- ii. All expired vaccine should be immediately segregated and marked as "DO NOT USE".
 - iii. POC Contact Information:
 - ARMY: usarmy.detrick.medcom-usamma.mbx.vaccines@mail.mil. Questions contact: Ms. Teresa Bess, email: teresa.e.bess.civ@mail.mil; Mr. Miguel Rivera, email: miguel.rivera13.ctr@mail.mil.
 - AIR FORCE: <https://medlog.us.af.mil/index.cfm?event=medlog.vacrepsys> Questions contact: Ms. Jan Mitchell, email: jan.mitchell@us.af.mil.
 - COAST GUARD: CAPT Daniel Hassenfang, email: daniel.l.hasenfang@uscg.mil.
 - f. Vaccine disposal procedures. Posted destruction codes and information can be found at the following web site:
<http://phc.amedd.army.mil/topics/envirohealth/wm/Pages/MIDI.aspx>.

12. Influenza Vaccination Requirements and Recommendations.

- a. Active / Reserve members: Influenza vaccination is mandatory IAW reference c.
- b. Civilian healthcare personnel (HCP): Influenza vaccination is required for all who provide direct patient care in DoD MTFs, as a condition of employment, unless there is a documented medical or religious reason not to be immunized, IAW reference d.
 - i. DHA-IHB will provide ASD(HA) with an annual report detailing DoD HCP influenza immunization compliance, IAW reference d.
 - ii. Service POCs will provide Service level HCP compliance reports to DHA-IHB NLT 1 May 2016. DHA-IHB will provide the consolidated HCP compliance report to ASD(HA) no later than 1 June 2016.
 - iii. Services may also consider offering influenza vaccine to HCP according to 2011 ACIP recommendations (Reference e). The ACIP expands upon the DoD definition of HCP, by recommending annual influenza vaccination for all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. According to the ACIP, HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Because of their contact with patients or infective material from patients, many HCP are at risk for exposure to (and possible transmission of) vaccine-preventable diseases. Employers and HCP have a shared responsibility to prevent occupationally acquired infections and avoid causing harm

to patients by taking reasonable precautions to prevent transmission of vaccine-preventable diseases.

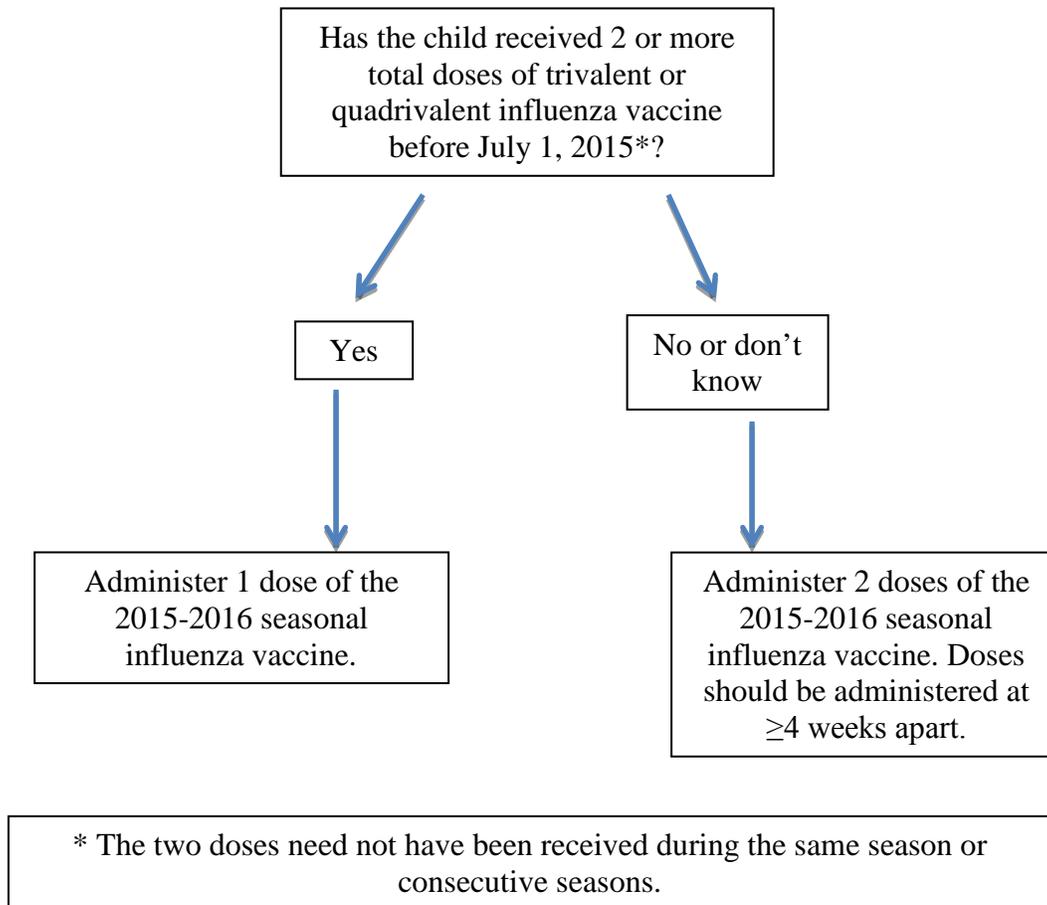
- iv. Facilities may utilize the National Healthcare Safety Network (NHSN) Surveillance for Healthcare Personnel Influenza Vaccination Module to report facility vaccination compliance through the influenza season. Information on the NHSN can be found at the following website: www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/index.html

13. TRICARE and the Federal Employee Health Benefit (FEHB) Influenza Vaccine Benefit.

- a. Active and Reserve Component personnel on full-time military status and located near an MTF should receive their vaccines through the MTF when possible.
- b. Service members who are not located on an installation with an MTF (and are considered to be geographically separated based on local determination) or those members in part time military status (Reserve or National Guard) should follow local policy for receiving their vaccination.
- c. All other beneficiaries are encouraged to receive their influenza immunization from their local MTF. However, to enhance vaccination coverage, TRICARE providers and network retail pharmacies are authorized to administer seasonal influenza vaccine at no cost to TRICARE beneficiaries.
- d. Federal employees and their families enrolled in the FEHB Program can be immunized influenza vaccine administered in pharmacies and other convenient community locations. http://vaccines.mil/documents/1839_FEHB-FluFlyer2015.pdf

14. The point of contact for this action is COL Margaret Yacovone, Chief of the Immunization Healthcare Branch of the DHA Public Health Division. COL Yacovone may be reached at margaret.a.yacovone.mil@mail.mil or 703-681-5554.

Appendix 1: Influenza vaccine dosing algorithm for children aged 6 months through 8 years - ACIP, United States, 2015–2016 influenza season.



Appendix 2: Influenza vaccines procured by DoD for 2015-2016.

Influenza Vaccines for Different Age Groups --- United States, 2015-2016 Season*

(DOD contracted vaccines are shaded in yellow)

Trade Name	Manufacturer	Presentation	Mercury (from thimerosal) µg/0.5 mL	Ovalbumin µg/0.5 mL	Latex	Age Indications	Route§	CVX
Inactivated Injectable Influenza Vaccine, trivalent (IIV3), standard dose								
<i>Contraindications*:</i> Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.								
<i>Precautions*:</i> Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.								
Afluria®	bioCSL	0.5 mL single-dose prefilled syringe	0.0	< 1	No	≥ 9 yrs***	IM	140
		5 mL multi- dose vial	24.5	< 1	No	≥ 9 yrs***	IM	141
Fluvirin®	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	≤ 1	≤ 1	Yes†	≥ 4 yrs	IM	140
		5 mL multi- dose vial	25.0	≤ 1	No	≥ 4 yrs	IM	141
Fluzone®	Sanofi Pasteur	5 mL multi- dose vial	25.0	§§	No	≥ 6 mos	IM	141
Inactivated influenza vaccine, trivalent (IIV3), high dose								
<i>Contraindications*:</i> Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.								
<i>Precautions*:</i> Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.								
Fluzone® High-Dose¶¶	Sanofi Pasteur	0.5 mL single-dose prefilled syringe	0.0	§§	No	≥ 65 yrs	IM	135
Recombinant Influenza Vaccine, trivalent (RIV3), standard dose								
<i>Contraindications*:</i> Severe allergic reaction to any vaccine component.								
<i>Precautions*:</i> Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.								

FluBlok [®]	Protein Sciences	0.5 mL single-dose vial	0.0	0.0	No	≥ 18 yrs	IM	155
Inactivated Influenza Vaccine, trivalent cell-culture-based (ccIIV3), standard dose <i>Contraindications*:</i> Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. <i>Precautions*:</i> Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.								
Flucelvax [®]	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	0.0	††	Yes [†]	≥ 18 yrs	IM	153
Inactivated Injectable Influenza Vaccine, quadrivalent (IIV4), standard dose <i>Contraindications*:</i> Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. <i>Precautions*:</i> Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.								
Fluarix [®]	GlaxoSmithKline	0.5 mL single-dose prefilled syringe	0.0	≤0.05	No	≥ 3 yrs	IM	150
FluLaval [®]	ID Biomedical Corp of Quebec (distributed by GlaxoSmithKline)	5 mL multi-dose vial	< 25.0	≤ 0.3	No	≥ 3 yrs	IM	158
Fluzone [®]	Sanofi Pasteur	0.25 mL single-dose prefilled syringe	0.0	§§	No	6-35 mos	IM	161
		0.5 mL single-dose prefilled syringe	0.0	§§	No	≥ 36 mos	IM	150
		0.5 mL single-dose vial	0.0	§§	No	≥ 36 mos	IM	150
		5 mL multi-dose vial	25.0	§§	No	≥ 6 mos	IM	158
Fluzone [®] Intradermal [¶]	Sanofi Pasteur	0.1 mL prefilled microinjection system	0.0	§§	No	18-64 yrs	ID†††	166

Live Attenuated Influenza Vaccine, quadrivalent (LAIV4)

- *Contraindications*:* Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Concomitant use of aspirin or aspirin-containing medications in children and adolescents.
- *In addition, ACIP recommends LAIV4 not be used for pregnant women, immunosuppressed persons, persons with egg allergy, and children aged 2 through 4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months.*
- *LAIV4 should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours.*
- *Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV4, or should avoid contact with such persons for 7 days after receipt.*
- *Precautions*:* Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine; asthma in persons aged 5 years and older; medical conditions which might predispose to higher risk for complications attributable to influenza.

FluMist^{®**}	MedImmune	0.2 mL single-dose prefilled intranasal sprayer	0.0	< 0.24 (per 0.2 ml)	No	2-49 yrs	IN	149
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Abbreviations: **IIV** = inactivated influenza vaccine; **IIV₃** = inactivated influenza vaccine, trivalent; **ccIIV₃** = cell culture-based inactive influenza vaccine, trivalent; **IIV₄** = inactivated influenza vaccine, quadrivalent; **RIV₃** = recombinant hemagglutinin influenza vaccine, trivalent; **LAIV₄** = live, attenuated influenza vaccine, quadrivalent.

LAIV, IIV, and RIV denote vaccine categories; numeric suffix specifies the number of influenza virus antigens contained in the vaccine.

IM = intramuscular; **ID** = Intradermal; **IN** = intranasal

* Immunization providers should check Food and Drug Administration approved prescribing information for 2015-16 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions. Package inserts for U.S. licensed vaccines are available at www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.

§ For adults and older children, the recommended site for intramuscular influenza vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Specific guidance regarding site and needle length for intramuscular administration may be found in the ACIP General Recommendations on Immunization, available at www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

§§ Available upon request from Sanofi Pasteur (1-800-822-2463 or MIS.emails@sanofipasteur.com).

¶ Quadrivalent inactivated vaccine, Intradermal: a 0.1-mL dose contains 9 µg of each vaccine antigen (36 µg total).

††† The preferred injection site is over the deltoid muscle. Fluzone Intradermal Quadrivalent is administered using the delivery system included with the vaccine

¶¶ Trivalent inactivated vaccine high-dose: a 0.5-mL dose contains 60 µg of each vaccine antigen (180 µg total).

*** Age indication per package insert is ≥ 5 years; however, ACIP recommends Afluria[®] not be used in children aged 6 months through 8 years because of increased risk of febrile reactions noted in this age group with bioCSL's 2010 Southern Hemisphere IIC3. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 - 8 years who has a medical condition that increases the child's risk for influenza complications, Afluria[®] can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria[®] before administering this vaccine. Afluria[®] may be used in persons aged ≥ 9 years.

† Syringe tip cap may contain natural rubber latex.

†† Information not included in package insert. Estimated to contain <50 femtograms (5×10^{-8} µg) of total egg protein (of which ovalbumin is a fraction) per 0.5 mL dose of Flucelvax.

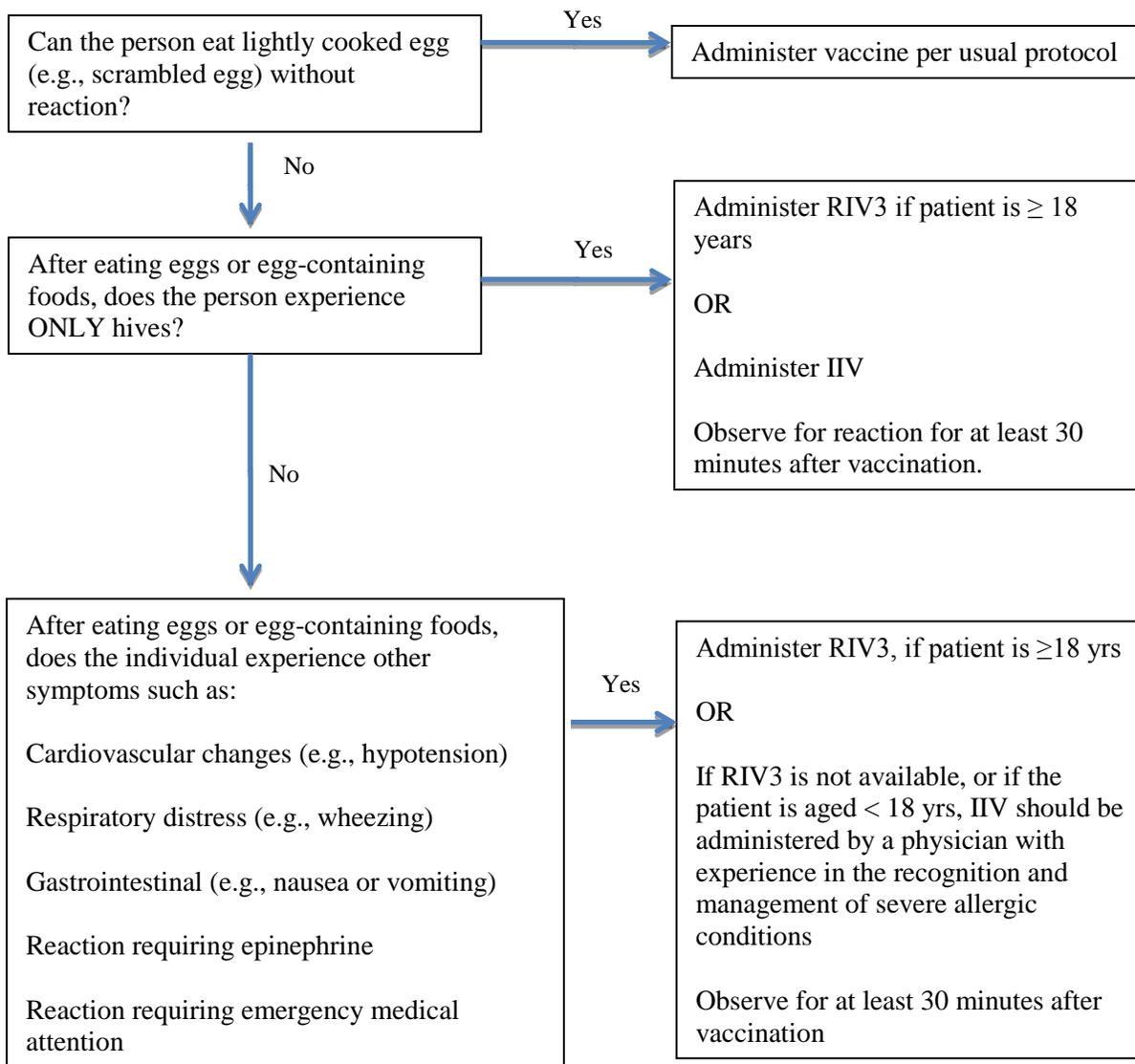
** FluMist is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health-care providers should consult the medical record, when available, to identify children aged 2-4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2-4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist.

Trivalent influenza vaccines contain three different vaccine strains: A/California/7/2009 (H1N1), A/Switzerland/9715293/2013 (H3N2), and B/Phuket/3073/2013 (B/Yamagata lineage). Quadrivalent influenza vaccines contain the same three antigens as trivalent vaccines, along with an antigen from a second influenza B vaccine virus strain B/Brisbane/60/2008 (B/Victoria lineage).

Appendix 3: Contraindications to Influenza Vaccination.

- a. Persons with an allergy to any component of influenza vaccine should not be vaccinated.
- b. People with a history of Guillain-Barre Syndrome should consult with a physician prior to receiving influenza vaccine.
- c. Persons with moderate-to-severe acute febrile illness should not be vaccinated with either IIV or LAIV until their symptoms have abated.
- d. Persons who report a history of egg allergy should be managed according to ACIP guidance which can be found here:
www.cdc.gov/mmwr/preview/mmwrhtml/mm6332a3.htm
- e. Contraindications to receiving LAIV:
 - i. Persons aged <2 years or >49 years
 - ii. Those with contraindications listed in the package insert:
 1. Children aged 2 through 17 years who are receiving aspirin or aspirin-containing products.
 2. Persons who have experienced severe allergic reactions to the vaccine or any of its components, or to a previous dose of any influenza vaccine.
 - iii. Pregnant women.
 - iv. Immunocompromised persons.
 - v. Persons with a history of egg allergy.
 - vi. Children aged 2 through 4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months. For persons aged ≥ 5 years with asthma, recommendations are described in item vii of this list
 - vii. Persons who have taken influenza antiviral medications within the previous 48 hours. Use of these medications should be avoided for 14 days after vaccination.
 - viii. In addition to the groups for whom LAIV is not recommended above, the "Warnings and Precautions" section of the LAIV package insert indicates that persons of any age with asthma might be at increased risk for wheezing after administration of LAIV. The package insert also notes that the safety of LAIV in persons with other underlying medical conditions that might predispose them to complications after wild-type influenza virus infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]), has not been established. These conditions, in addition to asthma in persons aged ≥ 5 years, should be considered precautions for the use of LAIV.
 - ix. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV, or should avoid contact with such persons for 7 days after receipt, given the theoretical risk for transmission of the live attenuated vaccine virus to close contacts.
 - x. HCP who are severely immunosuppressed should not be administering the LAIV vaccine to patients. However, LAIV may be administered by HCP who are pregnant, older than 50, or who have underlying medical conditions such as asthma.

Appendix 4: Recommendations regarding influenza vaccination of persons who report allergy to eggs*†- ACIP, United States, 2015–16 influenza season.



Abbreviations: IIV = inactivated influenza vaccine, trivalent or quadrivalent; RIV3 = recombinant influenza vaccine, trivalent.

* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

† For persons who have no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained before vaccination. Alternatively, RIV3 may be administered if the recipient is ≥ 18 years