

MODEL STANDING ORDERS – Updated December 2016

Seasonal Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV)

Update December 2016 - FluLaval: On 11-18-16, the FDA lowered the minimum age for use of FluLaval from 3 years to 6 months. FluLaval is approved as a 0.5 mL dose, including in this younger age group. This is different from Fluzone, which is approved as a 0.25 mL dose in those 6-35 months. Providers should be vigilant to ensure that patients 6-35 months receive the correct dose, depending on formulation used. See pages 2, 5 and 6. Updated language is highlighted in yellow.

These model standing orders are current as of December 2016. They should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Purpose: To reduce morbidity and mortality from influenza disease by vaccinating all children and adults as recommended by the Advisory Committee on Immunization Practices.

Procedure:

- **Assess children and adults in need of vaccination against influenza disease:**
 - Annual influenza vaccination is recommended for *everyone* 6 months of age and older.
 - Individuals who do not recall if they received influenza vaccine this season should be vaccinated.
- **Screen for contraindications and precautions to inactivated influenza vaccine**

Valid Contraindications
<p>Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any influenza vaccine or to a vaccine component, other than egg protein, see footnotes 1 and 2 for explanation.^{1,2}</p> <ul style="list-style-type: none"> • See package inserts for specific components. • Prefilled syringe tip caps of Fluvirin and Fluad might contain natural rubber latex (see package insert for latex and other specific components). • RIV does NOT contain egg protein.
Precautions
<p>Moderate to severe acute illness with or without fever. Guillain-Barré syndrome (GBS) \leq 6 weeks of receiving a dose of influenza vaccine³.</p>

¹ A severe allergic reaction to a previous dose of influenza vaccine or a vaccine component, other than egg protein is a **contraindication** to future receipt of the vaccine. See footnote #2 for evaluation and management of egg allergy.

² Although history of severe allergic reaction is a labeled contraindication to IIV, this year the ACIP currently recommends that **any** licensed influenza vaccine formulation may be administered to persons with egg allergy of **any** severity. To ensure safety, providers should follow the guidance outlined below:

- a. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. **Any** licensed and recommended influenza vaccine (i.e., any age-appropriate IIV or RIV) that is otherwise appropriate for the recipient’s age and health status may be used.
- b. Persons who report having had reactions to egg involving symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may similarly receive any licensed and recommended influenza vaccine (i.e., any age-appropriate IIV or RIV) that is otherwise appropriate for the recipient’s age and health status. The selected vaccine should be administered in an inpatient or outpatient setting (including but not necessarily limited to hospitals, clinics, and physician offices). **Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.** Clinics and practices will need to determine if they have the trained staff, protocols and equipment in place to safely vaccinate those with severe egg allergy or refer them to their medical home or another provider.
- c. A previous severe allergic reaction to influenza vaccine, regardless of vaccine component suspected of being responsible, is a contraindication to future receipt of the vaccine.
- d. The ACIP does not express a preference for the use of egg-free flu formulations in egg-allergic patients. However, an egg-free recombinant flu vaccine (RIV3), Flublok, is available for those \geq 18 years of age and some providers may choose to administer RIV3 to their severely egg-allergic patients. The cell culture vaccine, Flucelvax, has a much smaller amount of egg protein since the original virus was grown in eggs, but mass production of that vaccine does not occur in eggs. Flucelvax contains an estimated total egg protein that is less than 50 femtograms ($5 \times 10^{-8} \mu\text{g}$) total egg protein (and less ovalbumin) per 0.5 mL dose.

³ It may be prudent to avoid influenza vaccination of persons who are not at high risk of complications from influenza and who have experienced GBS within 6 weeks of a previous dose of influenza vaccine. As an alternative, consider antiviral chemoprophylaxis for these persons.

Invalid Contraindications - Okay to give inactivated influenza vaccine.

- Mild illness with or without fever
- Egg allergy of any severity (see footnotes 1 and 2 located on page 1)
- Nonanaphylactic allergy to any vaccine component
- HIV infection¹
- Pregnancy or breast feeding²
- Treatment with warfarin (Coumadin), theophylline, phenytoin, or aminophylline³
- Anticoagulation or bleeding disorder⁴

¹ Flu vaccination will benefit many HIV-infected patients, including HIV-infected pregnant women, but may not induce protective antibodies in patients with advanced disease. A 2nd dose during the same flu season *does not* improve immune response in these patients.

² Pregnant and postpartum women have an increased risk for complications from flu. No adverse fetal effects have been associated with inactivated flu vaccine. **Administer IIV in any trimester.**

³ Although flu vaccine can inhibit the clearance of warfarin, theophylline, phenytoin, and aminophylline, studies show no adverse clinical effects. High-risk patients who take these medications *should* receive flu vaccine.

⁴ Minimize the risk of bleeding after an IM injection in these patients by administering the vaccine immediately after the patient's receipt of replacement factor. Use a 23-gauge (or smaller) needle and immediately apply direct pressure to the vaccination site for ≥ 2 minutes.

• **Provide Vaccine Information Statements**

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS) available at www.immunize.org/vis. You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.

• **Determine the correct dose of influenza vaccine according to the age of the patient and formulation chosen.** See Table 1 on page 5 for *Approved Inactivated Influenza Vaccines for Different Ages*.

Inactivated influenza vaccine dosage, by age group - United States

Age Group	Vaccine (Manufacturer)	Dose	No. of Doses
6 – 35 months*	Fluzone (Sanofi)	0.25 mL	1 or 2
	FluLaval (ID Biomedical)	0.5 mL (NEW 12/2016)	
3 – 8 years	All Flu Vaccines	0.5 mL	1 or 2
≥ 9 years	All Flu Vaccines	0.5 mL	1

* Only certain formulations of Fluzone and FluLaval are approved for use in those 6-35 months. On 11-18 16, the FDA lowered the minimum age for use of FluLaval from three years old to six months old. FluLaval is approved as a 0.5 mL dose, including in this younger age group.

Note on children < 9 Years:

- For children 6 months through 8 years who are receiving influenza vaccine for the first time or who have had a total of only 1 dose of influenza vaccine in any previous seasons, administer 2 doses separated by ≥ 4 weeks. See Figure 1 on page 4 for additional guidance.
- Children 9 months through 8 years of age who have received a total of 2 doses in any season prior to July 1, 2016 need only 1 dose this season. Please note, the 2 doses need not have been received during the same season or consecutive seasons.

• **Prepare and administer vaccine.**

- Have adolescents and adults seated to prevent injury should syncope occur.
- Prepare a vaccine formulation as outlined below.
- Agitate the vial before withdrawing vaccine (or agitate the prefilled syringe in order to mix the vaccine thoroughly and obtain a uniform suspension before administering).
- If administering Fluzone Intradermal or Afluria by PharmaJet Stratis Needle-Free Injection System see package inserts and special manufacturer guidance for those products. Administer all other formulations of IIV intramuscularly (IM), according to the recommended age-specific dose and schedule. **Administer IM vaccines at a 90° angle with 22-25-gauge needle.** The needle length for IM injections depends upon the age, gender, and/or weight of the vaccine recipient (see table on next page).

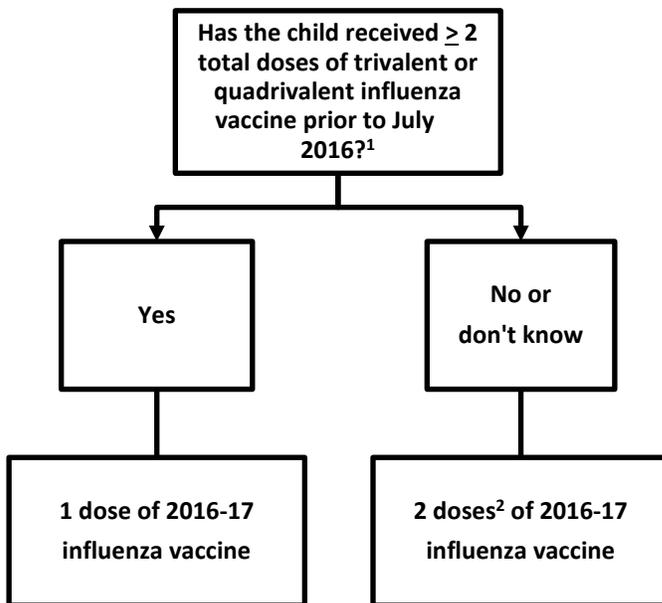
Choose the needle length and injection site according to the following chart:

Gender and Weight of Patient	Needle Length	Injection Site
6 months through 18 Years		
Infants (6-12 months)	1"	Anterolateral thigh muscle
Toddlers (1-2 years)	1-1¼"	Anterolateral thigh muscle
	⅝*-1"	Deltoid muscle of arm
Children and Teens (3-18 years)	⅝*-1"	Deltoid muscle of arm
	1-1¼"	Anterolateral thigh muscle
Adults 19 years and Older		
Female or male less than 130 lbs	⅝*-1"	Deltoid muscle of arm
Female or male 130–152 lbs	1"	
Female 153–200 lbs	1–1½"	
Male 153–260 lbs	1–1½"	
Female 200+ lbs	1½"	
Male 260+ lbs	1½"	

* A ⅝" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.

- Administer inactivated influenza vaccine simultaneously with, or any time before or after, all other live and inactivated vaccines indicated.
- If possible, observe patient for 15-20 minutes after administering vaccine.
- Schedule a follow-up appointment in ≥4 weeks for children under 9 years of age who are determined to need two doses.
- **Document Vaccination.**
Document each patient's vaccine administration information and follow up as described below.
 - **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
 - **Immunization Information System (IIS) or "registry":** Report the vaccination to the Massachusetts Immunization Information System (MIIS).
- **Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.**
Have personnel trained in CPR, signed emergency standing orders, epinephrine, and equipment for maintaining an airway available to treat anaphylactic reactions. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
See p. 12-13 of the General Recommendations on Immunization at www.cdc.gov/mmwr/pdf/rr/rr6002.pdf.
Model standing orders emergency treatment are available at www.mass.gov/eohhs/docs/dph/cdc/immunization/mso-emergency-treatment.pdf
- **Report all adverse reactions to VAERS.**
Report all vaccine adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at vaers.hhs.gov.
- **Report vaccine administration errors** (e.g., wrong route, wrong dose, and wrong age) to the Institute for Safe Medication Practices (ISMP) via the Vaccine Error Reporting Program (VERP) website <http://ismp.org>. Vaccine administration errors should also be reported to VAERS (as described above), and **MUST** be reported if they resulted in an adverse event.

Figure 1
Flu vaccine dosing algorithm for children 6 months through 8 years of age, 2016-2017*



¹ The 2 doses need not have been received during the same season or consecutive seasons.

² Doses should be administered ≥ 4 weeks apart.

Note: Children 6 months through 8 years of age who have not received a total of 2 or more doses in previous seasons as described above require 2 doses in 2016-17.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____
 name of practice or clinic

until rescinded or until _____.
 date

Medical Director's signature _____ Signature date _____ Effective date _____

Print Medical Directors Name: _____

Table 1. Approved Inactivated Influenza Vaccines for Different Ages 2016-2017^{1,2}

Vaccine	Trade Name	Manufacturer	Presentation	Mercury Content from Thimerosal (µg Hg/0.5 mL)	Age Indication	Dose	Route
IIV4 Standard Dose	Fluzone Quadrivalent	Sanofi Pasteur	0.25 mL PFS	0.0	6 - 35 mos	0.25 mL	IM
			0.5 mL PFS	0.0	≥ 3 years	0.5 mL	IM
			0.5 mL SDV	0.0	≥ 3 years	0.5 mL	IM
			5.0 mL MDV	25	6 - 35 mos	0.25 mL	IM
			≥ 3 yrs	0.5 mL			
	FluLaval Quadrivalent	ID Biomedical (distributed by GSK)	0.5 mL PFS	0	≥ 6 mos ³ <i>NEW (12/2016)</i>	0.5 mL	IM
			5.0 mL MDV	< 25.0			
	Fluarix Quadrivalent	GSK	0.5 mL PFS	0.0	≥ 3 yrs	0.5 mL	IM
Afluria Quadrivalent	Seqirus	0.5 mL PFS	0.0	≥ 18 yrs via needle	0.5 mL	IM	
Fluzone Intradermal ⁴	Sanofi Pasteur	0.1 mL prefilled microinjection	0.0	18-64 yrs	0.5 mL	ID	
IIV4 Cell Culture Based (ccIIV4) Standard Dose	Flucelvax ⁵ Quadrivalent	Seqirus	0.5 mL PFS	0.0	≥ 4 yrs	0.5 mL	IM
IIV3 Standard Dose	Fluvirin	Seqirus	0.5 mL PFS (Tip cap may contain natural rubber latex)	≤ 1	≥ 4 yrs	0.5 mL	IM
			5.0 mL MDV	25.0			
	Afluria Trivalent	Seqirus	0.5 mL PFS	0.0	≥ 9 yrs via needle ⁶	0.5 mL	IM
			5.0 mL MDV	24.5	≥ 9 yrs via 6 18-64 yrs via jet injector ⁶	0.5 mL	
Adjuvanted Trivalent Standard Dose (aIIV3)	Fluad ⁷	Seqirus	0.5 mL PFS (Tip cap contains natural rubber latex)	0.0	≥ 65 yrs	0.5 mL	IM
IIV3 High Dose	Fluzone High Dose ⁸	Sanofi Pasteur	0.5 mL PFS	0.0	≥ 65 yrs	0.5 mL	IM
Recombinant Trivalent (RIV3)	Flublok ⁹ (Does NOT contain any ovalbumin)	Protein Sciences	0.5 mL SDV	0.0	≥ 18 yrs	0.5 mL	IM

Abbreviations: IM= intramuscular; ID=intradermal; MDV = multi-dose vial; PFS = single-dose prefilled syringe; SDV = single-dose vial

(See footnotes next page.)

Footnotes:

- ¹ Check Food and Drug Administration for approved prescribing information for 2016-17 influenza vaccines for the most updated information, including (but not limited to) indications, contraindications, and precautions. Package inserts are available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>
- ² The column for ovalbumin concentration has been removed. Studies that have examined the use of both IIV and LAIV in egg-allergic and non-egg allergic patients indicate that severe allergic reactions in people with egg allergy are unlikely. Although history of severe allergic reaction to egg is a labeled contraindication to IIV and LAIV, the ACIP currently recommends that **any** licensed IIV or RIV may be administered to persons with egg allergy of **any** severity. However, persons with a history of severe egg allergy (i.e., any symptom other than hives) should be vaccinated with any licensed, recommended and age-appropriate influenza formulation in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, schools, and physician offices), under the supervision of a health care provider who is able to recognize and manage severe allergic reactions.
Please note: Flublok does **NOT** contain any egg protein (see footnote 8) and Flucelvax contains **<50 femtograms** (see footnote 4).
- ³ On 11-18-16, the FDA **lowered** the minimum age for use of FluLaval from 3 years old to 6 months old. FluLaval is approved as a **0.5 mL dose, including in this younger age group. New 12/2016**
- ⁴ Quadrivalent inactivated vaccine, intradermal: A 0.1-mL dose contains 9 µg of each vaccine antigen (36 µg total).
- ⁵ For Flucelvax this information is not included in the package insert. This cell culture vaccine has a much smaller amount of egg protein since the original virus was grown in eggs, but mass production of that vaccine does not occur in eggs. Flucelvax contains an estimated total egg protein that is less than 50 femtograms (5x10⁻⁸µg) total egg protein (and less ovalbumin) per 0.5 mL dose. (Personal communication Seqirus 8-2-16)
- ⁶ Age indication per package insert is ≥ 5 years; however, the ACIP recommends Afluria Trivalent 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 IIV3 formulation. 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 Trivalent can be used. Discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria Trivalent before administering this vaccine. Afluria Trivalent may be used in persons ≥9 years.
- ⁷ Trivalent inactivated vaccine, high-dose: A 0.5-mL dose contains 60 µg of each vaccine antigen (180 µg total).
- ⁸ Fluad is standard dose of IIV3 and contains MF-59 as an adjuvant.
- ⁹ Flublok is a recombinant vaccine that does **NOT** contain **ANY** ovalbumin.

Resources:

- CDC. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) - United States, 2016-17 Season. MMWR 2016;65:1-52.
<http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6505.pdf>
- CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases, Chapter 6 - Vaccine Administration. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington DC, Public Health Foundation, 2015.
<http://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html>
- Package inserts for all flu vaccine formulations:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>
- CDC. General Recommendations on Immunization: recommendations of the ACIP. MMWR 2011;60(RR-2):1-61.
www.cdc.gov/mmwr/PDF/rr/rr6002.pdf?source=govdelivery
- CDC. Immunization of health-care personnel: recommendations of the ACIP. MMWR 2011;60(No. 7)1-46.
<http://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf>
- IAC. Administering Vaccines: Dose, Route, Site and Needle Size, 6/16:
<http://www.immunize.org/catg.d/p3085.pdf>