

**MODEL STANDING ORDERS**

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

These model standing orders are current as of September 2017. 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.**

<b>Valid Contraindications</b>
<p><b>Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV)</b>                      Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any influenza vaccine or to a vaccine component, <b>other than</b> egg protein, see footnotes 1 and 2 for explanation.<sup>1,2</sup></p> <ul style="list-style-type: none"> <li>• <a href="#">See package inserts</a> for specific components.</li> <li>• Prefilled syringe tip caps of Fluvirin and Fluvad might contain natural rubber latex (see package insert for latex and other specific components).</li> <li>• RIV does <b>NOT</b> contain any egg protein.</li> </ul>
<b>Precautions</b>
<p>Moderate to severe acute illness with or without fever.                      Guillain-Barré syndrome (GBS) <math>\leq</math>6 weeks of receiving a dose of influenza vaccine.<sup>3</sup></p>

<sup>1</sup> 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.

<sup>2</sup> Although history of severe allergic reaction is a labeled contraindication to IIV, the ACIP recommends that **any** licensed appropriate 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 and RIV4), Flublok, is available for those  $\geq$ 18 years of age and some providers may choose to administer RIV to their severely egg-allergic patients. The cell culture vaccine, Flucelvax, has a much smaller amount of egg protein compared to egg-based IIVs since some original viruses are grown in eggs, but mass production of that vaccine does not occur in eggs. Flucelvax contains a theoretical maximum of  $5 \times 10^{-8}$   $\mu$ g per 0.5 mL dose of total egg protein.

<sup>3</sup> 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 infection<sup>1</sup>
- Pregnancy or breast feeding<sup>2</sup>
- Treatment with warfarin (Coumadin), theophylline, phenytoin, or aminophylline<sup>3</sup>
- Anticoagulation or bleeding disorder<sup>4</sup>

<sup>1</sup> 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.

<sup>2</sup> Pregnant and postpartum women have an increased risk for complications from flu. Pregnant women may receive any licensed, recommended and age appropriate **IIV or RIV** at any time during pregnancy.

<sup>3</sup> 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.

<sup>4</sup> If the patient receives antihemophilia or similar therapy, intramuscularly administered vaccinations can be scheduled shortly after such therapy is administered. A fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes. The patient or family should be given information on the risk for hematoma from the injection. Patients receiving anticoagulation therapy presumably have the same bleeding risk as patients with clotting factor disorders and should follow the same guidelines for intramuscular administration. If possible, vaccination could be scheduled prior to the use of these medications, so that the patients' risk of bleeding is not increased by their therapeutic action.

• **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](http://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](http://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 Volume	No. of Doses
6 – 35 months*	Fluzone (Sanofi)	0.25 mL <sup>1</sup>	1 or 2
	FluLaval (ID Biomedical)	0.5 mL <sup>1</sup> ( <b>NEW</b> )	
3 – 8 years	All Flu Vaccines	0.5 mL	1 or 2
≥9 years	All Flu Vaccines	0.5 mL <sup>2</sup>	1

<sup>1</sup>**Take Care to Use Correct Volume Per Dose for Young Children.** For children ages 6 through 35 months of age, two IIV products are currently licensed by the FDA. The dose volumes differ for these formulations. Children in this age group may receive either a 0.5 mL dose of FluLaval Quadrivalent, OR 0.25 mL dose of Fluzone Quadrivalent for **any** dose needed. For those children who need 2 doses this season, the 2 doses do **not** need to be the same product.

<sup>2</sup>Exception. Fluzone Intradermal Quadrivalent which is given as an 0.1 mL dose ID. See Table 1 on page 5 and the package insert for additional guidance.

**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 prior to July 1, 2017, administer 2 doses (of the **appropriate** dose volume for age and formulation, as described above) separated by ≥4 weeks. See Figure 1 on page 4 for additional guidance.
- Children 6 months through 8 years of age who have received a total of 2 doses in any season prior to July 1, 2017 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 below).

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

Gender and Weight of Patient	Needle Length	Injection Site
<b>6 months through 18 Years</b>		
Infants (6-11 months)	1”	Anterolateral thigh muscle
Toddlers (1-2 years)	1-1¼”	Anterolateral thigh muscle (preferred site)
	5/8*-1”	Deltoid muscle of arm**
Children (3-10 years)	5/8*-1”	Deltoid muscle of arm (preferred site)
	1-1¼”	Anterolateral thigh muscle
Children (11-18 years)	5/8*-1”	Deltoid muscle of arm (preferred site)
	1-1½”	Anterolateral thigh muscle
<b>Adults 19 years and Older</b>		
Female or male less than 130 lbs	5/8*-1”	Deltoid muscle of arm
Female or male 130–152 lbs	1”	
Female 152–200 lbs	1–1½”	
Male 152–260 lbs	1–1½”	
Female 200+ lbs	1½”	
Male 260+ lbs	1½”	

\* A 5/8” needle may be used in patients weighing less than 130lbs (<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.

\*\* The deltoid muscle can be used if the muscle mass is adequate.

- 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 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.**

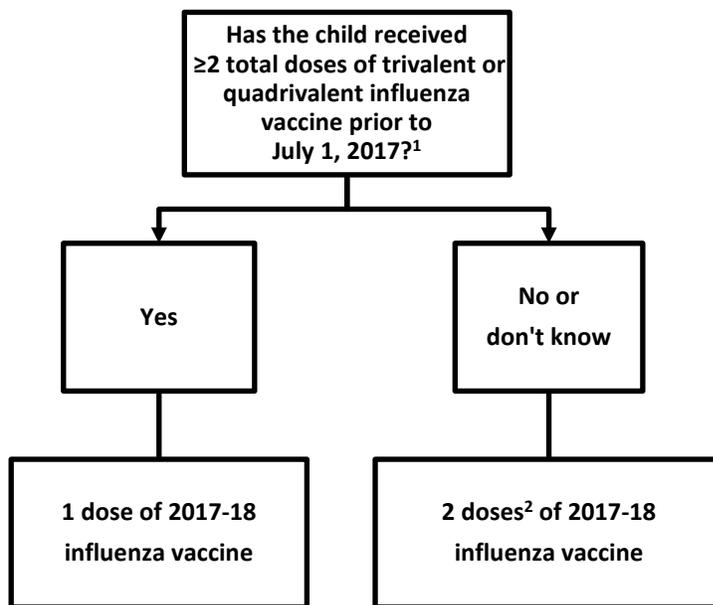
Document each patient’s vaccine administration information and follow up as described below.

- **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. We also recommend the vaccine type be recorded. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Offer the vaccine to the patient at the next visit.
- **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 page 66-81 of the General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.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](http://vaers.hhs.gov) or (800) 822-7967. To submit a VAERS form online (preferred) or to download a writable PDF form, go to [vaers.hhs.gov](http://vaers.hhs.gov). Information about the National Vaccine Injury Compensation Program and Vaccine Injury Table can be found at: <https://www.hrsa.gov/vaccinecompensation/>
- **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, 2017-2018**



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

<sup>2</sup> Doses should be administered  $\geq 4$  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 (of the appropriate dose volume for age and formulation) in 2017-18. Care should be taken to administer the correct dose.

### 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 2017-2018<sup>1,2</sup>**

Vaccine	Trade Name	Manufacturer	Presentation	Mercury Content from Thimerosal	Age Indication	Dose	Route
<b>IIV4 Standard Dose</b>	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 (µg Hg/0.5 mL)	6 - 35 mos ≥3 yrs	0.25 mL 0.5 mL	IM
	FluLaval Quadrivalent	ID Biomedical (distributed by GSK)	0.5 mL PFS	0	≥6 mos <sup>3</sup> <b>NEW</b>	0.5 mL	IM
			5.0 mL MDV	< 25.0 (µg Hg/0.5 mL)			
	Fluarix Quadrivalent	GSK	0.5 mL PFS	0.0	≥3 yrs	0.5 mL	IM
	Afluria Quadrivalent	Seqirus	0.5 mL PFS	0.0	≥5 yrs via needle <sup>4</sup> <b>NEW</b>	0.5 mL	IM
			5.0 mL MDV	24.5 (µg Hg/0.5 mL)	≥ 5 yrs via needle <sup>4</sup> <b>NEW</b> 18 - 64 yrs via jet injector <sup>4</sup>	0.5 mL	IM
	Fluzone Intradermal <sup>5</sup>	Sanofi Pasteur	0.1 mL prefilled microinjection	0.0	18 - 64 yrs	0.1 mL	ID
<b>IIV4 Cell Culture Based (ccIIV4) Standard Dose</b>	Flucelvax <sup>6</sup> Quadrivalent	Seqirus	0.5 mL PFS	0.0	≥4 yrs	0.5 mL	IM
			5.0 mL MDV <b>NEW</b>	25 (µg Hg/0.5 mL)	≥4 yrs	0.5 mL	IM
<b>IIV3 Standard Dose</b>	Fluvirin	Seqirus	0.5 mL PFS (Syringe tip cap may contain natural rubber latex)	≤1 (µg Hg/0.5 mL)	≥4 yrs	0.5 mL	IM
			5.0 mL MDV	25 (µg Hg/0.5 mL)			
	Afluria Trivalent	Seqirus	0.5 mL PFS	0.0	≥5 yrs via needle <sup>4</sup> <b>NEW</b>	0.5 mL	IM
			5.0 mL MDV	24.5 (µg Hg/0.5 mL)	≥5 yrs via needle <sup>4</sup> <b>NEW</b> 18 - 64 yrs via jet injector <sup>4</sup>	0.5 mL	
<b>Adjuvanted Trivalent Standard Dose (aIIV3)</b>	Fluad <sup>7</sup>	Seqirus	0.5 mL PFS (Syringe tip cap contains natural rubber latex)	0.0	≥65 yrs	0.5 mL	IM
<b>IIV3 High Dose</b>	Fluzone High Dose <sup>8</sup>	Sanofi Pasteur	0.5 mL PFS	0.0	≥65 yrs	0.5 mL	IM
<b>Recombinant Quadrivalent (RIV4)</b> <b>NEW</b>	Flublok <sup>9</sup> (Does NOT contain any ovalbumin)	Protein Sciences	0.5 mL PFS	0.0	≥18 yrs	0.5 mL	IM
<b>Recombinant Trivalent (RIV3)</b>	Flublok <sup>9</sup> (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:**

<sup>1</sup> Check Food and Drug Administration for approved prescribing information for 2017-18 influenza vaccines for the most updated information, including (but not limited to) indications, contraindications, and precautions. Package inserts are available at <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

<sup>2</sup> 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, age-appropriate and recommended IIV or RIV may be administered to persons with egg allergy of **any** severity. See footnote 1 on page 1 for more details.

**Please note:** Flublok does **NOT** contain any egg protein (see footnote 9) and Flucelvax contains a theoretical maximum of  $5 \times 10^{-8}$  µg per 0.5 mL dose of total egg protein (see footnote 5).

<sup>3</sup> In November 2016, 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.**

<sup>4</sup> Afluria (IIV3) and Afluria Quadrivalent (IIV4) can both now be given in persons  $\geq 5$  years via needle. Afluria was previously only recommended for persons  $\geq 9$  years. ACIP reviewed data from studies performed by the manufacturer concerning the cause of an increase in the rate of febrile seizures which occurred in association with the 2010 Southern Hemisphere formulation of this product, and resulting changes in the vaccine manufacturing process. These changes resulted in an acceptable safety profile. The ACIP recommendation for Afluria is now consistent with the approved FDA labelling for that product. In addition, Afluria Quadrivalent (IIV4), which had only been approved for use in those  $\geq 18$  years and older, is also now approved for persons  $\geq 5$  years.

<sup>5</sup> Quadrivalent inactivated vaccine, intradermal: A 0.1 mL dose contains 9 µg of each vaccine antigen (36 µg total).

<sup>6</sup> For Flucelvax, information about egg protein is not included in the package insert. For this cell culture vaccine, viruses are propagated in mammalian cells rather than eggs, so it has a much smaller amount of egg protein. However, some of the viruses provided by the manufacturer are egg-derived, and therefore egg protein may potentially be introduced at the start of the manufacturing process. Once these viruses are received by the manufacturer, no eggs are used and dilutions at various steps during the manufacturing process result in a theoretical maximum of  $5 \times 10^{-8}$  µg per 0.5 mL dose of total egg protein. (ACIP statement.)

<sup>7</sup> Fluad is standard dose of IIV3 and contains MF-59 as an adjuvant.

<sup>8</sup> Fluzone High-Dose (IIV3) contains 60 µg of each vaccine antigen (180 µg total) per 0.5 mL dose.

<sup>9</sup> Flublok (RIV) is a recombinant vaccine that does **NOT** contain **ANY** ovalbumin. It contains 45 µg of each HA antigen (135 µg total for trivalent, and 180 µg total for quadrivalent).

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**Resources:**

CDC. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) - United States, 2017-18 Season. MMWR 2017;66(RR-2):1-20.

<https://www.cdc.gov/mmwr/volumes/66/rr/pdfs/rr6602.pdf>

CDC. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization (ACIP) – United States, 2017-2018, Summary of Recommendations. Available at:

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/downloads/ACIP-recs-2017-18-summary.pdf>

Package inserts for all flu vaccine formulations:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

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>

Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)

<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf>, OR

<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

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>

Influenza Products for the 2017-2018 Influenza Season. Immunization Action Coalition.

<http://www.immunize.org/catg.d/p4072.pdf>