

IHS Influenza Kick Off

Overview

- Recap of the 2015-16 Influenza Season
- 2016-17 influenza vaccine recommendations
- IHS Influenza Vaccine Coverage
- IHS Health Care Personnel Influenza Vaccination Policy
- Update from the IHS National Supply Service Center

IHS Influenza Update

Lisa Grohskopf Influenza Division, CDC

September 21, 2016

Overview

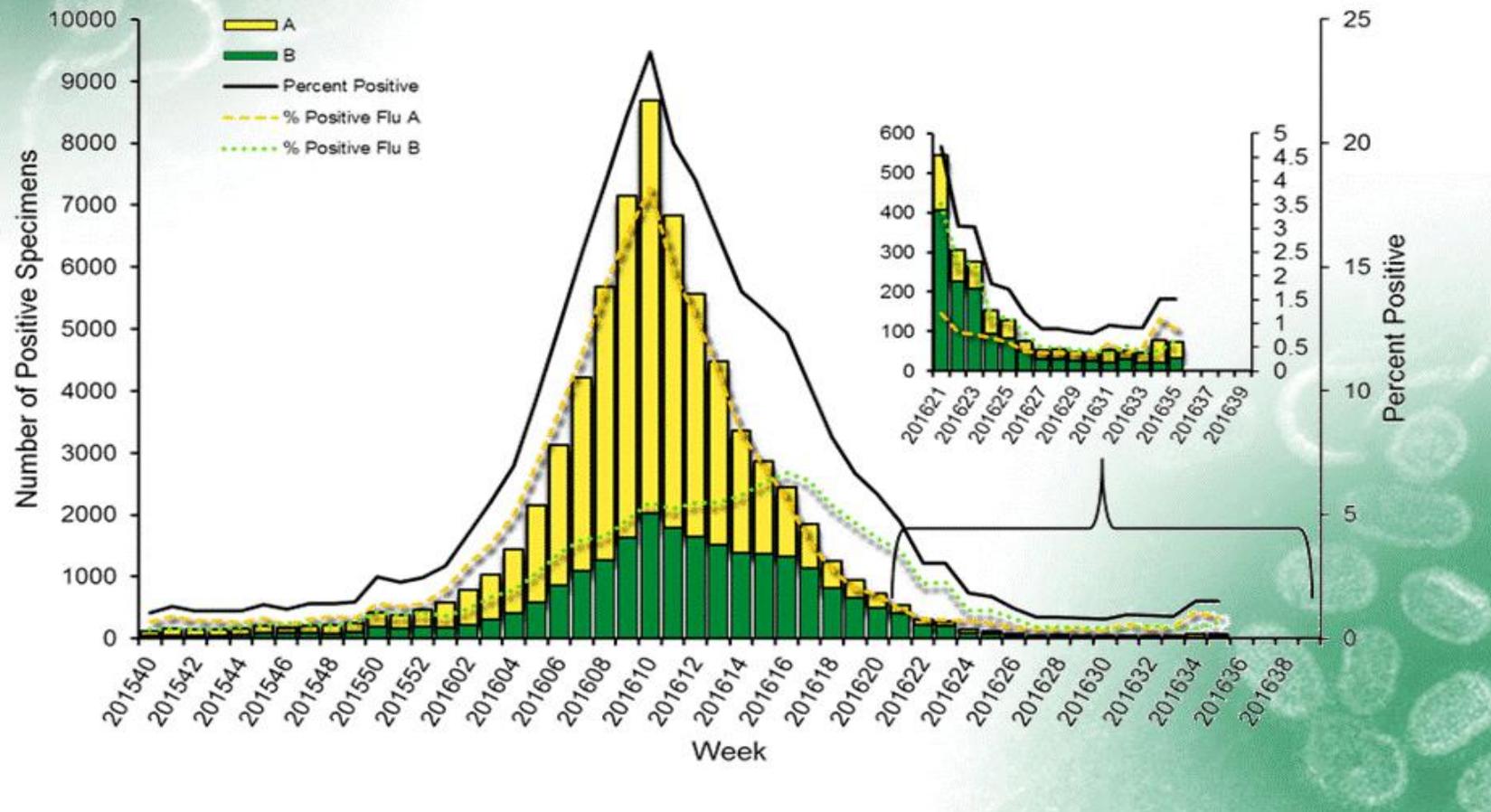
- ❑ **Surveillance update**
- ❑ **Vaccine effectiveness update**
- ❑ **ACIP recommendations update**

FLUVIEW



A Weekly Influenza Surveillance Report Prepared by the Influenza Division

Influenza Positive Tests Reported to CDC by U.S. Clinical Laboratories, National Summary, 2015-2016 Season

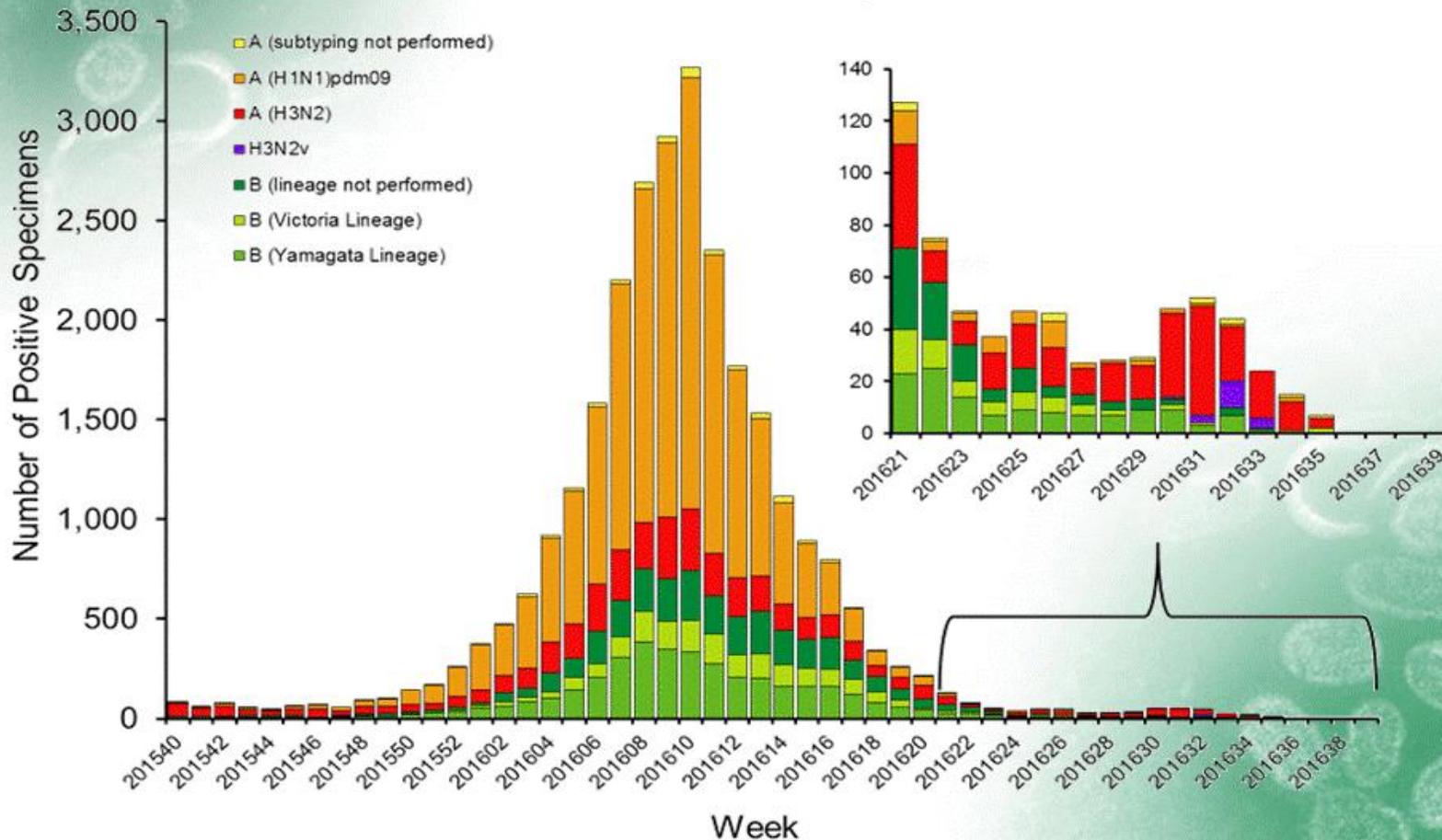


FLUVIEW



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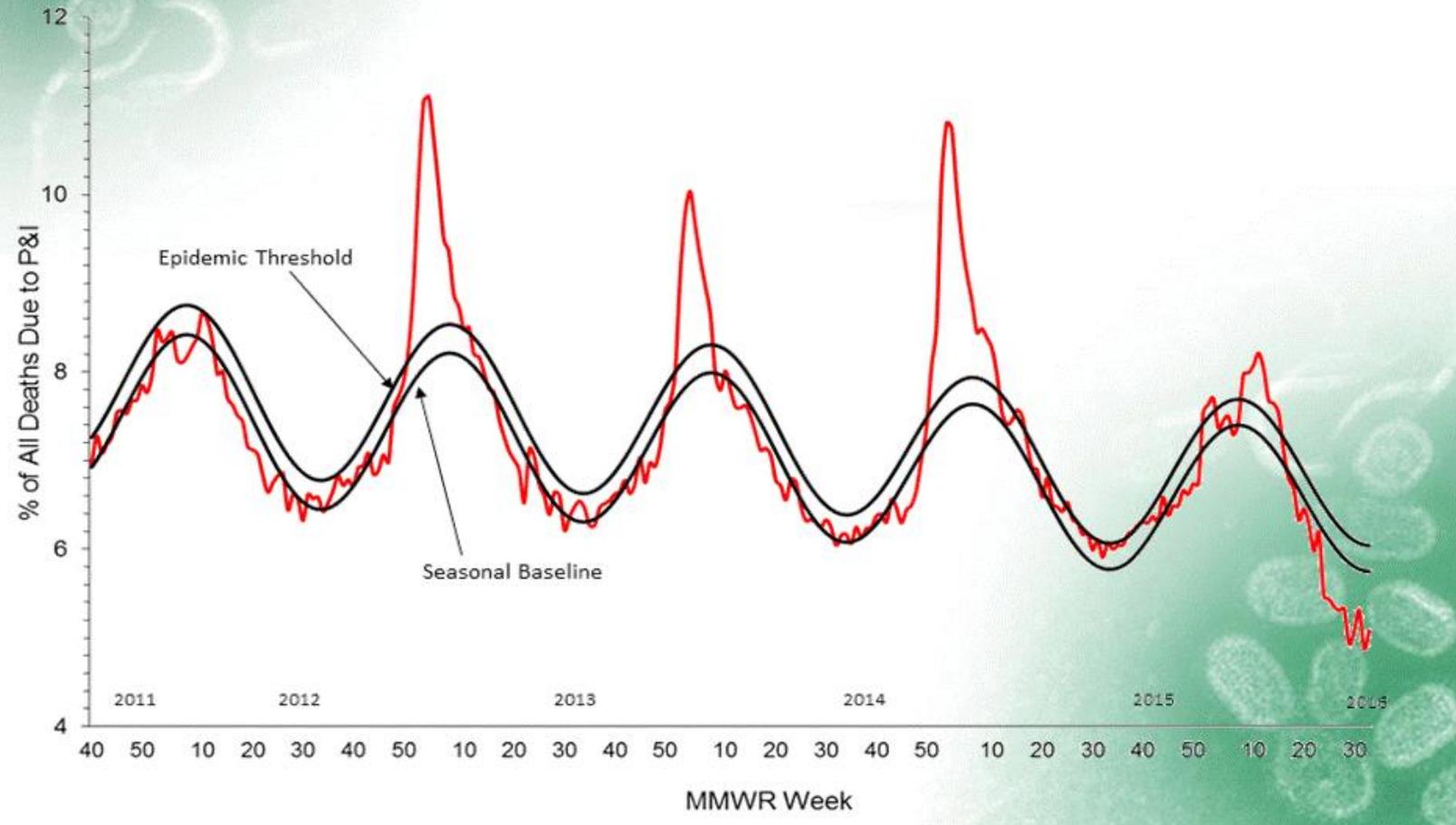


FLUVIEW



A Weekly Influenza Surveillance Report Prepared by the Influenza Division

Pneumonia and Influenza Mortality from the National Center for Health Statistics Mortality Surveillance System Data through the week ending August 20, 2016, as of September 8, 2016

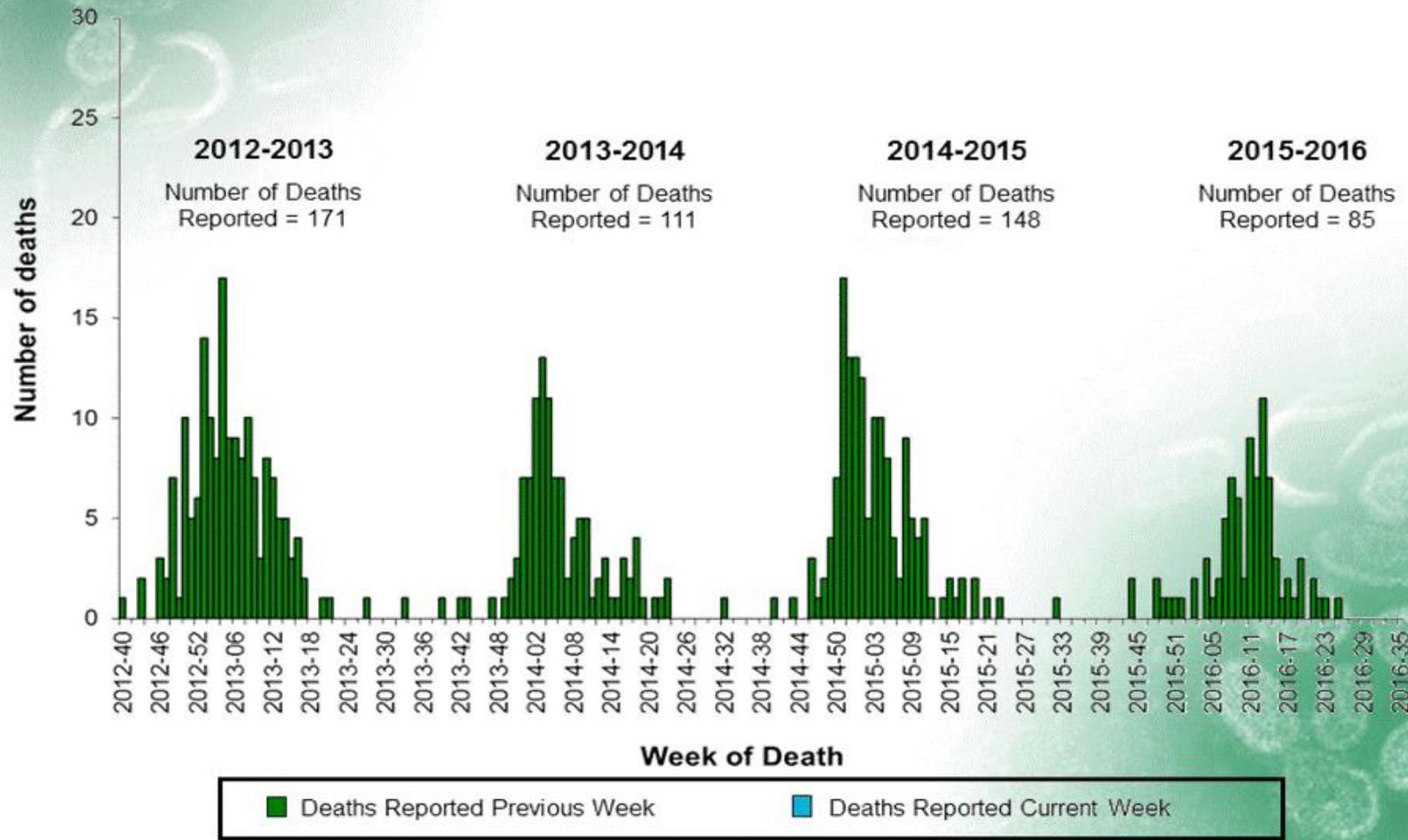


FLUVIEW



A Weekly Influenza Surveillance Report Prepared by the Influenza Division

Number of Influenza-Associated Pediatric Deaths by Week of Death: 2012-2013 season to present

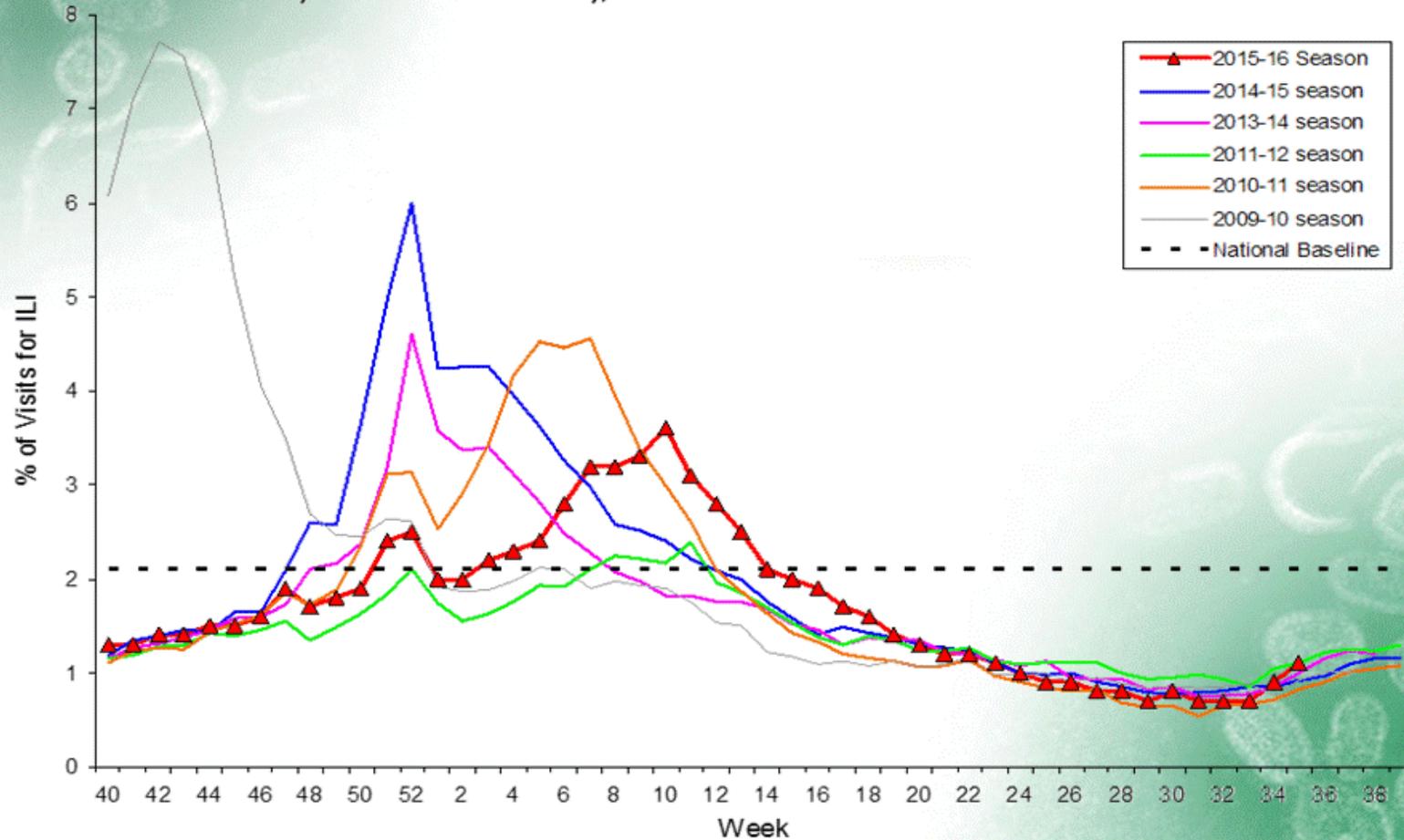


FLUVIEW



A Weekly Influenza Surveillance Report Prepared by the Influenza Division

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2015-2016 and Selected Previous Seasons



2015-2016 Surveillance: Antiviral Resistance Testing

Virus	Osetamivir Virus Samples tested (n)	Osetamivir Resistant Viruses, Number (%)	Zanamivir Virus Samples tested (n)	Zanamivir Resistant Viruses, Number (%)	Peramivir Virus Samples tested (n)	Peramivir Resistant Viruses, Number (%)
Influenza A (H1N1)pdm09	2,090	18 (0.9)	1,036	0 (0.0)	2,090	18 (0.9)
Influenza A (H3N2)	699	0 (0.0)	699	0 (0.0)	611	0 (0.0)
Influenza B	1,104	0 (0.0)	1,104	0 (0.0)	1,104	0 (0.0)

Adjusted VE against medically attended influenza, US Flu VE Network, 2015-16

Vaccine Effectiveness

<u>Any influenza A or B virus</u>	Influenza Positive N vaccinated/ Total	(%)	Influenza Negative N vaccinated/ Total	(%)	Unadjusted VE %	Unadjusted 95% CI	Adjusted VE %	Adjusted* 95% CI
Overall	514/1332	39	3037/5708	53	45	(38 to 51)	47	(39 to 53)
6m – 8 y	108/277	39	765/1410	54	46	(30 to 59)	48	(31 to 61)
9–17 y	33/164	20	277/694	40	62	(43 to 75)	64	(44 to 77)
18–49 y	146/499	29	841/1957	43	45	(32 to 56)	48	(35 to 59)
50–64 y	149/283	53	562/918	61	30	(8 to 46)	23	(-3 to 43)
≥65 y	78/109	72	592/729	81	42	(8 to 63)	45	(10 to 66)
IIV3/4, all ages	472/1290	37	2893/5564	52	47	(40 to 53)	49	(41 to 56)

* Multivariate logistic regression models adjusted for site, age categories (6m-8y, 9-17y, 18-49y, 50-64y, ≥65y), sex, race/Hispanic ethnicity, self-rated general health status, interval from onset to enrollment, and calendar time (biweekly intervals)

2016-17 ACIP Influenza Statement--Overview

□ **Published in MMWR August 26, 2016**

□ **Principal changes**

- LAIV not recommended during the 2016-17 season
- New/recent vaccine licensures
 - Fluvad
 - Flucelvax Quadrivalent
- Changes to egg allergy recommendations

Change in LAIV Recommendations--Language

“In light of concerns regarding low effectiveness against influenza A(H1N1)pdm09 in the United States during the 2013–14 and 2015–16 seasons, for the 2016–17 season, ACIP makes the interim recommendation that live attenuated influenza vaccine (LAIV4) should not be used.”

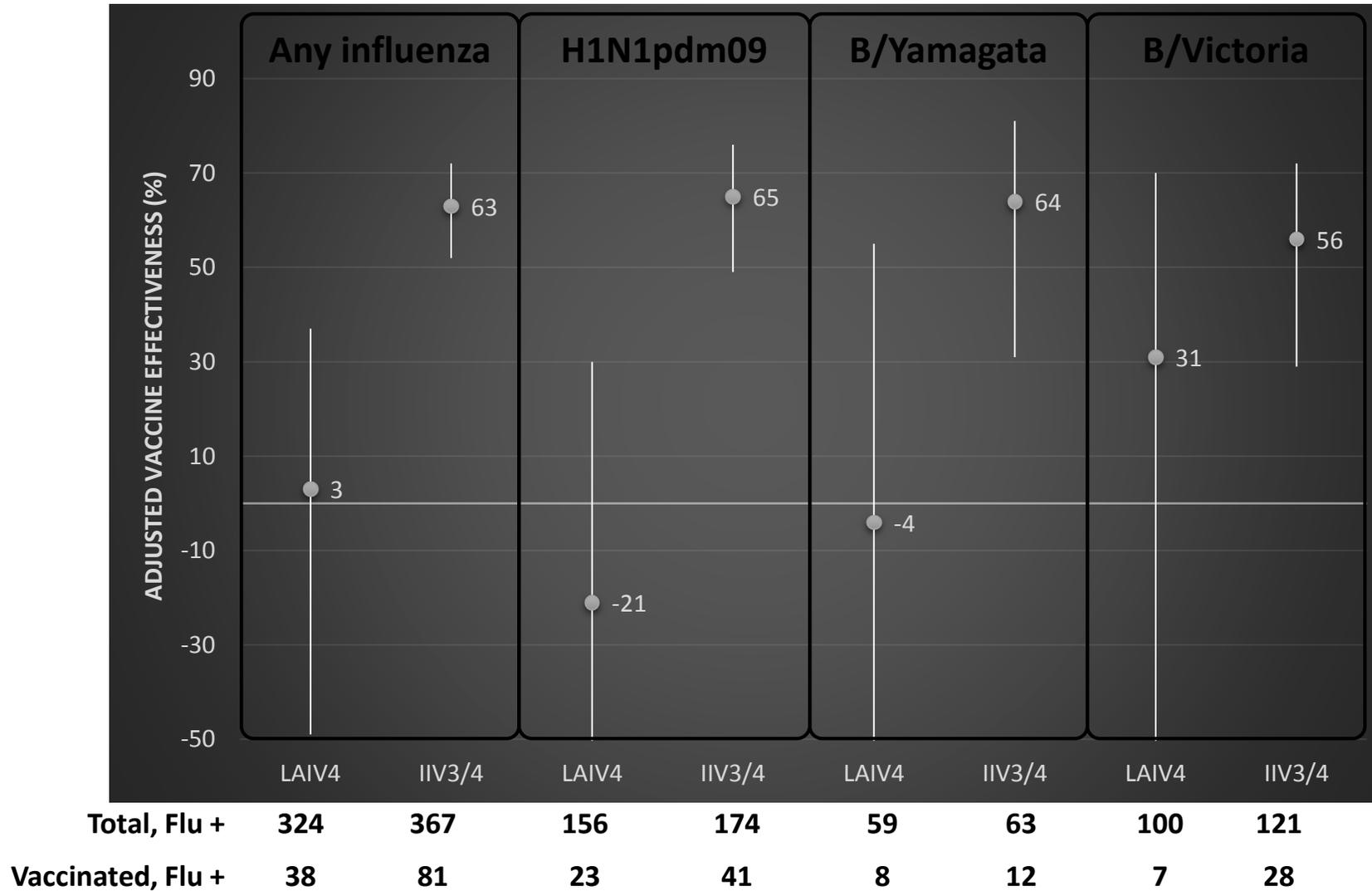
Change in LAIV Recommendations—History (1)

- LAIV licensed in 2003**
- Early randomized comparative trials of LAIV vs. IIV (conducted in 2002-03 and 2004-05 seasons) demonstrated superior efficacy of LAIV among young children**
 - Lead to ACIP expressing a preference for LAIV for healthy 2 through 8 year olds for 2014-15
- Analysis of complete US Flu VE Network data for 2013-14 revealed no effectiveness of LAIV against H1N1pdm09**
 - First H1N1-predominant season since 2009 pandemic
 - IIV was effective against H1N1pdm09
- LAIV no more effective than IIV against drifted H3N2 during 2014-15 season**
- ACIP did not renew preferential recommendation for LAIV for 2015-16 season**

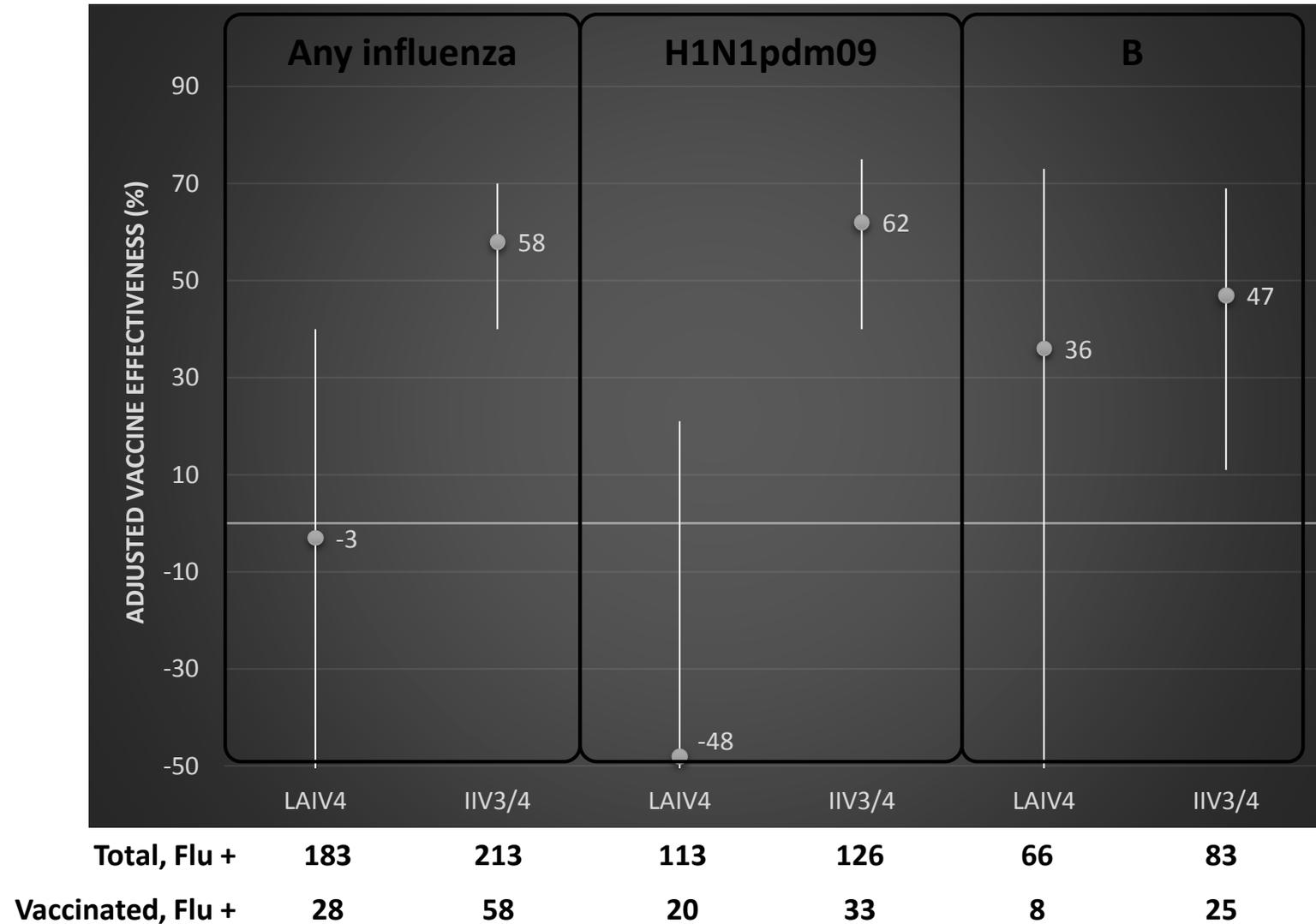
Change in LAIV Recommendations—History (2)

- In June 2016, ACIP reviewed LAIV VE data for children 2 through 17 years of age, for the 2015-16 season, from three U.S. observational studies.**
- VE against all influenza A and B**
 - US Flu VE Network: 3%, not statistically significant
 - MedImmune: 46%, statistically significant
 - US Department of Defense: 53%, statistically significant
- VE against influenza A(H1N1)pdm09**
 - US Flu VE Network: -21%, not statistically significant
 - MedImmune: 50%, not statistically significant
 - US Department of Defense: 15%, not statistically significant
- Concerns regarding low VE against H1N1pdm09 lead ACIP to recommend LAIV not be used during the 2016-17 season.**

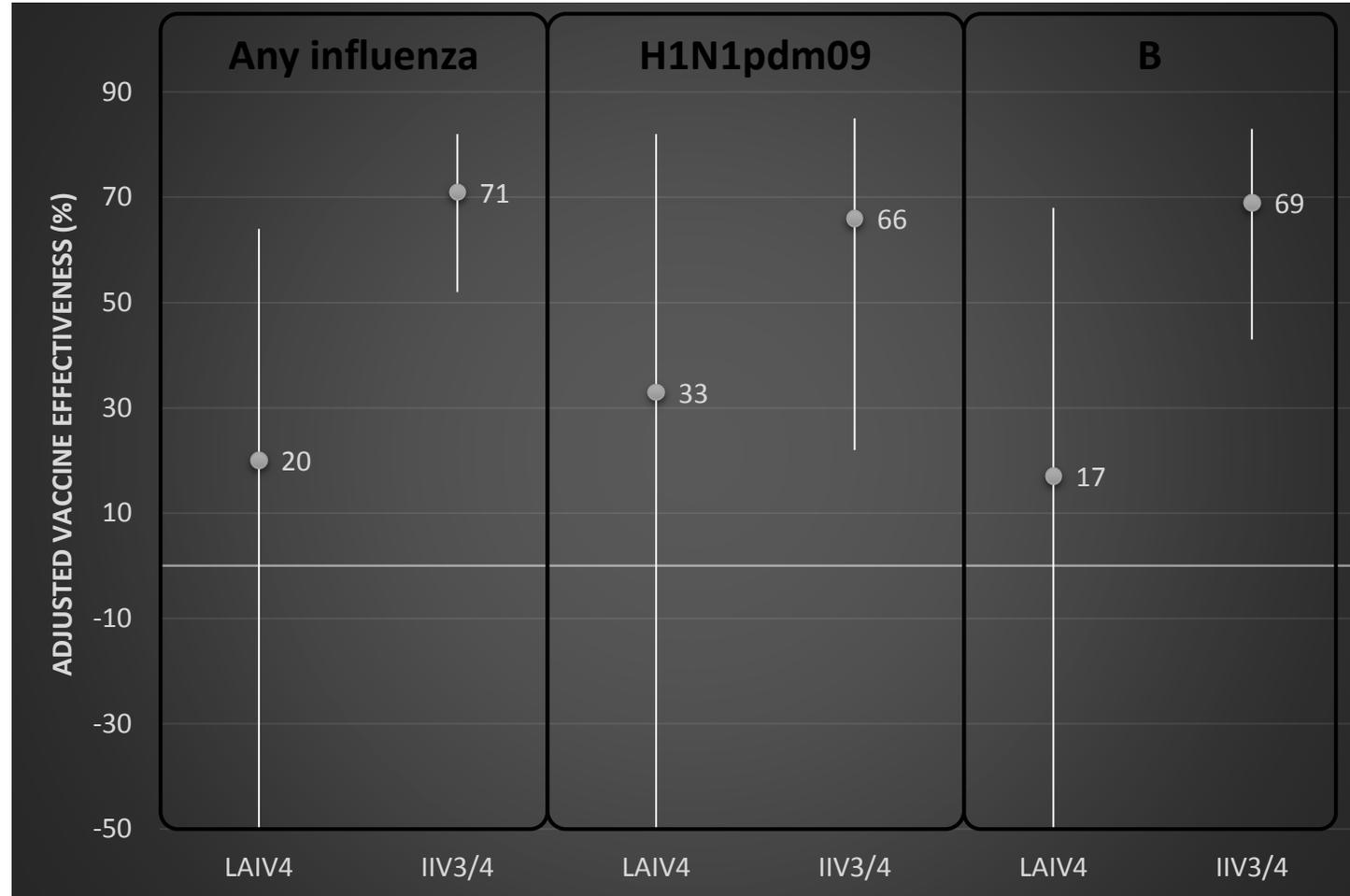
LAIV and IIV vaccine effectiveness ages 2–17 years, by influenza type/subtype, 2015-16



LAIV and IIV vaccine effectiveness ages 2–8 years, by influenza type/subtype, 2015-16

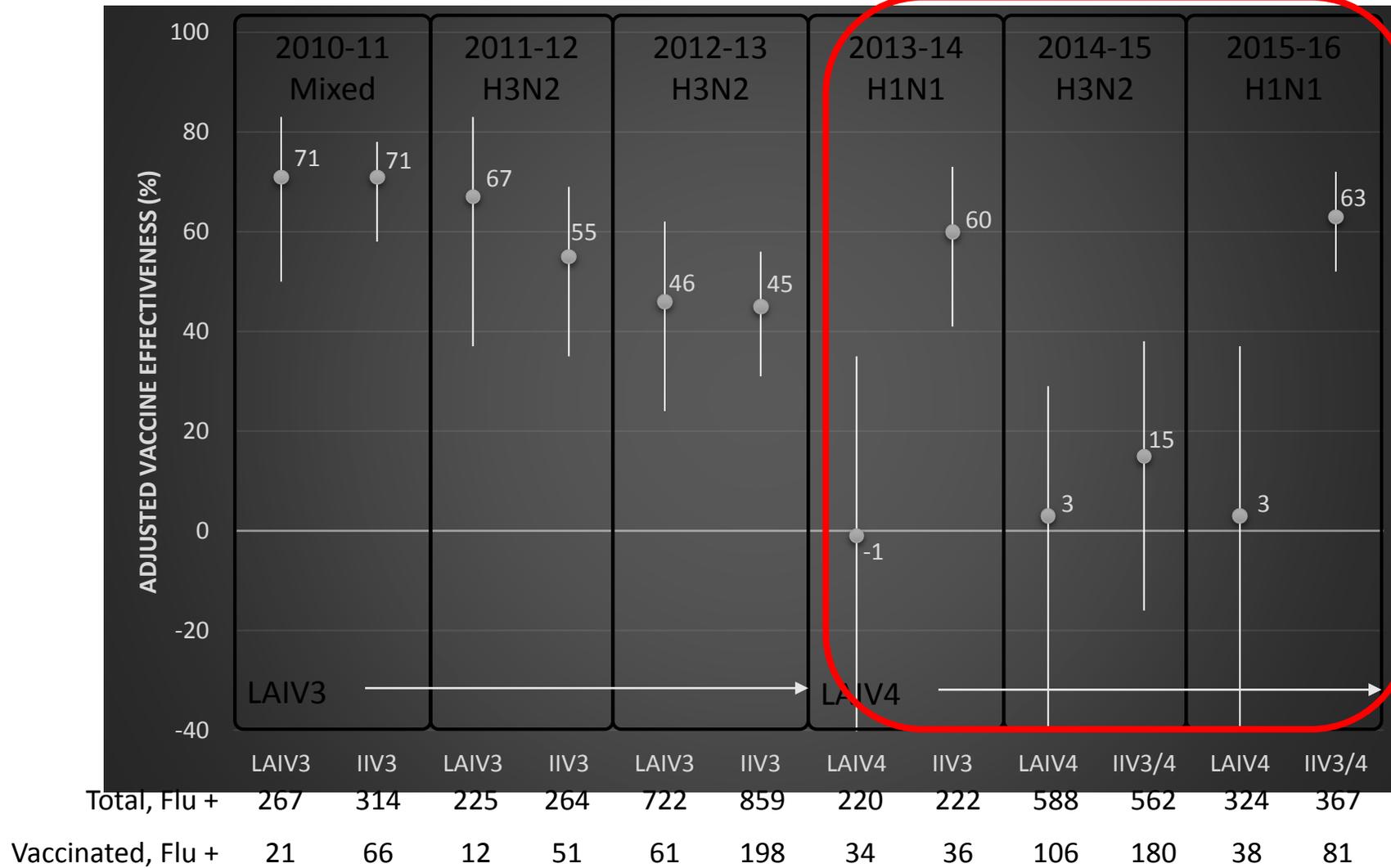


LAIV and IIV vaccine effectiveness ages 9–17 years, by influenza type/subtype, 2015-16



Total, Flu +	141	154	43	48	92	100
Vaccinated, Flu +	10	23	3	8	7	15

U.S. Flu VE Network: LAIV and IIV VE age 2-17 yrs Any Influenza A or B



New Vaccines for 2016-17

□ Flud

- MF59-adjuvanted trivalent IIV
- Indicated for persons aged 65 years and older
- Immunogenically non-inferior to licensed comparator IIV3 in preclinical studies
- Canadian observational study noted 60% relative effectiveness compared with unadjuvanted IIV3 among adults 65 years and older

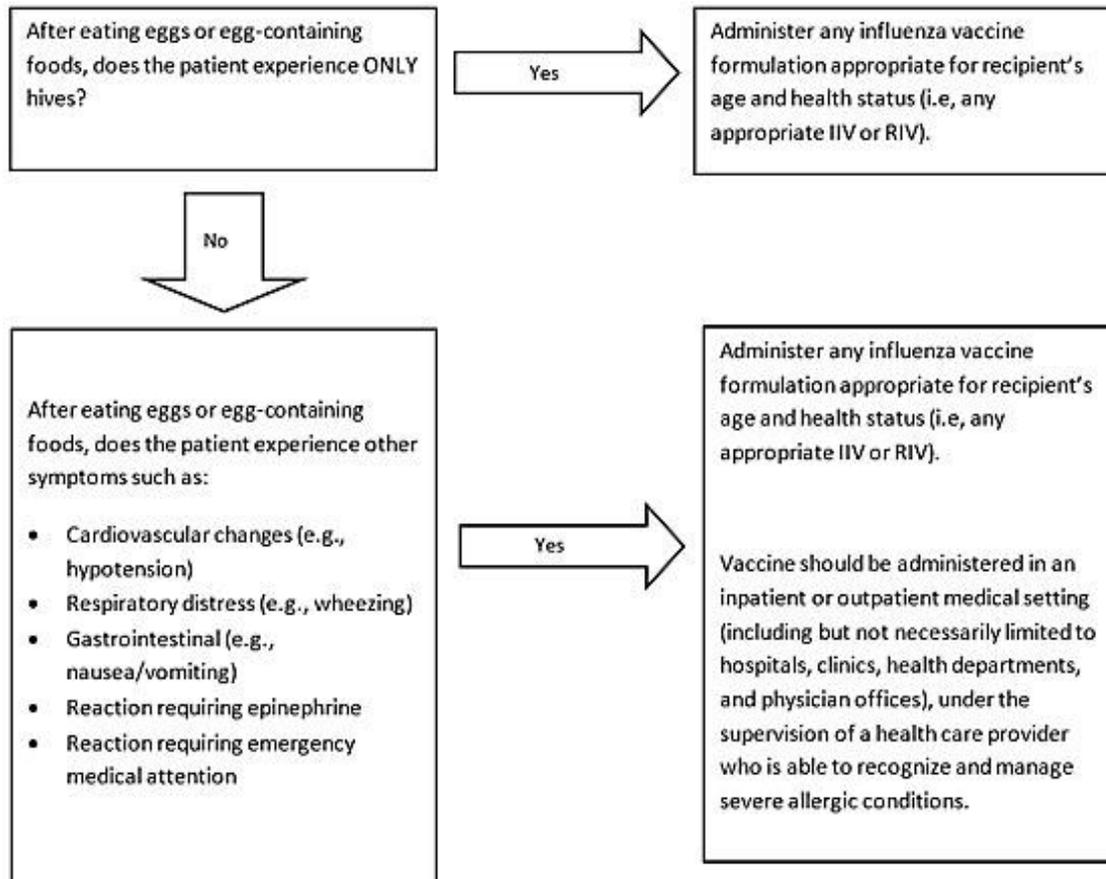
□ Flucelvax Quadrivalent

- Will replace trivalent Flucelvax for 2016-17
- Licensed for persons aged 4 years and older
- Vaccine viruses propagated in Madin-Darby canine kidney cells instead of eggs
- Immunogenically noninferior to trivalent formulation

Changes to Egg Allergy Language

- ❑ **Removal of the 30-minute post-vaccination observation period**
- ❑ **Egg allergic persons can receive any licensed, recommended vaccine that is otherwise appropriate (IIV or IIV)**
- ❑ **One additional measure remains for persons with a history of severe allergic reaction to egg (i.e., any symptom other than hives)**
 - “The selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic conditions.”

NOTE: Regardless of a recipient's allergy history, all vaccination providers should be familiar with the office emergency plan and be currently certified in cardiopulmonary resuscitation. Epinephrine and equipment for maintaining an airway should be available for immediate use. (CDC. General recommendations on immunization—recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2011;60(No. RR-2)



IIV=Inactivated Influenza Vaccine; RIV=Recombinant Influenza Vaccine.

Egg Allergy Algorithm

❑ No longer printed in the MMWR

❑ Available on the CDC Web Pages at:

<http://www.cdc.gov/flu/protect/vaccine/egg-allergies.htm>

CDC Antiviral Recommendations

- **All patients in the following categories with suspected or confirmed influenza should be treated as soon as possible, without waiting for confirmatory influenza testing**
 - Hospitalized patients
 - Patients with severe, complicated, or progressive illness
 - Patients at high risk for complications from influenza (either outpatient or hospitalized)

- **Antiviral treatment may be prescribed on the basis of clinical judgment for any previously healthy (non-high risk) outpatient with suspected or confirmed influenza**

Persons at High Risk for Influenza Complications

- ❑ Children <2 years
- ❑ Adults \geq 65 years
- ❑ Pregnant and postpartum women (within 2 weeks after delivery)
- ❑ American Indians and Alaska Natives
- ❑ Persons who are morbidly obese (BMI \geq 40)
- ❑ Residents of long-term care facilities



Persons at High Risk for Influenza Complications (continued)

- ❑ **Persons with immunosuppression**
- ❑ **Persons <19 years who are receiving long-term aspirin therapy**
- ❑ **Persons with underlying medical conditions: chronic pulmonary, cardiovascular (except hypertension alone), renal, hepatic, hematologic, and metabolic disorders (incl. diabetes), or neurologic and neurodevelopment conditions**

CDC Antiviral Recommendations

- ❑ **Decisions about antiviral treatment should not wait for laboratory confirmation of influenza**
- ❑ **Clinical benefit is greatest when antiviral treatment is initiated early, but treatment initiated later than 48 hours after onset can still be beneficial for some patients**
- ❑ **Focus is on prevention of severe outcomes**
 - Treatment of those with severe disease and persons at highest risk of severe influenza complications
 - No RCTs available
- ❑ **Considers data from observational studies and meta-analyses of antiviral effectiveness**
- ❑ **Recommendations common to ACIP, IDSA, AAP**

Influenza Antiviral Drugs: 2016–2017

- ❑ **Adamantanes: rimantadine and amantadine**
 - M2 ion channel blockers (influenza A)
 - High levels of resistance
 - *Not recommended* for use during this season
- ❑ **Neuraminidase inhibitors: oral oseltamivir (Tamiflu[®], generic oseltamivir phosphate approved by FDA 8/3/16), inhaled zanamivir (Relenza[®]), IV peramivir (Rapivab[®])**
 - For treatment and prevention of influenza A and B
 - >99% of all circulating viruses were susceptible to NAIs during 2014-15 and 2015-16
 - *Are recommended* for use during this season
- ❑ **Investigational: IV zanamivir**

Acknowledgements

Joe Bresee

Lynette Brammer

Lenee Blanton

Brendan Flannery

Alicia Fry

Jessie Clippard

Thank You!
Questions?

IHS Influenza Vaccine Coverage for 2015-2016

GREAT PLAINS TRIBAL CHAIRMEN'S HEALTH BOARD
NORTHERN PLAINS TRIBAL EPIDEMIOLOGY CENTER
Our Place Today
Chairmen's Health Board

**I KEEP THE CIRCLE STRONG.
I GET MY FLU VACCINE.
DO YOU?**

As Native American people, we need to keep our circle protected and strong.
It is up to **EACH AND EVERY ONE OF US** to make sure that our loved ones are protected from the dangers of the flu.
GET YOUR FLU VACCINE TODAY.
Check out cdc.gov/flu for more information.

The flu is a dangerous disease — it should never be taken lightly.	Getting a flu vaccine every year is the best way to protect yourself and your family from the flu.	Talk to your doctor or other provider about getting a flu vaccine today.
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GREAT PLAINS TRIBAL CHAIRMEN'S HEALTH BOARD
NORTHERN PLAINS TRIBAL EPIDEMIOLOGY CENTER
1770 Rural Road, Rapid City, SD 57702—(P) 605.721.1922—(F) 605.721.1922—www.gphhb.org

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**ONE PROBLEM I CAN'T AFFORD TO HAVE?
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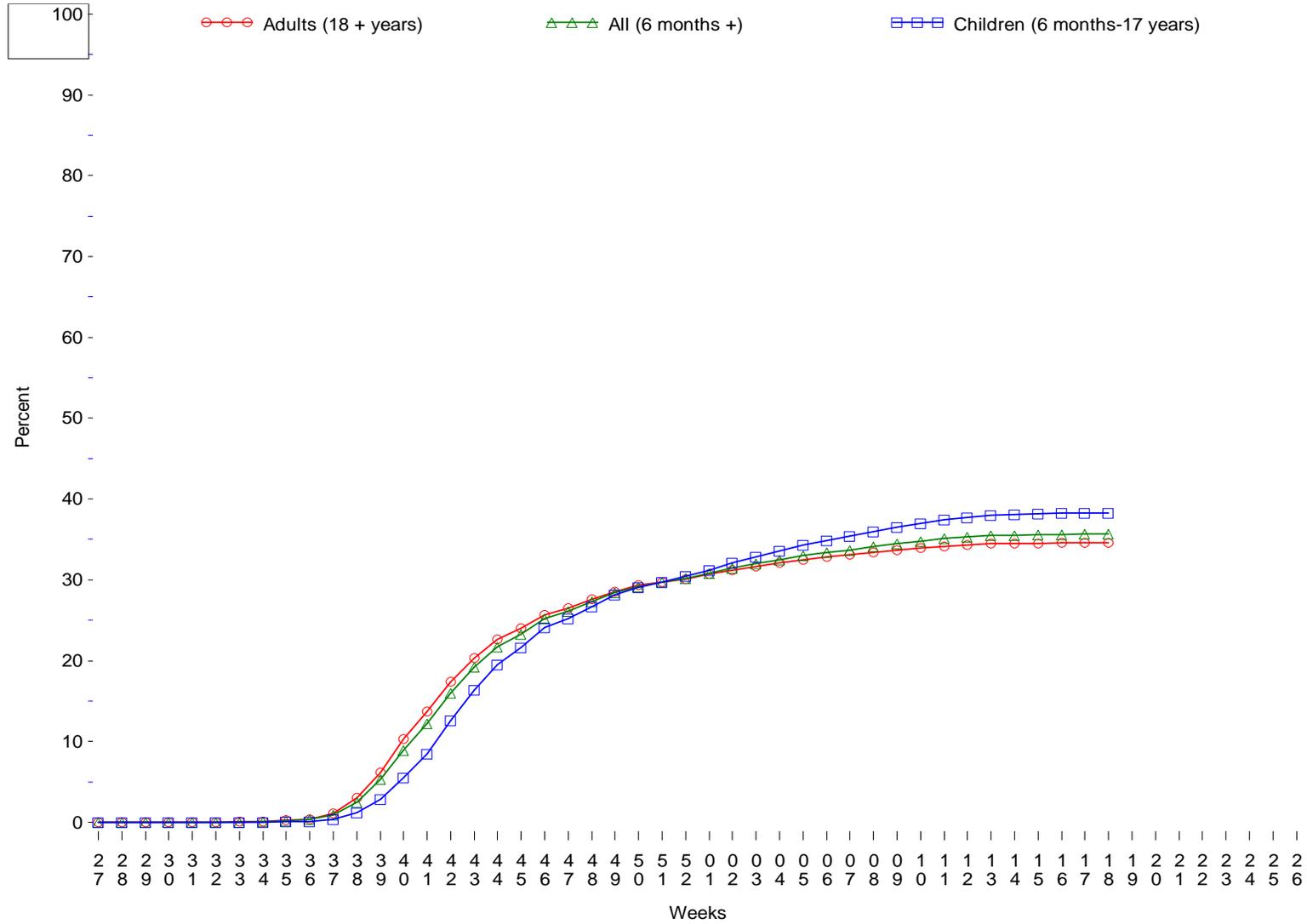
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All IHS Areas

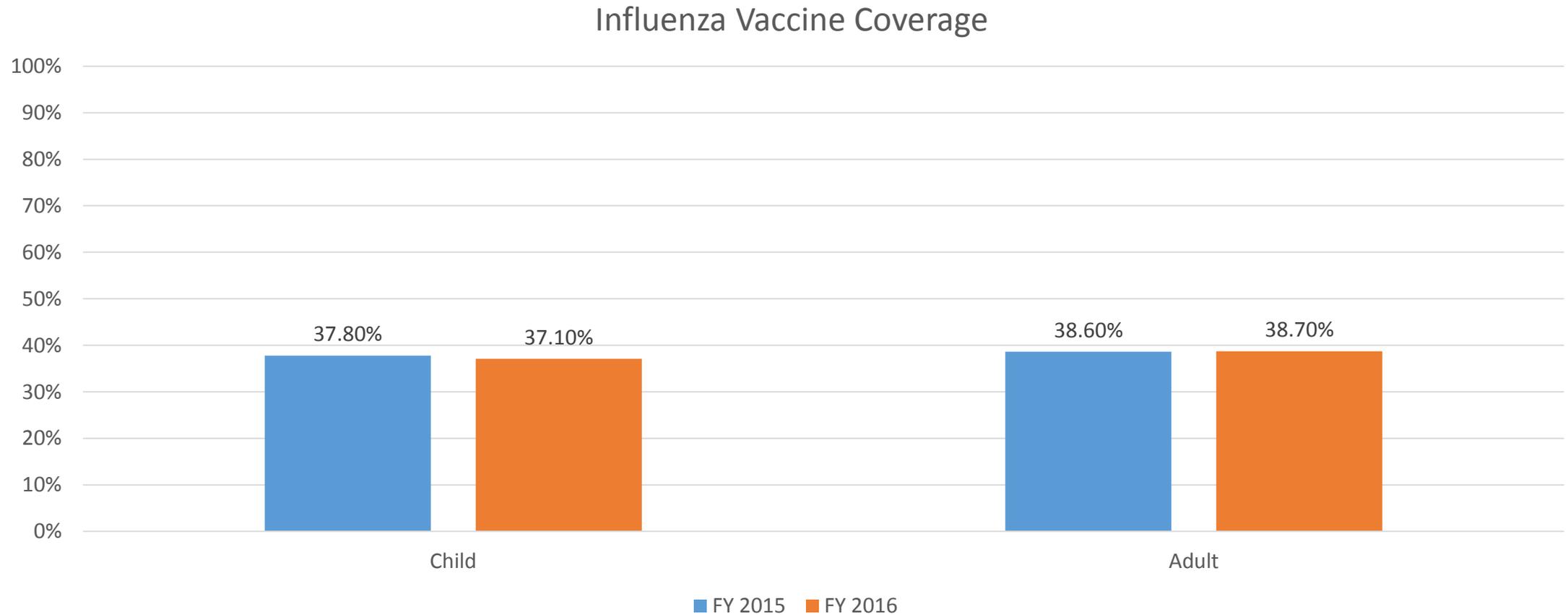
Cumulative One-Dose Seasonal Influenza Vaccine Coverage

07/05/15 to 05/07/16

Active Clinical Population

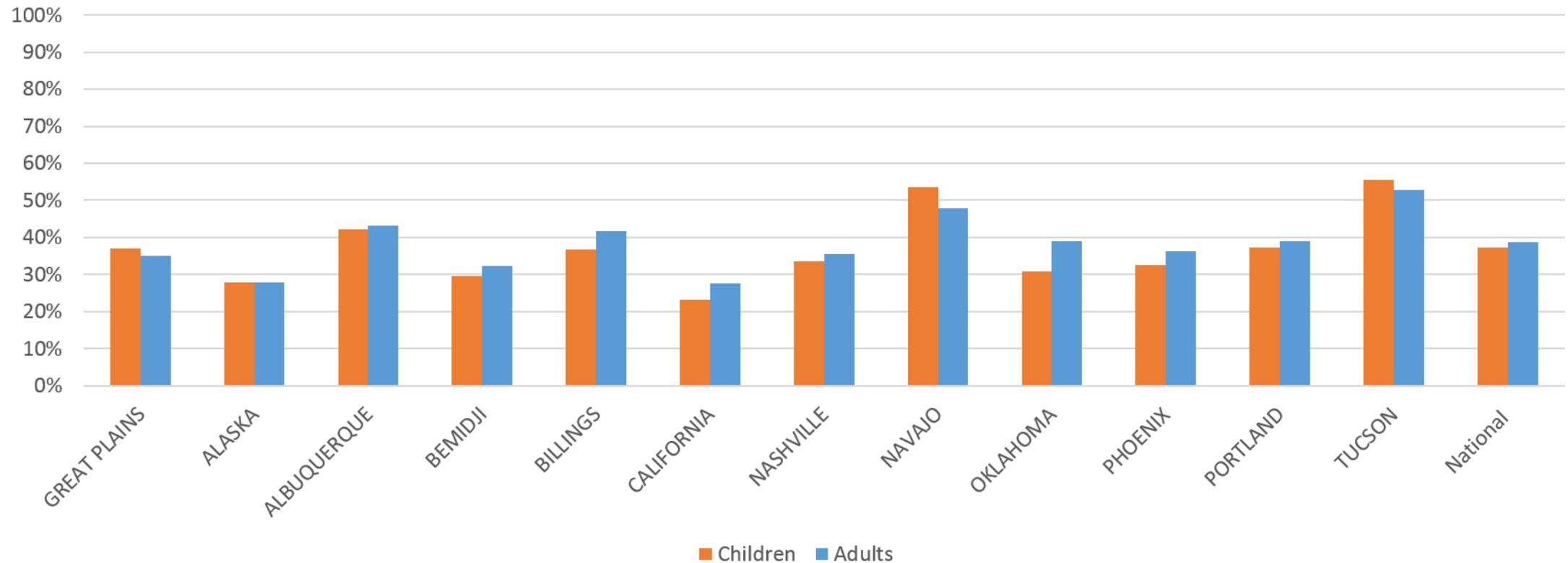


IHS Influenza Vaccine Coverage GPRA FY 2015 vs. GPRA FY 2016

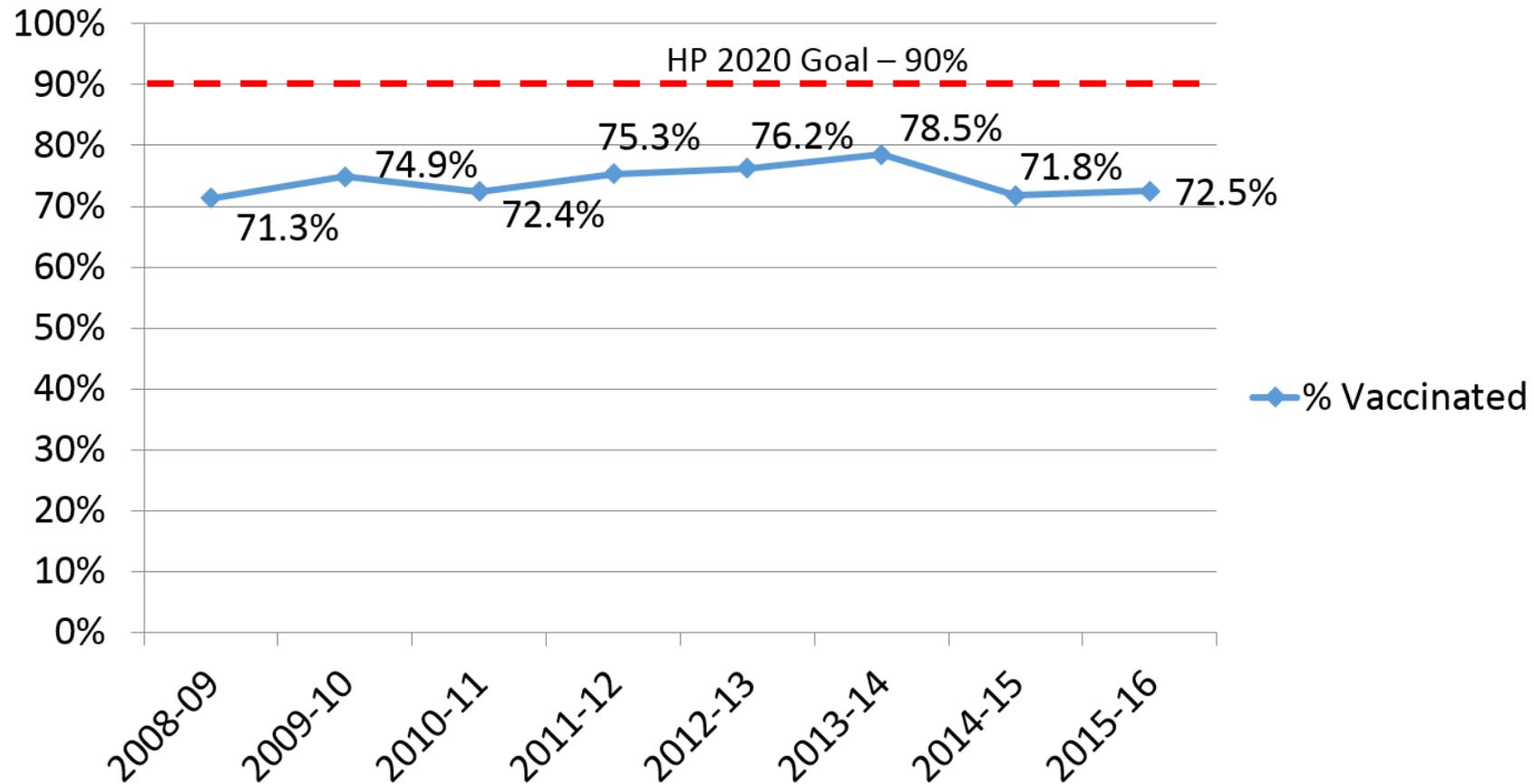


GPRA Influenza Vaccine Coverage by IHS Area FY 2016 (2015-2016 Influenza Season)

Influenza Vaccine Coverage



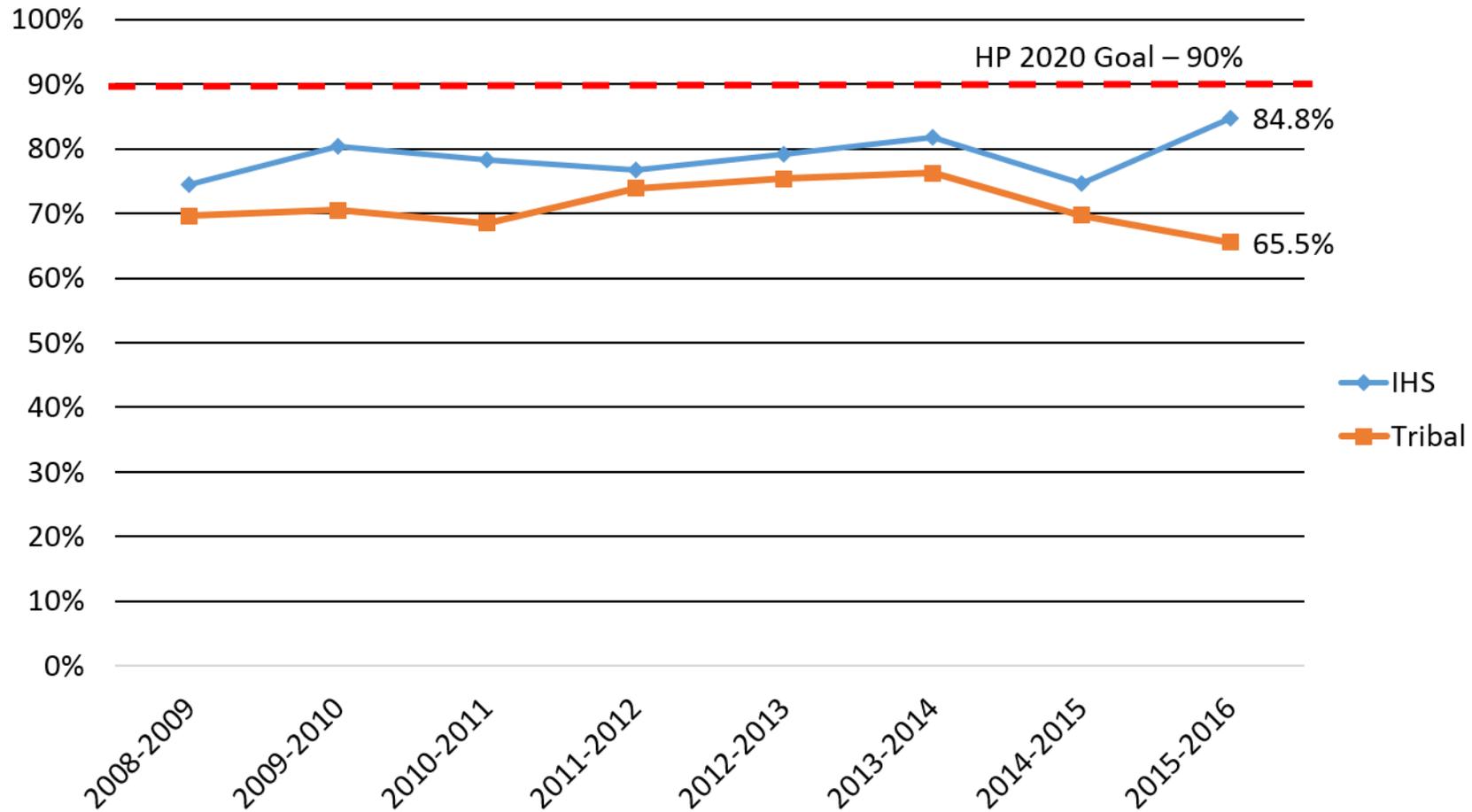
IHS Health Care Personnel (HCP) Influenza Vaccine Coverage All I/T/U Facilities



Data as of March 31st, 2016

IHS National Immunization Reporting System

HCP Influenza Vaccine Coverage IHS and Tribal Sites

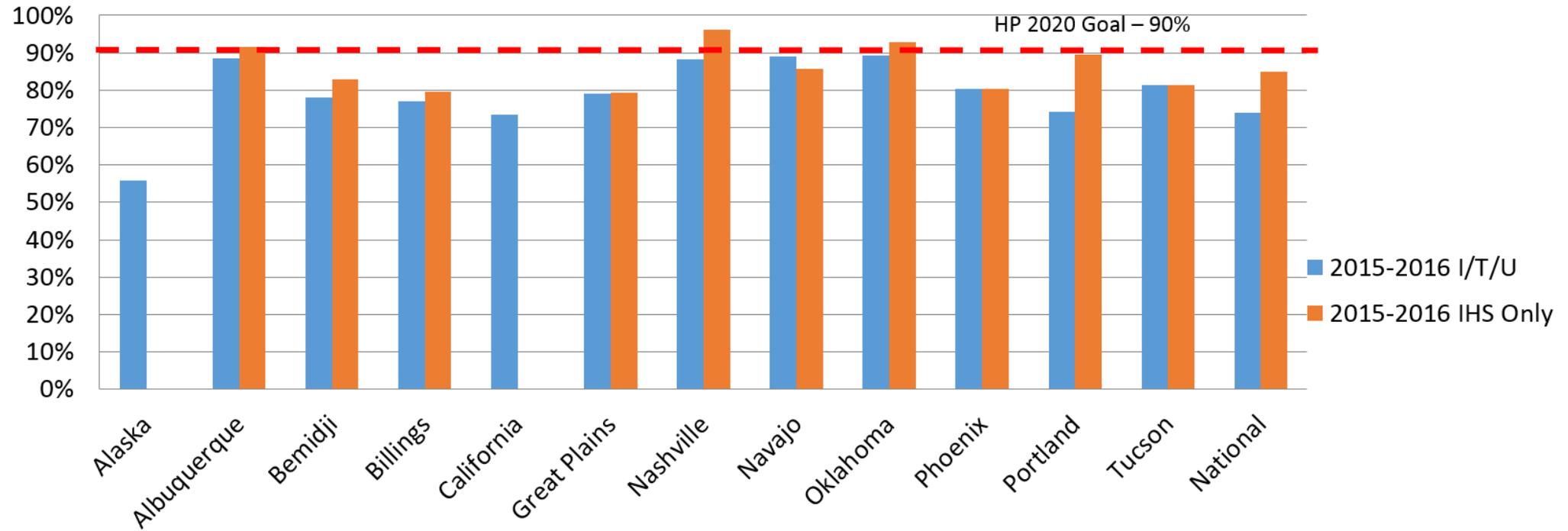


Data Source: IHS National Immunization Reporting System
Data as of March 31, 2016

HCP Coverage by IHS Area

All facilities vs. IHS only

HCP Influenza Vaccine Coverage by Area
2015-2016



Healthy People 2020 Goals

- No IHS Areas achieved the HP 2020 goal of 70% influenza vaccine coverage among children and adults
- Three IHS Areas achieved the HP 2020 Goal of 90% or higher influenza vaccine coverage among HCP in IHS facilities
 - Albuquerque Area
 - Nashville Area
 - Oklahoma Area



Mandatory HCP Influenza Policy Status: 2016-2017

- Conversations with unions resulted in revisions to allow religious exemptions
- Revised IHS SGM signed July 28th, 2016
 - https://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_circ_main&circ=ihs_circ_1604
- Successfully bargained with 2 of the 3 unions
 - 97% of union employees
- Full implementation for all IHS employees anticipated for the 2016-2017 season
- IHS HCP Flu Webinar – Oct. 4th, 2016

RPMS Updates

New Influenza Vaccines and Manufacturer

- Quadrivalent cell culture (Flucelvax Quadrivalent[®]) - CVX 171
- Trivalent adjuvanted – (Fluad[®]) – CVX code 168
- New influenza vaccine manufacturer – Seqirus (CSL and Novartis)
- **All included in Patch 13 of the Immunization Package (BI)
(Released August 29, 2016)**

Influenza Vaccine Codes in RPMS

Influenza Vaccine CVX Codes
2016-2017

CVX Code	Full vaccine name (CDC abbreviation)	RPMS Short Name	Brand	Manufacturer	Age Indication
Trivalent Inactivated Vaccines (IIV3) Available for 2016-2017 Season					
135	influenza, high dose seasonal, preservative-free	FLU-HIGH	Fluzone® High Dose	Sanofi Pasteur	≥65yrs
140	influenza, seasonal, injectable, preservative free, trivalent	FLU-IIV3pf	Afluria®, single dose syringe	Seqirus	≥9 yrs
			Fluvirin®, single dose syringe	Seqirus	≥4 yrs
141	influenza, seasonal, injectable, trivalent	FLU-IIV3	Afluria®, multi-dose vial	Seqirus	≥9 yrs
			Fluvirin®, multi dose vial	Seqirus	≥4 yrs
155	Seasonal, trivalent, recombinant, injectable influenza vaccine, preservative free (RIV)	FLU-RIV3	FluBlok®	Protein Sciences	≥18 yrs
168	influenza, trivalent, adjuvanted	FLU-IIV3ad	Fluad®	Seqirus	≥65yrs
Quadrivalent Inactivated Vaccines (IIV4) Available for 2016-2017 Season					
150	influenza, injectable, quadrivalent, preservative free	FLU-IIV4pf	Fluarix® Quadrivalent, single dose syringe	GSK	≥3 yrs
			FluLaval® Quadrivalent, single dose syringe	GSK	≥3 yrs
			Fluzone® Quadrivalent, single dose syringe, single dose vial	Sanofi Pasteur	≥36 mos
158	influenza, injectable, quadrivalent	FLU-IIV4	FluLaval® Quadrivalent, multi dose vial	GSK	≥3 yrs
			Fluzone® Quadrivalent, multidose vial	Sanofi Pasteur	≥6 mos
161	influenza, injectable, quadrivalent, preservative free, pediatric, 0.25 ml	FLU-PEDIV4	Fluzone® Quadrivalent, single dose syringe	Sanofi Pasteur	6-35 mos
166	influenza, intradermal, quadrivalent, preservative free	FLU-DERM4	Fluzone® Intradermal Quadrivalent	Sanofi Pasteur	18-64 years
171	influenza, injectable, MDCK, preservative free, quadrivalent	FLU-cciV4	Flucelvax® Quadrivalent	Seqirus	≥4 yrs
Quadrivalent Live Attenuated Virus Vaccines (LAIV4) (Note: Not recommended for use)					
149	influenza, live, intranasal, quadrivalent (LAIV4)	FLU-LAIV4	FluMist®	Medimmune	2-49 yrs
Codes that should ONLY be used to record vaccines given elsewhere, if formulation is unknown					
88	influenza virus vaccine, unspecified formulation	FLU-NOS	None	None	
Codes that should not be used this influenza season - Inactivate them in your vaccine table					
15	influenza virus vaccine, split virus (incl. purified surface antigen)-retired CODE	FLU-TIVhx			
16	influenza virus vaccine, whole virus	FLU-WHOLE			
111	influenza virus vaccine, live, attenuated, for intranasal use, trivalent (LAIV3)	FLU-LAIV3			
123	influenza virus vaccine, H5N1, A/Vietnam/1203/2004 (national stockpile)	FLU-H5N1			
144	influenza, seasonal, intradermal, preservative free, trivalent	FLU-DERMAL			
153	influenza, injectable, Madin Darby Canine Kidney, preservative free (cell culture) (cciV3)	FLU-cciV3			
160	influenza A monovalent (H5N1), ADJUVANTED-2013	H5N1, adj	Influenza A (H5N1) -2013		

Available at www.ih.gov/flu, under ‘Provider Resources’

2016-17 Seasonal Influenza Vaccine and Antiviral Procurement

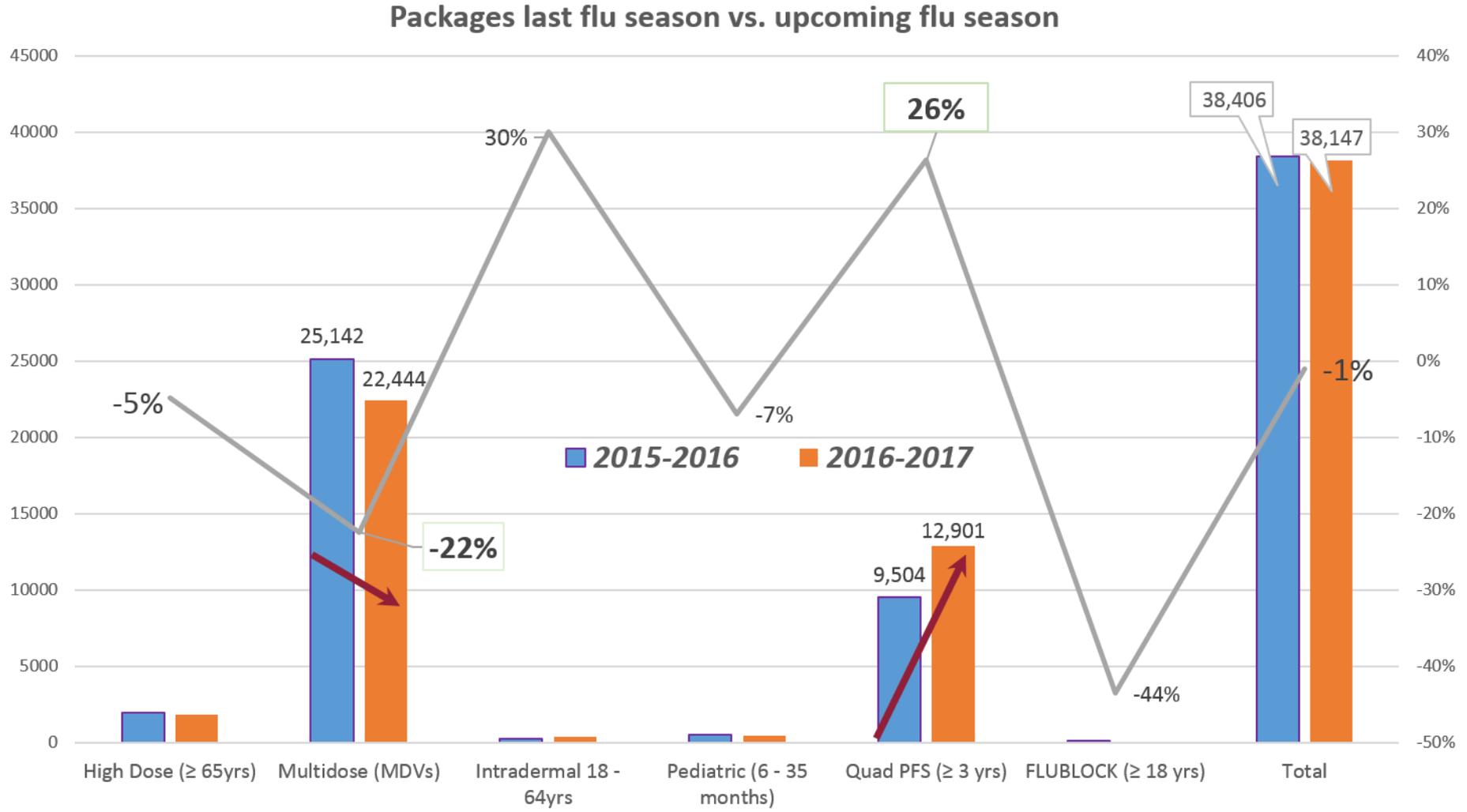
IHS National Supply Service Center
Pharmacy Support Branch
James J. Cummings, PharmD
James.Cummings@ihs.gov

NSSC 2016-17 Influenza Vaccines

Product Name	Dosage Form	NDC	Price/dose
Afluria®	Multi-Dose Vial (MDV) -10 doses/vial Peds/Adult (9 years & older)	33332-0116-10	\$5.49
Fluzone® Quadrivalent	PFS - 0.25mL - 10 doses/package Pediatric (6-35 months)	49281-0516-25	\$17.53
Fluarix® Quadrivalent	PFS – 0.5mL – 10 doses/package Peds/Adult (3 years & older)	58160-0905-52	\$12.78
Fluzone® HD	PFS – High Dose - 10 doses/package	49281-0399-65	\$28.33
Fluzone® ‡ Intradermal	PFS 0.1ml – 10 doses/package	49281-0710-40	\$13.64
Flumist® ‡ Intranasal	PFS 0.2ml – 10 doses/package	<i>Did not offer</i>	N/A
Flublok® ‡	Single Dose Vial – 0.5mL—10 doses/box	42874-0016-10	\$25.04

‡ Vaccine is supplemental to the four contract vaccines and IHS receiving FSS pricing

Seasonal Vaccine Procurement Overview 2025-16 vs. 2016-17



Flu Vaccine Ordering Post-Solicitation

- Contact “Gabe” Wyatt aaron.wyatt@ihs.gov
 - He will forward a Flu 413 Form for ordering
- Submit Seasonal Flu Form 413 to NSSC
 - NSSC may have stock of additional contract vaccine
 - If not NSSC will contact manufacturers to obtain and if authorized, will purchase additional vaccine
 - If contract vaccine not available NSSC will contact additional vendors to find best price
- Occasionally, FSS priced vaccine available through McKesson but no guarantees

Antiviral Ordering & Procurement

- Tamiflu® 75mg Capsules may purchase from NSSC at substantially reduced prices by contacting “Gabe” Wyatt (Aaron.Wyatt@ihs.gov) and he will forward a 413 form
- Complete 413 and fax to “Gabe” (405) 951-6054 or e-mail
- Other dosage forms & strengths available thru McKesson
- Relenza® available thru McKesson Connect

Influenza Antiviral

- **Tamiflu[®] Capsules, 75mg, BT/10 priced at \$19.24 per bottle – Expires April 2017 (part of the Shelf Life Extension Program (SLEP) for on hand Please contact NSSC for purchasing**

NSSC can ship overnight delivery if needed the next day. Typically, we ship 2-3 day ground.