

Influenza Vaccination for the 2013- 2014 Season

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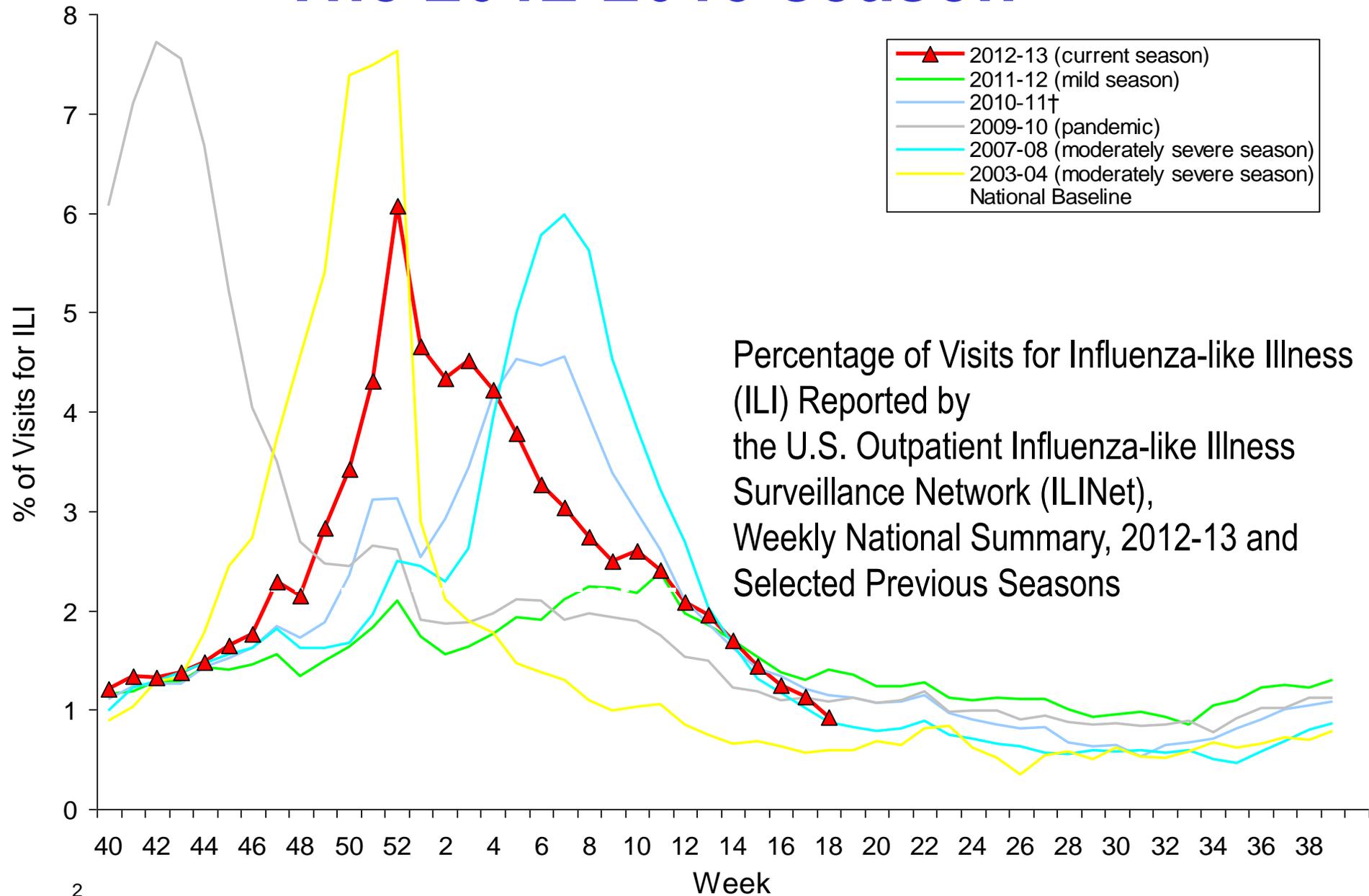
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The 2012-2013 season



Impact of the 2012-2013 season

- **158 influenza-associated pediatric deaths reported in the 2012-13 season**
 - **52% of children had influenza B infections**
 - **64% of children were 5 years of age or older**
 - **48% had a high risk condition**
 - **90% of children who died were not vaccinated**

Impact of the 2012-2013 season

- **H7N9 influenza in China**
 - **First 3 cases were reported by China on March 31**
 - **Virus is different from other H7 viruses that have infected humans**
 - **Better adapted for infecting mammals than H5N1 but not fully adapted**
 - **Poultry believed to be the source of human infections**
 - **Low pathogenicity in poultry**
 - **All eyes on fall 2013...**

ACIP recommendations

- **RIV recommended for vaccination of persons 18 through 49 years of age with egg allergy of any severity**
 - individuals with a severe egg allergy consult with a physician about their allergic conditions prior to vaccination if RIV3 is not available
- **For individuals 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 prior to vaccination**

Can the individual eat lightly cooked egg (e.g., scrambled egg) without reaction?*†

Yes

Administer vaccine per usual protocol

No

After eating eggs or egg-containing foods, does the individual experience ONLY hives?

Yes

Administer RIV, if patient aged 18 through 49 yrs.;

OR

Administer IIV

Observe for reaction for at least 30 minutes following vaccination

No

After eating eggs of egg-containing foods, does the individual experience other symptoms such as:

- Cardiovascular changes (e.g., hypotension)
- Respiratory distress (e.g., wheezing)
- Gastrointestinal (e.g., nausea/vomiting)
- Reaction requiring epinephrine
- Reaction requiring emergency medical attention

Yes

Administer RIV, if patient aged 18 through 49 yrs.;

OR

Refer to a physician with expertise in management of allergic conditions for further evaluation

Algorithm for those with egg allergies

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immunize.org

Has the child ever received influenza vaccine?

No/Don't know

2 doses

Yes

Did the child receive a total of 2 or more doses of seasonal influenza vaccine since July 1, 2010?

No/Don't know

2 doses

Yes

1 dose

Pediatric Algorithm

ACIP recommendations

- **Other New items:**
 - New abbreviations (IIV [3 or 4]; RIV; cclIV)
 - Four new vaccine products available for 2013-14
 - RIV3; cclIV3; LAIV4; IIV4
 - No preferential recommendations otherwise
- **Some questions to consider:**
 - Preferential use for:
 - Elderly – Fluzone HD®??
 - Those with egg allergies – Flucelvax®??
 - Children – Better Efficacy – LAIV??
 - Those who fear needles – LAIV or Fluzone ID®??
 - When do we start vaccinating?
 - Is waning immunity through season truly a problem?

Latest Estimates of Vaccine Coverage

- **54.9% of children vaccinated**
- **35.1% of adults vaccinated**
- **Health-Care Personnel**
 - **70.5 % vaccinated**
 - **Long-term care facilities had lower coverage than other facility types**
 - **Non-pharmacist/non-physician/non-nurse had lower coverage than other occupations**
- **Pregnant Women**
 - **53% vaccinated**
 - **Majority vaccinated during pregnancy**
- **Results are preliminary**
 - **Final 2012-13 season results available in fall 2013**

Things of focus for the next season

- **Increase influenza vaccination coverage rates among all individuals \geq 6 months.**
 - Among adults in certain racial and ethnic groups.
 - Among health-care personnel, especially those working in long-term care facilities and non-pharmacist/physician/nurses.
 - Among pregnant women by recommending and offering vaccine
- **Implement strategies to increase vaccination coverage in upcoming influenza seasons.**
 - Enhancing Access to Vaccination Services
 - Increasing Community Demand for Vaccinations
 - Provider- or System-Based Interventions
 - Community-Based Interventions Implemented in Combination

Latest Vaccine Efficacy data (CDC)

- **Adjusted VE against influenza A and B was 53% (47-58%)**
 - Similar to early unadjusted VE of 62% (51-71%) and mid-season adjusted VE of was 56% (47-63%) against A and B
 - Similar to international interim VE estimates
- **Vaccination reduced the risk of outpatient medical visits:**
 - Due to influenza A(H3N2) by half (45%); exceptions for aged 9-17 and 65+ years
 - Due to influenza B by two-thirds (63%); consistent for all ages
- **Similar VE against vaccine lineage B (Yamagata) and excluded B (Victoria)**
 - Need further research to confirm and understand age differences
 - Need better understanding of cross-protection

Influenza Vaccine for 2013-2014 Season

- **New Formulation**
 - Introduction of IIV4 (Inactivated Influenza Vaccine – quadrivalent)
 - Vs. IIV3 (Inactivated Influenza Vaccine – trivalent)
- **New technology**
 - First cell culture based vaccine in the US (ccIIV)
 - Flucelvax®
 - First recombinant vaccine in the US (RIV)
 - Flublok®

2013-2014 Influenza Vaccine Strains

- **A/California/7/2009 (H1N1)-like virus**
- **H3N2 virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011**
- **B/Massachusetts/2/2012-like virus**

Quadrivalent influenza vaccines should contain the above three strains and the following additional B strain:

- **B/Brisbane/60/2008-like virus**

New Influenza Vaccine Formulation - Quadrivalent

- **Contains 2 influenza A and 2 influenza B strains**
 - Currently approved from MedImmune, GSK, and Sanofipasteur.
- **Addresses the 50% possibility of a mismatch for the B strain each season**
- **IIV4 and LAIV quadrivalent likely to have some premium pricing**
- **No visibility as to how many doses are available**
 - GSK and sanofi will have both IIV3 and IIV4 on the market simultaneously
 - All LAIV will be quadrivalent
 - No preferential use recommendation

New Influenza Vaccine Technology – Cell Culture Vaccine

- **Flucelvax® from Novartis Vaccines**
 - trivalent
 - Uses cultured animal mammalian cells instead of chicken eggs to grow vaccine virus
 - The production process may *not* be totally egg free but rather "functionally" egg free
 - No guidance on use in those with egg allergies
 - Side effects similar to IIV3
 - FDA approved for adults 18 years and older
- **CPT Code: 90661**

New Influenza Vaccine Technology – Cell Culture Vaccine

- **Flucelvax® from Novartis Vaccines (CMS payment)**
 - Prior to FDA approval, CPT code 90661 was not payable by CMS
 - With FDA approval of Flucelvax®, CMS is revising the ASC payment indicator for CPT code 90661 from “Y5” to “L1” (Influenza vaccine; pneumococcal vaccine. Packaged item/service; no separate payment made.) effective November 20, 2012.
 - CMS can now pay for Flucelvax®.

New Influenza Vaccine Technology – Recombinant DNA

- **Flublok® from Protein Sciences**
 - **trivalent**
 - **HA DNA sequence produced by recombinant technology and expressed in baculovirus that infects an insect cell line.**
 - **Totally egg-free process**
 - **ACIP recommends use in those with severe egg allergies**
 - **Side effects similar to IIV3; no latex in vial stoppers**
 - **FDA approved for adults 18 – 49**
 - **16 week shelf life**
 - **CPT code: 90673**

Other Influenza Vaccines

- **Fluzone ID®**
 - Novel microinjection system for intradermal delivery
 - Ultra-fine needle that is 90% shorter than the typical needle
 - Licensed for use in adults 18-64 years of age
 - Contains 9 mcg of influenza virus hemagglutinin for each strain
 - Similar safety profile as TIV, erythema most common complaint
 - CPT code: 90654
 - CMS payment: \$18.981 (2012)

Other Influenza Vaccines

- **Fluzone HD®**

- Contains 4 times the amount of antigen - 60 mcg of influenza virus hemagglutinin for each strain
- Indicated for 65 and older; most common complaint is injection site pain and erythema
- Medicare covers this higher dose formulation
 - CPT code: 90662
 - Payment Rate: \$\$30.923 (2012)
- FDA approval based on serological data; effectiveness studies ongoing. Data collection hindered by past few “mild” flu seasons

Q codes (Medicare only)

- **Q2033: Influenza Vaccine, Recombinant Hemagglutinin Antigens, For Intramuscular Use (Flublok).**
- **Q2034: Influenza virus vaccine, split virus, for intramuscular use (Agriflu)**
- **Q2035: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Afluria)**
- **Q2036: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Flulaval)**
- **Q2037: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Fluvirin)**
- **Q2038: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Fluzone)**
- **Q2039: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Not Otherwise Specified)**

Influenza Vaccines 2013-2014

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

Manufacturer	Trade Name (vaccine abbreviation) ¹	How Supplied	Mercury Content (µg Hg/0.5mL)	Age Group	Product Code
CSL Limited	Afluria (IIV3)	0.5 mL (single-dose syringe)	0	9 years & older ²	90656
		5.0 mL (multi-dose vial)	24.5		90658 Q2035 (Medicare)
GlaxoSmithKline	Fluarix (IIV3)	0.5 mL (single-dose syringe)	0	3 years & older	90656
	Fluarix (IIV4)	0.5 mL (single-dose syringe)	0	3 years & older	90686
ID Biomedical Corp. of Quebec, a subsidiary of GlaxoSmithKline	FluLaval (IIV3)	5.0 mL (multi-dose vial)	<25	18 years & older	90658 Q2036 (Medicare)
MedImmune	FluMist (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	90672
Novartis	Fluvirin (IIV3)	0.5 mL (single-dose syringe)	≤1	4 years & older	90656
		5.0 mL (multi-dose vial)	25		90658 Q2037 (Medicare)
	Flucelvax (ccIIV3)	0.5 mL (single-dose syringe)	0	18 years & older	90661
Protein Sciences Corp.	Flublok (RIV3)	0.5 mL (single-dose vial)	0	18 through 49 years	90673 Q2033 (Medicare)
sanofi pasteur	Fluzone (IIV3)	0.25 mL (single-dose syringe)	0	6 through 35 months	90655
		0.5 mL (single-dose syringe)	0	3 years & older	90656
		0.5 mL (single-dose vial)	0	3 years & older	90656
		5.0 mL (multi-dose vial)	25	6 through 35 months	90657
		5.0 mL (multi-dose vial)	25	3 years & older	90658 Q2038 (Medicare)
	Fluzone (IIV4)	0.25 mL (single-dose syringe)	0	6 through 35 months	90685
		0.5 mL (single-dose syringe)	0	3 years & older	90686
		0.5 mL (single-dose vial)	0	3 years & older	90686
	Fluzone High-Dose (IIV3)	0.5 mL (single-dose syringe)	0	65 years & older	90662
	Fluzone Intradermal (IIV3)	0.1 mL (single-dose microinjection system)	0	18 through 64 years	90654

Manufacturer Production Estimates

- **Sanofipasteur**
 - Anticipates delivering same number of doses of IIV3 (in multiple formulations) as previous season (60M doses)
- **Protein Sciences**
 - Anticipate delivering 250,000 doses of RIV3
- **Novartis Vaccines**
 - Anticipate delivering 30M doses of IIV3 and cclIV3
- **Merck Vaccines**
 - Anticipates delivering 10M doses of IIV3
 - CSL Biotherapies will resume distribution of Afluria® in the United States for the 2014–2015 season by initiating the prebooking of the vaccine late 2013
- **MedImmune**
 - Anticipates delivering 12 - 15M doses of LAIV4 (no LAIV3 in market)
- **GSK Vaccines**
 - Anticipates delivering 22 - 24M doses, with up to 10M doses of IIV4

Web-based Vaccine Locator

- **Second year for the web-based Influenza Vaccine Locator!**
 - Powered by HealthMap from Harvard University
 - Search by address, zip, city/state, or pharmacy name
 - Results display in order of proximity from search criteria
 - Advanced search- 5-50 mile radius
- **Also includes all adult vaccines!**

Web-based Vaccine Locator

- **700+ provider accounts registered with 65,000+ locations**
 - More than 20,000 have already included information on all adult vaccines
- **Simple provider registration process – batch upload or manual entry (for small sized providers)**
- **Physician practices are welcome to sign up**
- **Go to: flushot.healthmap.org**

Continuing issue of attention for providers

- **Complementary providers and partners have increasing interest and role in influenza immunization**
 - Includes pharmacy, community immunizers, occupational health immunizers, and obstetrical providers
 - Pharmacy business model does not want to intrude on the pediatric medical home
 - Anytime, anywhere concept may be reducing some of market share for traditional appointment-based vaccination clinics
 - Anecdotally, large marketing campaigns by retail pharmacies appeared to have driven increased vaccination in physician offices
 - Involve more partners to further help communications among diverse provider types
 - Opportunity to bring together disparate providers to iron out differences of opinion

Continuing influenza messaging...

- **Key communication messages will continue**
 - **Continue to focus on tailoring message to specific target populations**
 - Pregnant women
 - Healthcare professionals
 - Adults over 65 years of age
 - Adults with chronic conditions
- **NIVW announced: December 8 -14, 2013**

Continuing influenza messaging...

- We have routine universal recommendation – that part is simple
- But now, we have multiple vaccine types that are indicated for different populations! Will need to have clear and unified guidance and messaging. Eg.
 - Should IIV4 be preferred over IIV3?
 - What about Fluzone HD®?
 - Should cclIV (less than 50 femtograms of ovalbumin) be used for those with confirmed severe egg allergies?
- And questions about efficacy and duration abound
- And where will we will with regard to H7N9?

- **IAC Influenza Resources:**
www.immunize.org/influenza/
- **Summit Web site:**
www.preventinfluenza.org
- **Thank You for your kind attention!**
- **Any questions?**

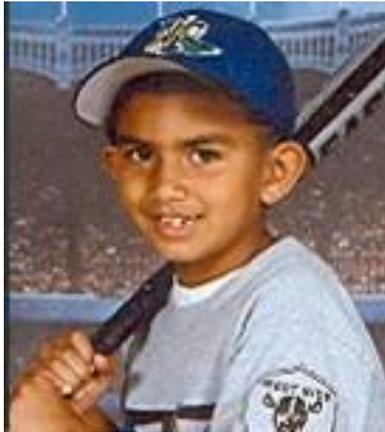


Amanda, died at age 4½ yrs from influenza

Why do we immunize against influenza?



Breanne, died at age 15 mos from influenza complications



Lucio, died at age 8 yrs from influenza complications



Alana, died at age 5½ yrs from influenza



Barry, a veteran fire-fighter, died at age 44 yrs from influenza

Slide Courtesy of Families Fighting Flu