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webinar series

What's New with Flu in 2014-2015

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Summit
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Disclosures

- I have received honoraria from Baxter, Pfizer, Merck, Novartis, Temptime Corp., TruMedSystems, and Sanofi Pasteur for service as a scientific consultant.
 - My honoraria is donated to the IAC
- I do NOT intend to discuss an unapproved or investigative use of a commercial product/device in my presentation.



Disclaimer

The opinions expressed in this presentation are solely those of the presenter and do not necessarily represent the official positions of the Immunization Action Coalition, or the United States Adult and Influenza Immunization Summit

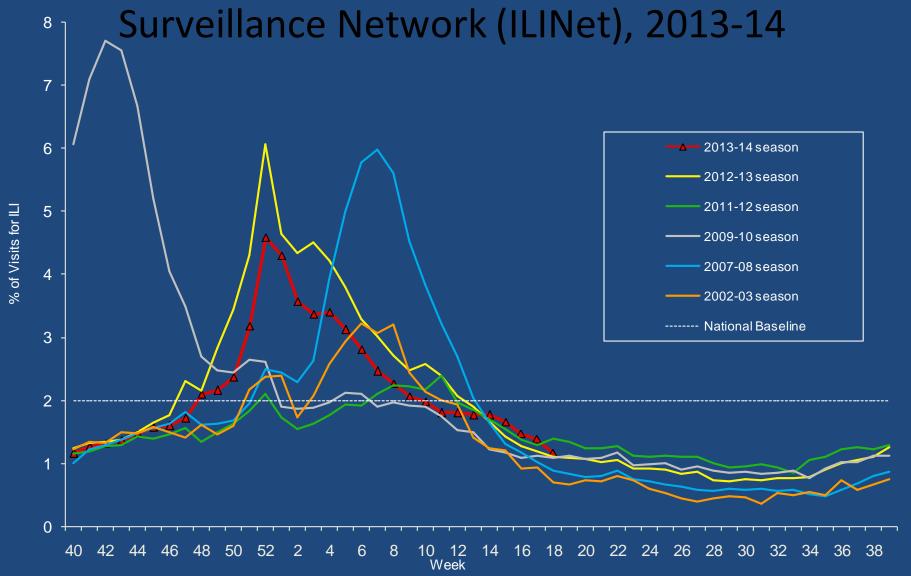


Outline

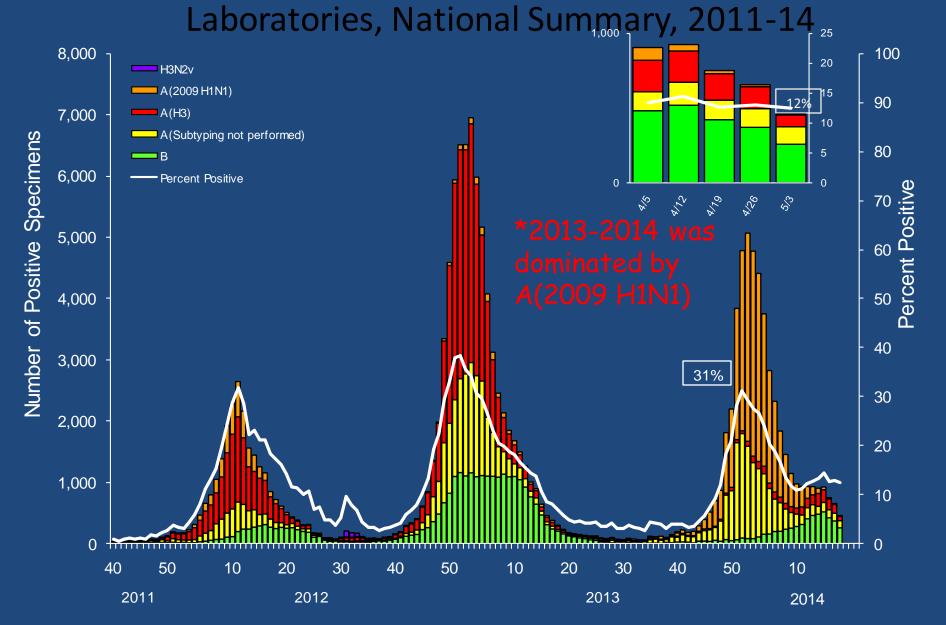
- Explain the impact of influenza in the US
- Review 2013-2014 influenza season activity and vaccination coverage rates
- Discuss the importance of annual influenza immunization
- Describe influenza recommendations and vaccines available for 2014-2014 influenza season



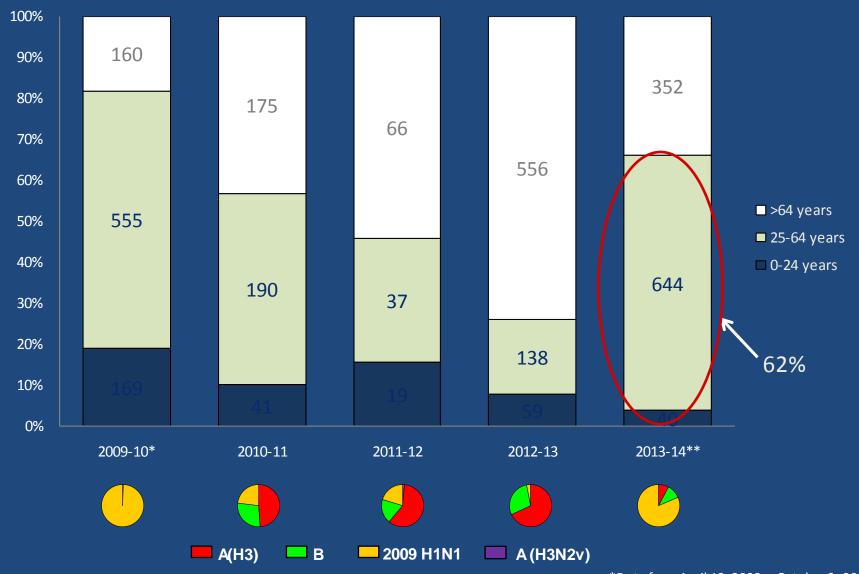
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness



U.S. World Health Organization and National Respiratory and Enteric Virus Surveillance System Collaborating



Deaths with Influenza as Underlying or Contributing cause by Age Group



^{*}Data from April 12, 2009 – October 2, 2010

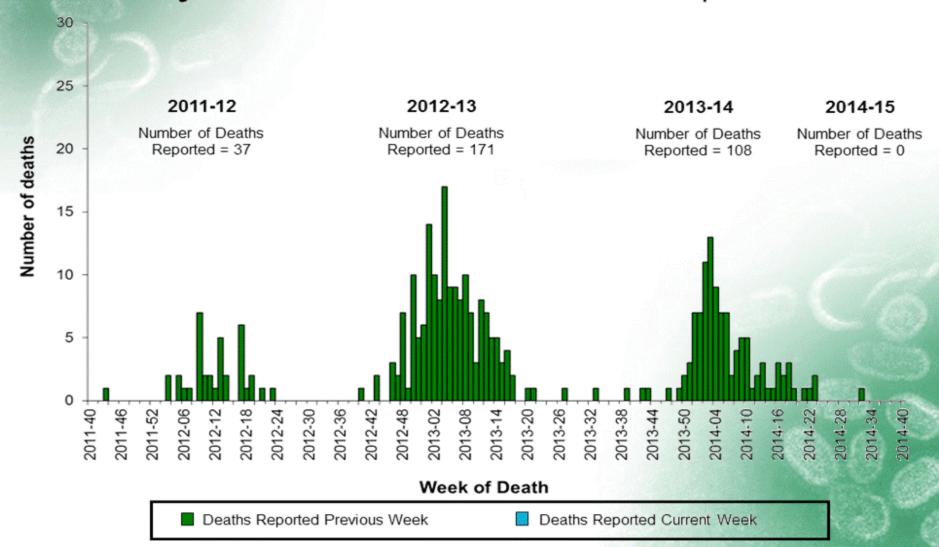
^{**}Data through May 3, 2014

FLUVIEW

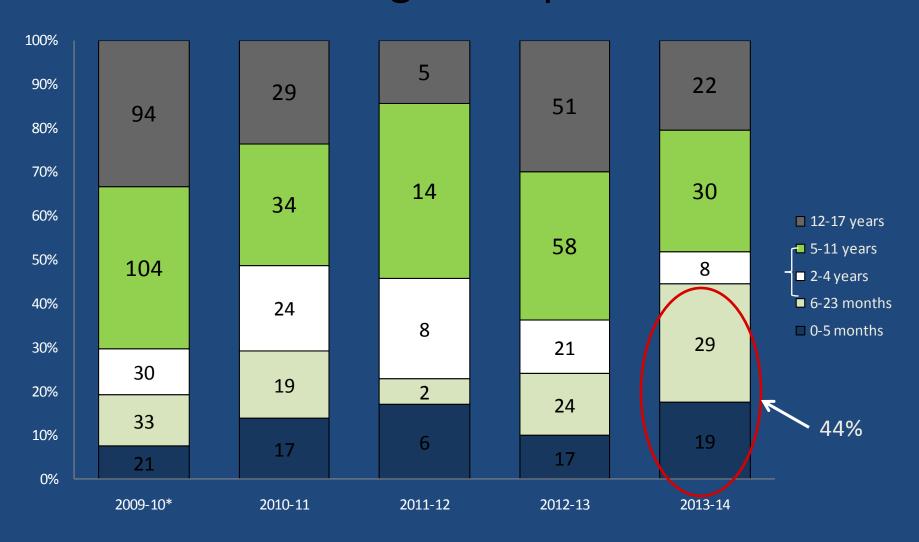


A Weekly Influenza Surveillance Report Prepared by the Influenza Division

Number of Influenza-Associated Pediatric Deaths by Week of Death: 2011-12 season to present



Influenza-Associated Pediatric Deaths by Age Group



Summary of Influenza Activity 2013-2014

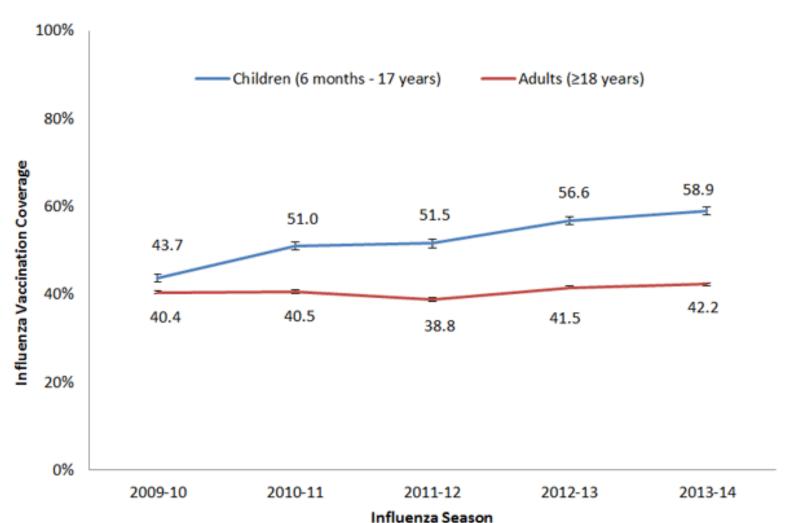
- Influenza activity began approximately 4 weeks earlier than usual, and disease was considered tp be moderate
 - Activity peaked in late December/early January
 - •2009 H1N1 viruses predominated through the peak of the season
 - A late season increase in influenza B activity occurred
- First season where A(2009 H1N1) predominated since the 2009 pandemic



Summary of Influenza Activity 2013-2014 (cont.)

- The high rate of hospitalizations and deaths among young adults is not common in most seasons
 - This age group had lower attack rates during the A(2009H1N1) pandemic (compared to their younger counterparts) and may have less cross protective immunity
 - This age group had the lowest vaccination coverage rates for this and past seasons
- Hospitalization rates were still the highest among those ≥65 years
 - Despite some partial protection from previous exposures to similar viruses
 - Elderly are at increased risk of complications due to frailty, waning immune systems, and the presence of underlying chronic medical conditions

Figure 1. Seasonal Flu Vaccination Coverage, by Age Group and Season, United States, 2009-2014



Error bars represent 95% confidence intervals around the estimates.

The 2009-10 estimates do not include the influenza A (H1N1) pdm09 monovalent vaccine.

Starting with the 2011-12 season, adult estimates reflect changes in BRFSS survey methods: the addition of cellular telephone samples and a new weighting method.



2013-2014 Influenza Vaccination Coverage

- 46.2% of those 6 months of age and higher vaccinated (cf. 45% previous year)
 - 58.9 % of children 6 months through 17 years of age vaccinated through February (cf. 54.7% previous year)
 - 42.2% of adults 18 years of age and above vaccinated through February (cf. 41.5% previous year)
 - 46.3% of adults 18-64 years of age with at least one high-risk medical condition vaccinated (cf. 45.4% previous year)
- Health-Care Personnel (cf. 72.0% previous year)
 - -75.2% vaccinated!
 - Long-term care facilities had lower coverage (63%) than other facility types
 - Coverage highest among pharmacists (89.9%) & physicians (84.3%), followed by nurses (79.3%), and NPs/PAs (77.8%).
 - Flu vaccination coverage was where employers required (88.8%) or recommended (70.1%) it cf. facilities with no employer policy regarding flu vaccination (44.3%)
- Pregnant Women (HP 2020 goal of 80%)
 - 52.2% vaccinated through January 2014 (cf. 50.5% previous year)



Some coverage thoughts

- For adults overall, flu vaccination coverage increased only slightly for the 2013-14 season
- Influenza vaccination coverage appears to still be well below HP2020 targets
 - Significant disparities exist in the non-Hispanic, black and Hispanic adult populations
- Need to continue to implement strategies to improve coverage
 - Improve use of evidence-based practices at medical sites to increase access to vaccination services
 - Expand access through use of non-traditional settings
 - Utilize IISs to guide vaccination decisions

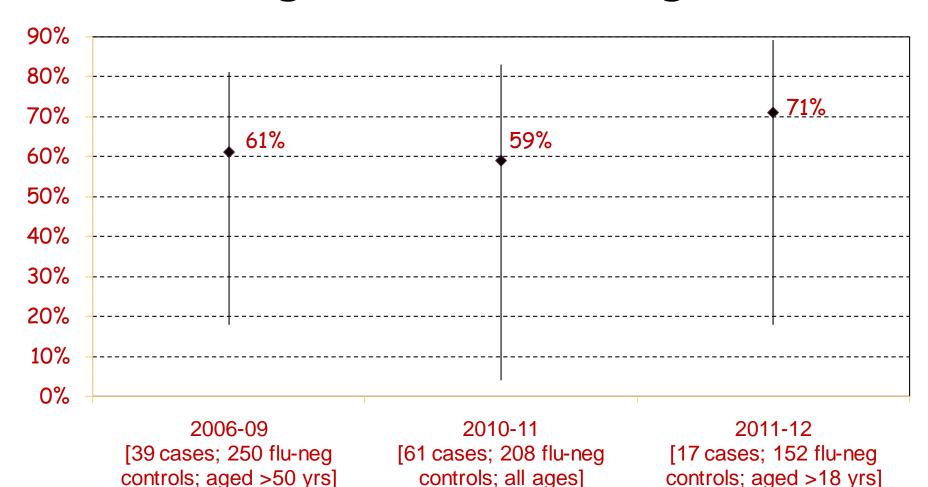


Interim adjusted VE estimates for ≥1 dose of 2013-14 seasonal influenza vaccine

	_		_			
	Flu pos	% vaccinated	Flu neg	% vaccinated	Adjusted VE	(95% CI)
Influenza A and B						
All ages	784	29%	1535	50%	61%	(52 to 68)
Age group (yrs)						
6 mos-17	172	24%	528	48%	67%	(51 to 78)
18–49	360	21%	536	38%	60%	(44 to 71)
50–64	195	37%	286	59%	60%	(39 to 73)
≥65	57	61%	185	79%	52%	(2 to 77)
Influenza A (H1N1pdm09)						
All ages	742	28%	1535	50%	62%	(53 to 69)
Age group (yrs)						
6 mos-17	168	24%	528	48%	67%	(51 to 78)
18–49	339	21%	536	38%	61%	(45 to 72)
50–64	184	36%	286	59%	62%	(42 to 75)
≥65	51	59%	185	79%	56%	(7 to 79)

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Adjusted VE (95% CI) against hospitalization using influenzanegative control design



Vaccine Effectiveness (VE) Summary

- A (2009 H1N1) virus predominated during 2013-14 season in US
 - Ability to estimate VE for influenza A(H3N2) or B infections for 2013-14 season will depend upon final sample size
- Estimated vaccine effectiveness against medically attended A(2009H1N1) illness was 62% (95% CI: 53-69)
 - Similar for all age groups
 - Similar to VE estimates for H1N1pdm09 from previous seasons
 - Consistent with laboratory data for current season
- Significant vaccine benefit at reducing hospitalizations



2014-2015 Influenza Vaccine Strains

- No strain change from last year!
- Trivalent Vaccine will contain:
 - A/California/7/2009 (H1N1)-like virus
 - A/Texas/50/2012 (H3N2)-like virus/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



Influenza Vaccine Refresher



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 has a price premium (~ \$4 for the injectable)
- No clarity on how many total doses are available
 - GSK and sanofi continue to have both IIV3 and IIV4 on the market simultaneously
 - All LAIV will be quadrivalent
 - No preferential use recommendation



Cell Culture Influenza Vaccine

- Flucelyax® 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



Recombinant DNA Influenza Vaccine

- 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 IIV, erythema most common complaint
- CPT code: 90654
- CMS payment: \$18.918 (2013)



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
- Trial of 30,000 participants, Fluzone HD was 24.2% more effective in preventing influenza in adults ≥65 years of age than Fluzone vaccine*
- CPT code: 90662
 - Payment Rate: \$31.823 (2013)



Q codes (Medicare only)

- Q2033: Influenza Vaccine, Recombinant Hemagglutinin Antigens, For Intramuscular Use (Flublok) - \$36.480 (2013)
- Q2035: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Afluria) -\$11.543 (2013)
- Q2036: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Flulaval) -\$8.579 (2013)
- Q2037: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Fluvirin) -\$14.963 (2013)
- Q2038: Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (Fluzone) -\$12.044 (2013)
- Q2039: Influenza virus vaccine, adult (Not Otherwise Specified) payment allowance is to be determined by the local claims processing contractor

Influenza Vaccines 2014-2015 (http://www.immunize.org/catg.d/p4072.pdf)

Influenza Vaccine Products for the 2014–2015 Influenza Season

Manufacturer	Trade Name (vaccine abbreviation) ¹	How Supplied	Mercury Content (µg Hg/0.5mL)	Age Group	Product Code
bioCSL, Inc.	Affreis (III/2)	0.5 mL (single-dose syringe)	0	9 years & older ^{2,3}	90656
	Afluria (IIV3)	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	Fluid arreal (III)(2)	0.5 mL (single-dose syringe)	0	3 years & older	90656
	FluLaval (IIV3)	5.0 mL (multi-dose vial)	<25	3 years & older	90658 • Q2036 (Medicare)
	FluLaval (IIV4)	0.5 mL (single-dose syringe)	0	3 years & older	90686
	Tiucavai (iiv+)	5.0 mL (multi-dose vial)	<25	3 years & older	90688
MedImmune	FluMist (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	90672
Novartis Vaccines and Diagnostics, Inc.	Fluvirin (IIV3)	0.5 mL (single-dose syringe)	<u>≤</u> 1	4 years & older	90656
	Fluvinin (IIV3)	5.0 mL (multi-dose vial)	25	4 years & older	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
Sanofi Pasteur, Inc.		0.5 mL (single-dose syringe)	0	3 years & older	90656
	Fluzone (IIV3)	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)
		0.25 mL (single-dose syringe)	0	6 through 35 months	90685
		0.5 mL (single-dose syringe)	0	3 years & older	90686
	Fluzone (IIV4)	0.5 mL (single-dose vial)	0	3 years & older	90686
		5.0 mL (multi-dose vial)	25	6 through 35 months	90687
		5.0 mL (multi-dose vial)	25	3 years & older	90688
	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

FOOTNOTES

Technical content reviewed by the Centers for Disease Control and Prevention www.immuniza.org/catg.d/p4072.pdf = Item #P4072 (9/14)



IIV3 = egg-based and cell culture-based trivalent inactivated influenza vaccine (injectable); where necessary to refer to
cell culture-based vaccine, the prefix "cc" is used (e.g., ccllV3). IIV4 = egg-based quadrivalent inactivated influenza
vaccine (injectable); LAIV4 = egg-based quadrivalent live attenuated influenza vaccine (nasal spray); RIV3 = trivalent
recombinant hemagglutinin influenza vaccine (injectable).

^{2.} In 2010, ACIP recommended that Affurta not be used in children younger than age 9 years. If no other age-appropriate IIV is available, Affurta may be considered for a child age 5 through 8 years at high risk for influenza complications, after risks and benefits have been discussed with the parent or guardian. Affurta should not be used in children younger than age 3 years. This recommendation continues for the 2014–2015 influenza season.

Affurta is approved by the Food and Drug Administration for intramuscular administration with the Pharmajet Stratis Needle-Free Injection System for persons age 18 through 64 years.

Manufacturer Production Estimates

- Sanofipasteur
 - Anticipates delivering 60M doses; delay in production but anticipates all doses out by 10/31
- Protein Sciences
 - Anticipate delivering 500,000 doses of RIV3
- Novartis Vaccines
 - Anticipate delivering 30M doses of IIV3 and ccIIV3
- bioCSL
 - Anticipates delivering 13.5M doses of IIV3
- AstraZeneca (MedImmune)
 - Anticipates delivering 18M doses of LAIV4
- GSK Vaccines
 - Anticipates delivering 28-33M doses, with 2/3 being IIV4



ACIP Influenza Recommendations

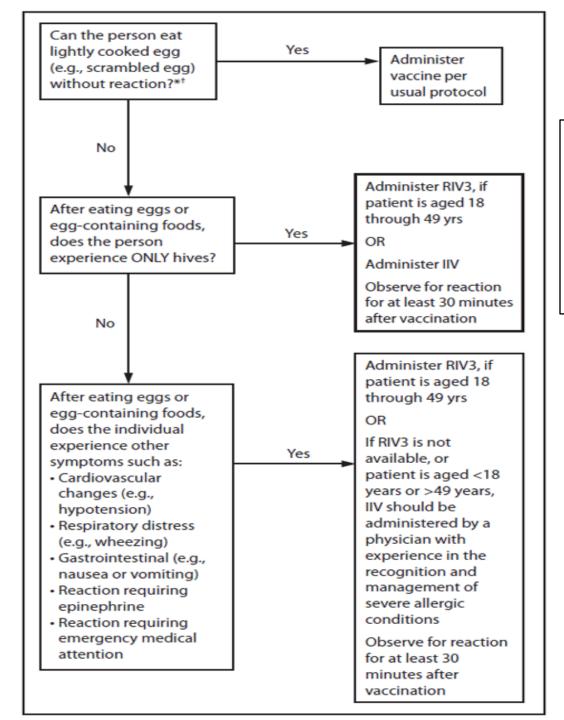
- All persons 6 months of age or older should receive influenza immunization
 - Influenza vaccination should not be delayed to procure a specific vaccine preparation if an appropriate one is already available
- Immunization should begin as soon as vaccine is available (optimally before influenza circulates in the community) and continue as long as influenza is circulating
- Final recommendations published in the August 15, 2014 issue of the MMWR:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6332a3.
htm?s_cid=mm6332a3_w.
immunizations/14

ACIP Influenza Recommendations

- RIV recommended for vaccination of persons 18 through 49 years of age with egg allergy of any severity
 - —IIV should be administered to individuals with a severe egg allergy, or if outside age range for RIV, by a physician with experience in the recognition and management of severe allergic conditions.
- 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

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Algorithm for those with egg allergies



The 2014 – 2015 pediatric recommendations

- When immediately available, LAIV should be used for healthy children aged 2 through 8 years who have no contraindications or precautions.
 - If LAIV is not immediately available, IIV should be used. Do not delay vaccination to secure LAIV.
- Check ACIP recommendations for contraindications to use of LAIV:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6332a3.htm?s cid=mm6332a3 w



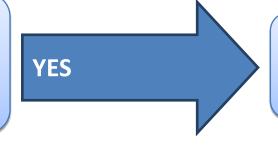
Did the child receive at least one dose of 2013-2014 seasonal influenza vaccine?

No/don't Know

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

No/don't Know

2 doses*



1 dose of 2014-2015 seasonal influenza vaccine

Pediatric Algorithm†

YES

1 dose of 2014-2015 seasonal influenza vaccine

* Doses should be administered at least 4 weeks apart.

† If a child aged 6 months through 8 years is known to have received either 1) at least 1 dose of 2013–14 seasonal influenza vaccine, or 2) at least two seasonal influenza vaccines during any previous season; and at least 1 dose of a 2009(H1N1)–containing vaccine (i.e., seasonal vaccine since 2010–11 or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2014–15.

immunizations

The 2014 – 2015 pediatric algorithm (strains did not change)

- If a child 6 months to 8 years received:
 - At least one dose of 2013-2014 seasonal vaccine; or
 - A total of at least 2 doses of seasonal influenza vaccine since July 1, 2010
- Then administer one dose of 2014-2015 vaccine.
 Otherwise, administer two doses of 2014-2015 vaccine
- However, if you know child's influenza vaccination history prior to 2010 season, then:
 - If child 6 months to 8 years received one dose of 2013-14 seasonal vaccine or at least 2 doses of seasonal influenza vaccine during any prior season, and at least 1 dose of a 2009(H1N1)-containing vaccine, then give 1 dose of 2014-2015 vaccine. Otherwise give two doses.
 immunizations

ACIP clarification regarding the LAIV package insert

- 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 safety of LAIV in persons with other underlying medical conditions that might predispose them to complications after wild-type influenza 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.



More on the ACIP

- Summary:
- Multiple vaccine products available for 2014-15
 - IIV3; IIV4; RIV; ccIIV3; LAIV
- New preferential recommendation for LAIV
- Continuing preferential recommendation for RIV;
 language changed to give IIV to severely allergic under physician supervision
- A question to consider:
 - Preferential use for elderly Fluzone HD®??

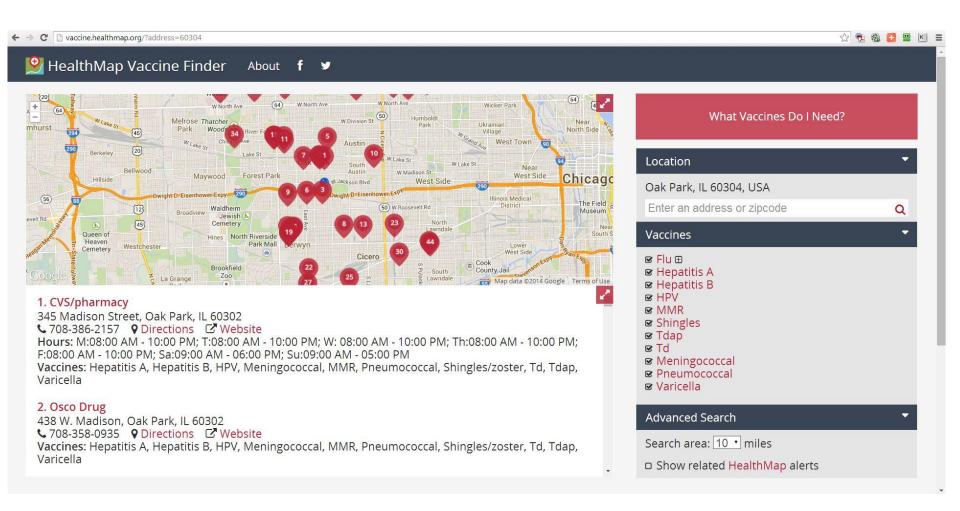


Web-based Vaccine Locator

- Third 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
 - Last flu season (Sept 2013- April 2014), over half a million page views
- Also includes all adult vaccines!



Web-based Vaccine Locator





Web-based Vaccine Locator

- >2,300 provider accounts registered with >47,000 locations
 - Most have already included information on all adult vaccines
- Simple provider registration process batch upload or manual entry (for small sized providers)
 - vaccine.healthmap.org/admin/signup
- Physician practices are welcome to sign up currently only 189 practices are enrolled
- Go to: vaccine.healthmap.org



Continuing issue for providers

- New Standards for Adult Immunization Practice
 - http://www.publichealthreports.org/issueopen.cfm?articleID=3145.
- Complementary providers and partners have increasing importance in influenza immunization
 - Includes pharmacy, community immunizers, occupational health immunizers, and obstetrical providers
 - Concern that the pharmacy business model will intrude on the pediatric medical home
 - Anytime, anywhere concept may be reducing some of market share for traditional appointment-based vaccination clinics
 - Involve more partners to further help communications among diverse provider types
 - » Opportunity to bring together disparate providers to iron out differences of opinion

immunizations

CDC communication plans for the 2014-2015 season

- CDC is using vaccine coverage data from the 2013-2014 season to guide its communications efforts for the upcoming season.
 - 18-64 years, no high-risk
 - Healthcare workers, particularly those in long-term care
 - Continued poor coverage in adults with chronic conditions
 - Continued need for improvement in pregnant women



CDC 2014-2015 Influenza Campaign Planning*

- Target audience objective:
- Everyone 6 months and older including:
 - Healthy Adults (Healthy Young/Middle-Age Adults)
 - Pregnant women
 - High risk conditions
 - Parents
 - Older Adults 65+
 - Health Care Workers
 - Long term care health professionals, assistants, aides, etc.

CDC-identified communication challenges for the 2014-2015 season

- Barriers and Challenges:
 - Consumers: vaccine misconceptions
 - HCPs, particularly in LTC
- Unique Challenges:
 - Vaccine options and availability
 - Vaccine formulation same as 2013-2014
 - Changes to ACIP recommendations
- Vaccine effectiveness
- Vaccination coverage disparities



Vaccine Effectiveness?

- Questions about efficacy and duration remain
 - Do not base efficacy or duration of immunity discussions on one season but look collectively at multiple seasons
 - Vaccine in the patient is 50%-60% effective; vaccine on the shelf is 0% effective.
 - Past season had about 62% effectiveness...



Some communications thoughts

- Be transparent regarding flu VE
- Use caution when discussing "match"
 - With a good match, flu vaccine can reduce the risk of having to go to the doctor for flu by about 60% among the overall population.
 - -This number may be higher for some groups of people and lower for others (e.g., older people with weaker immune systems)
- Use impact data and data over multiple years to provide perspective on vaccine benefits
- At all opportunities, continue to educate providers, partners and the public on the reasons people may get sick with ILI following flu vaccination.
 - -http://www.cdc.gov/flu/about/qa/misconceptions.htm



Some communications thoughts

- Vaccination also can reduce the risk of hospitalizations and deaths.
 - -vaccine preventable disability
- Important benefits can be gained by increasing vaccination rates across all age groups with currently available vaccines.
- One CDC study* concluded that flu vaccination prevented an estimated 13.6 million flu cases, 5.8 million medical visit & nearly 113,000 flu-related hospitalizations in the United States over a 6-year period (2005-2011).



Communicating on multiple influenza vaccine options

- Multiple products can create challenges
- General public have limited knowledge of, and interest in, the composition of flu vaccines
 - Trust their providers to tell them which vaccine is right for them
 - They have greater interest in mode of vaccination
- CDC research shows "quadrivalent" vaccine information well-received, but raised concerns about: safety, effectiveness, cost, and availability
 - Past season experience suggests that there is provider/consumer demand for quadrivalent vaccine



Communicate on multiple vaccine options at high level!

- Let patients know that there are different options, including mode (intramuscular, intradermal, nasal spray).
- Inform seniors about high dose vaccine.
- Discuss the egg-free options and this season's limitations.
- Be cognizant of quadrivalent vaccine supply.
- Encourage people to talk to their provider or visit CDC website if they want to learn more.
- CDC expresses preference for LAIV (children) and RIV (egg allergic), but states that the most important thing is that people get an annual flu vaccine.



CDC communication strategies for the 2014-2015 season

- Multi-Media Materials: General Population and Heath Disparate Populations
- Educational Tools
- Media Events/Telebriefings:
- National Immunization Awareness Month
- NFID/CDC influenza season launch
- National Influenza Vaccination Week: December 7 -13, 2014
- National Council on Aging/CDC
- Media Buys: strategic digital and traditional placement with partner cross collaboration activities
- Key messages: targeted; address old and new challenges
- Engagement: personal stories; pledges; digital media
- Partnership Outreach



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Thank You!

