

Influenza Vaccination for the 2013- 2014 Season

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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; Sanofi has application under FDA review.
- 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 (pending approval) 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
 - No guidance on use in those with egg allergies
 - Side effects similar to IIV3; no latex in vial stoppers
 - FDA approved for adults 18 – 49
 - 16 week shelf life
 - CPT code pending

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

Influenza Vaccines 2013-2014

Table 2: Influenza Vaccines
General Recommendations on Immunization from ACIP - cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

Vaccine	Manufacturer	Comments	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
Influenza vaccines	several	n/a	See recommendations below	varies	AAP: pediatrics.aappublications.org/content/130/4/780.full CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm CDC Seasonal: cdc.gov/flu Red Book Online Influenza Resource Page: aapredbook.org/flu
Vaccine – Inactive Trivalent	Manufacturer	Comments	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
Influenza – IIV3 (Agrimiflu®)	Novartis	IM	Greater than or equal to 18 years of age	2009	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV3 (Afluria®)	CSL Biotherapies	IM	Greater than or equal to 5 years of age	Aug 2010	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV3 (Fluarix®)	GlaxoSmithKline (GSK)	IM	Greater than or equal to 3 years of age	Aug 2005 (≥18 yr) Oct 2009 (3-17 yr)	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV3 (FluBlok®)	Protein Sciences Corporation	IM, Novel recombinant expression vector (baculovirus)	18 through 49 years of age	Jan 2013	
Influenza – IIV3 (Flucelvax®)	Novartis	IM, Cell culture derived	Greater than or equal to 18 years of age	Nov 2012	
Influenza – IIV3 (FluLaval®)	ID Biomedical Corp. of Québec	IM	Greater than or equal to 18 years of age	Oct 2006	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV3 (Fluvirin®)	Novartis	IM	Greater than or equal to 4 years of age	2012	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV3 (Fluzone®)	Sanofi Pasteur	IM	6 months of age and older	1980	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV3 (Fluzone® High-Dose)	Sanofi Pasteur	IM, High dose	65 years of age and older	Dec 2009	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV3 (Fluzone® Intradermal)	Sanofi Pasteur	Intradermal	18 through 64 years of age	May 2011	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Vaccine – Inactive Quadrivalent (IM)	Manufacturer	Comments	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
Influenza – IIV4 (Fluarix®)	GlaxoSmithKline (GSK)	IM, QIV; includes 2 B strains	Greater than or equal to 3 years of age	Dec 2012	CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – IIV4 (FluLaval®)	ID Biomedical Corp. of Québec	IM, QIV; includes 2 B strains	Greater than or equal to 18 years of age	To be reviewed	Pending licensure
Influenza – IIV4 (Fluzone®)	Sanofi Pasteur	IM, QIV; includes 2 B strains	6 months of age and older	To be reviewed	Pending licensure
Vaccine – Live Attenuated (Nasal)	Manufacturer	Comments	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
Influenza – LAIV-Trivalent (FluMist®)	MedImmune	Nasal, 2012-2013 season only	24 months through 49 years of age	2003	CDC 2012-13: cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm
Influenza – LAIV-Quadrivalent (FluMist® Quadrivalent)	MedImmune	Nasal, 2013-2014 season; includes 2 B strains	24 months through 49 years of age	Feb 2012	

ACIP Influenza Recommendations for 2013 – 2014 season

- Unlikely to be different since we have a universal recommendation
- Questions to consider:
 - Preferential use for:
 - Elderly – Fluzone HD®??
 - Those with egg allergies – Flucelvax® or Flublok®??
 - 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?

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
- Vaccine manufacturers will provide first estimates of production at the National Adult and Influenza Immunization Summit
 - Hyatt Regency Atlanta, May 14-16, 2013
- 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 and/or RIV be preferred for those with confirmed severe egg allergies?
- And questions about efficacy and duration abound
- And where will we will with regard to H7N9?



- Thank You!

- Summit Web site:
www.preventinfluenza.org



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