

## 2018-2019 Influenza Kick-Off



# Overview

- Recap of the 2017-18 Influenza Season
- 2018-19 Influenza Vaccine Recommendations
- IHS 2017-18 Influenza Surveillance and Vaccine Coverage
- Update from the IHS National Supply Service Center



# **Update: 2017-18 Influenza Season, 2018-19 ACIP Influenza Vaccination Recommendations, and CDC Influenza Antiviral Recommendations**

Lisa Grohskopf  
Influenza Division, CDC

IHS 2018-2019 Influenza Season Kick-Off  
October 4, 2018

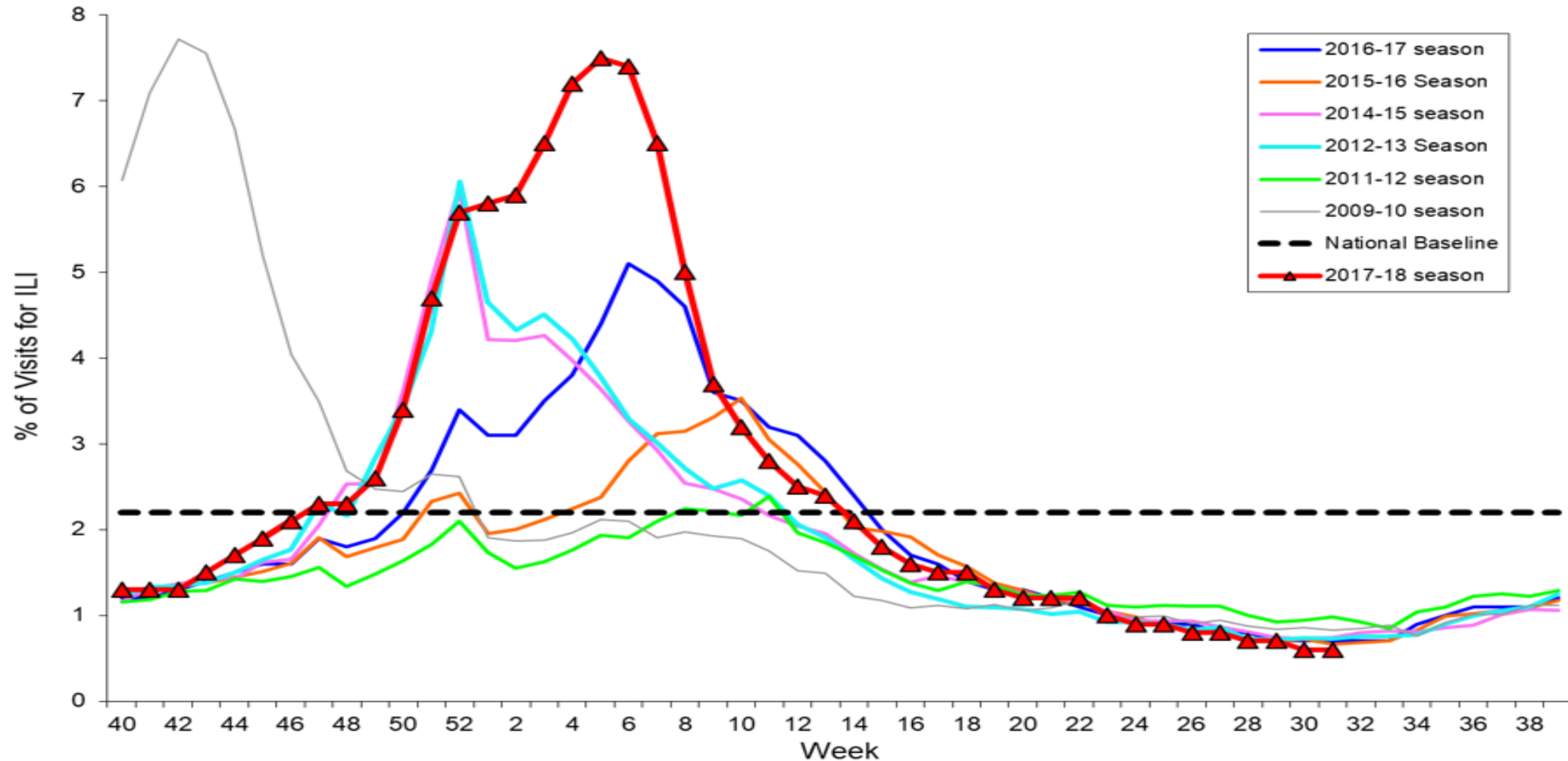
# A Review of Last Season...



- High severity season
  - High levels of outpatient clinic and emergency department visits for ILI
  - High influenza-related hospitalization rates
  - Elevated and geographically widespread activity across the country for an extended period
- Activity began increasing in November and reached an extended period of high activity during January and February
- Influenza A(H3N2) viruses predominated overall
  - Influenza B viruses were reported more frequently than influenza A viruses from early March until mid-June
- The majority of circulating viruses were similar to the cell-grown reference viruses representing the 2017-18 influenza vaccine viruses

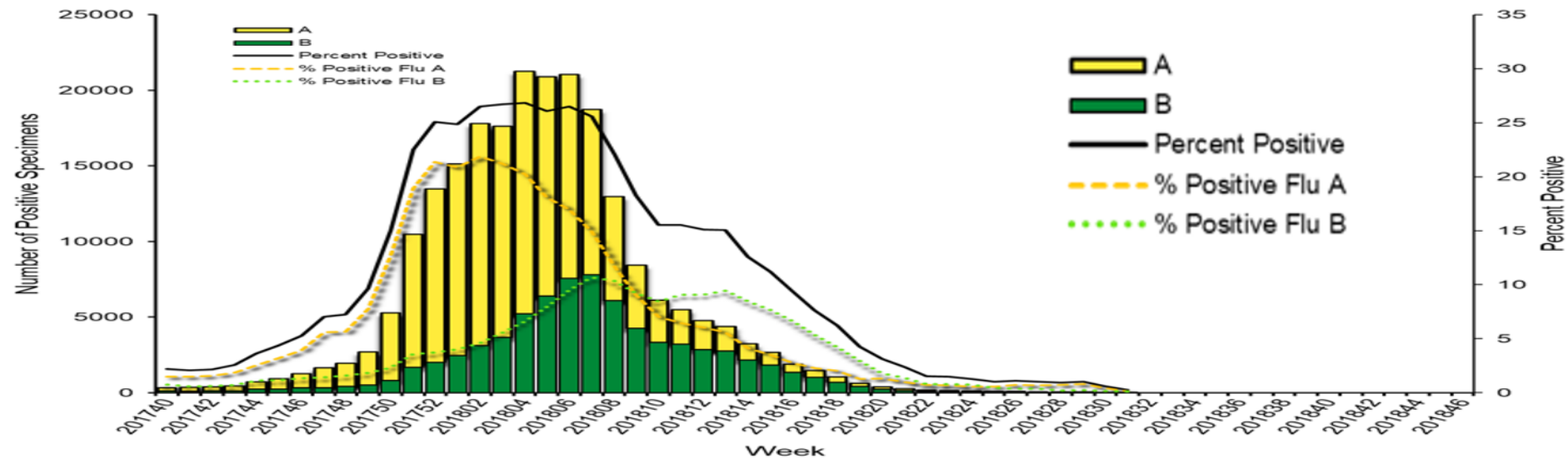
# Percentage of Visits for Influenza-like Illness (ILI)

## Weekly National Summary, 2017-18 & Selected Previous Seasons

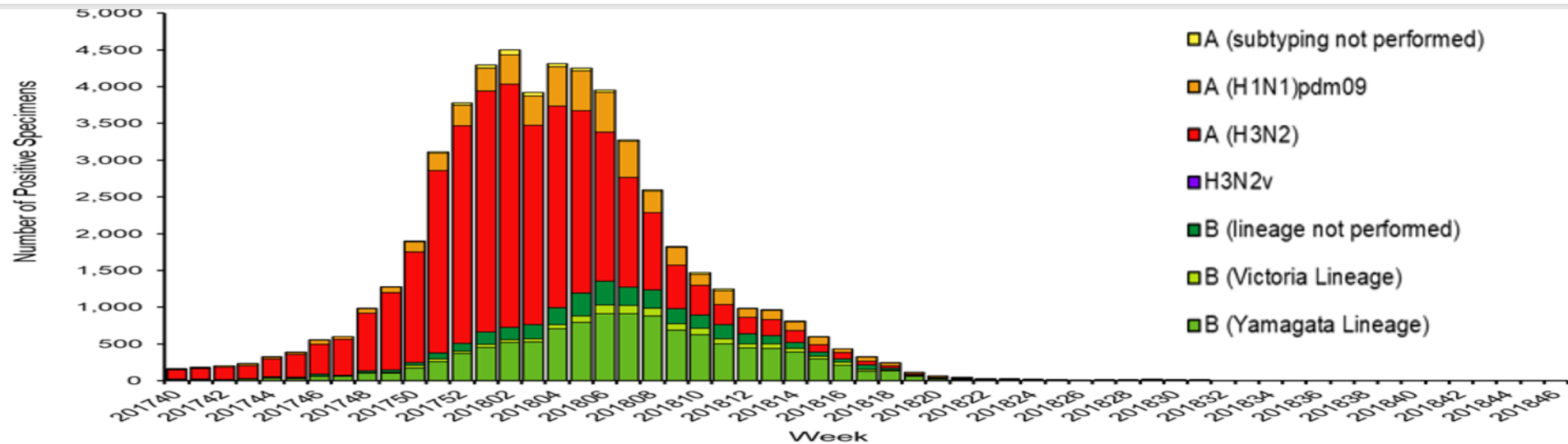


# Influenza Positive Tests Reported to CDC by U.S. Clinical and Public Health Laboratories

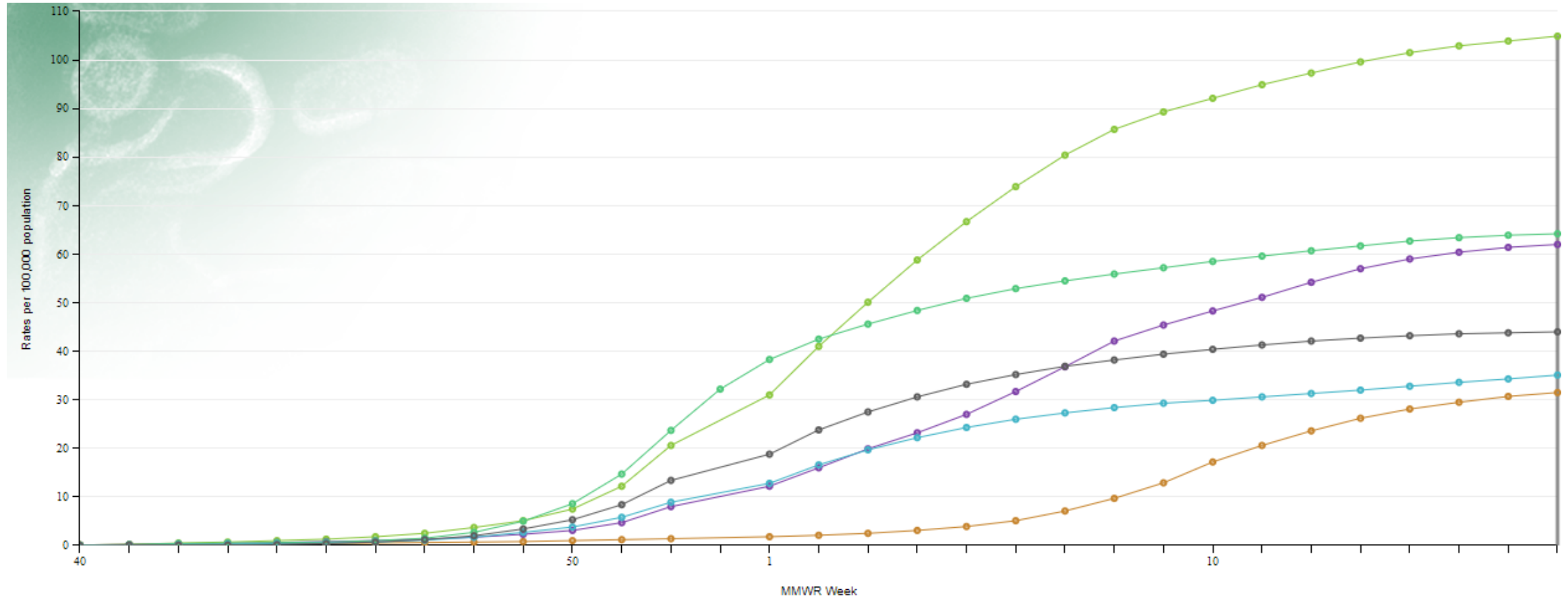
Clinical  
Laboratories



Public Health  
Laboratories



# Laboratory-Confirmed Influenza-Associated Hospitalizations, Cumulative Rate, 2017-18 and Previous 5 Seasons



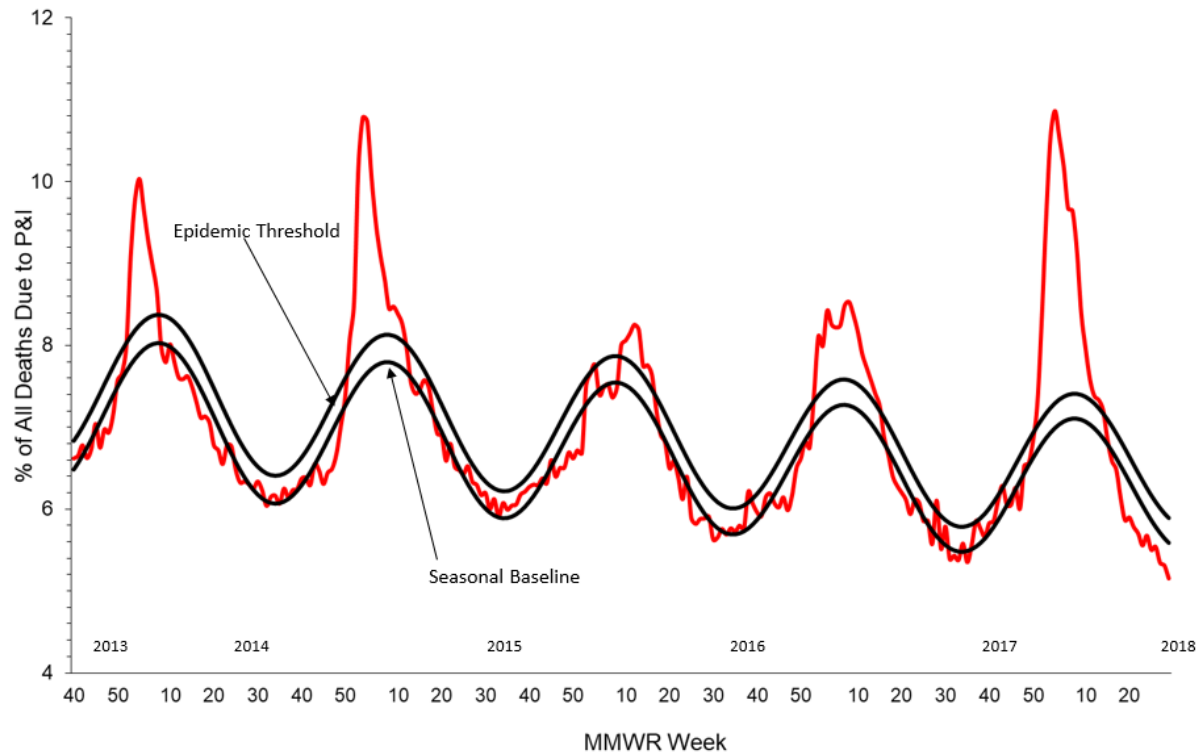
Age group: Overall, Week: 17

Rates per 100,000 by Age Group

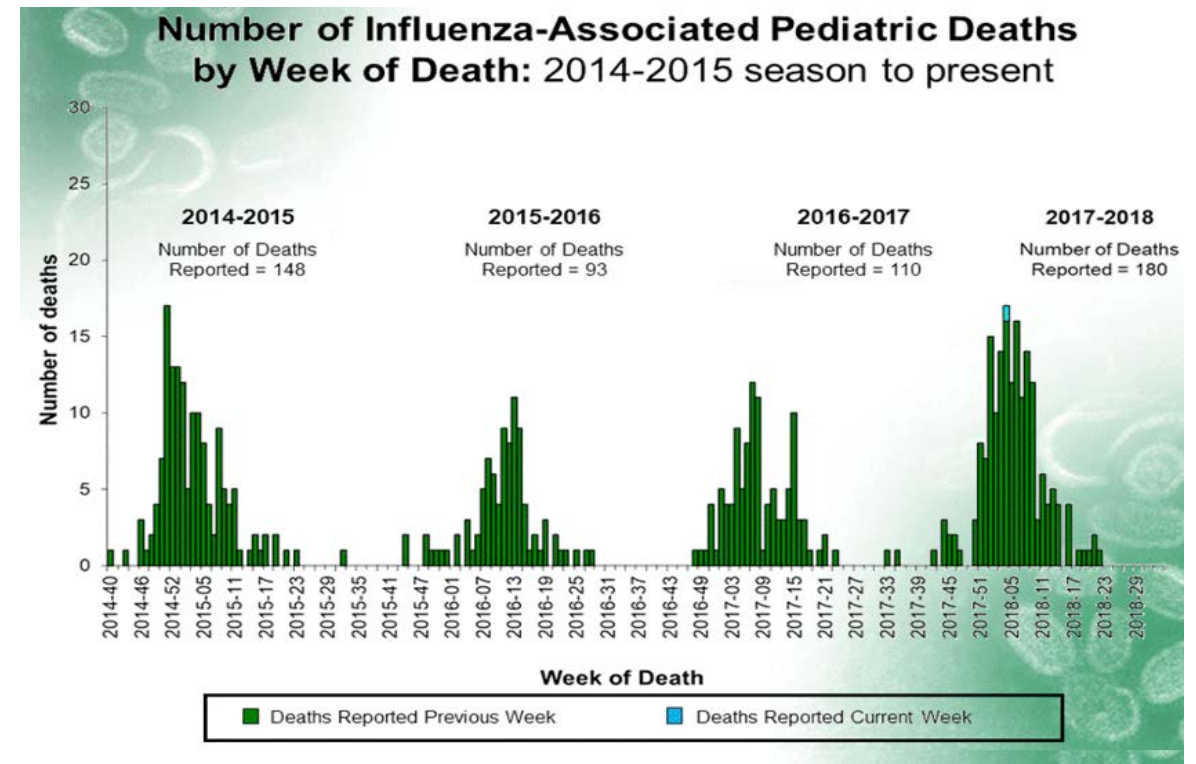
— 2017-18 104.9 — 2016-17 62 — 2015-16 31.5 — 2014-15 64.2 — 2013-14 35.1 — 2012-13 44

# Mortality Surveillance: 2017-18 and Previous Seasons

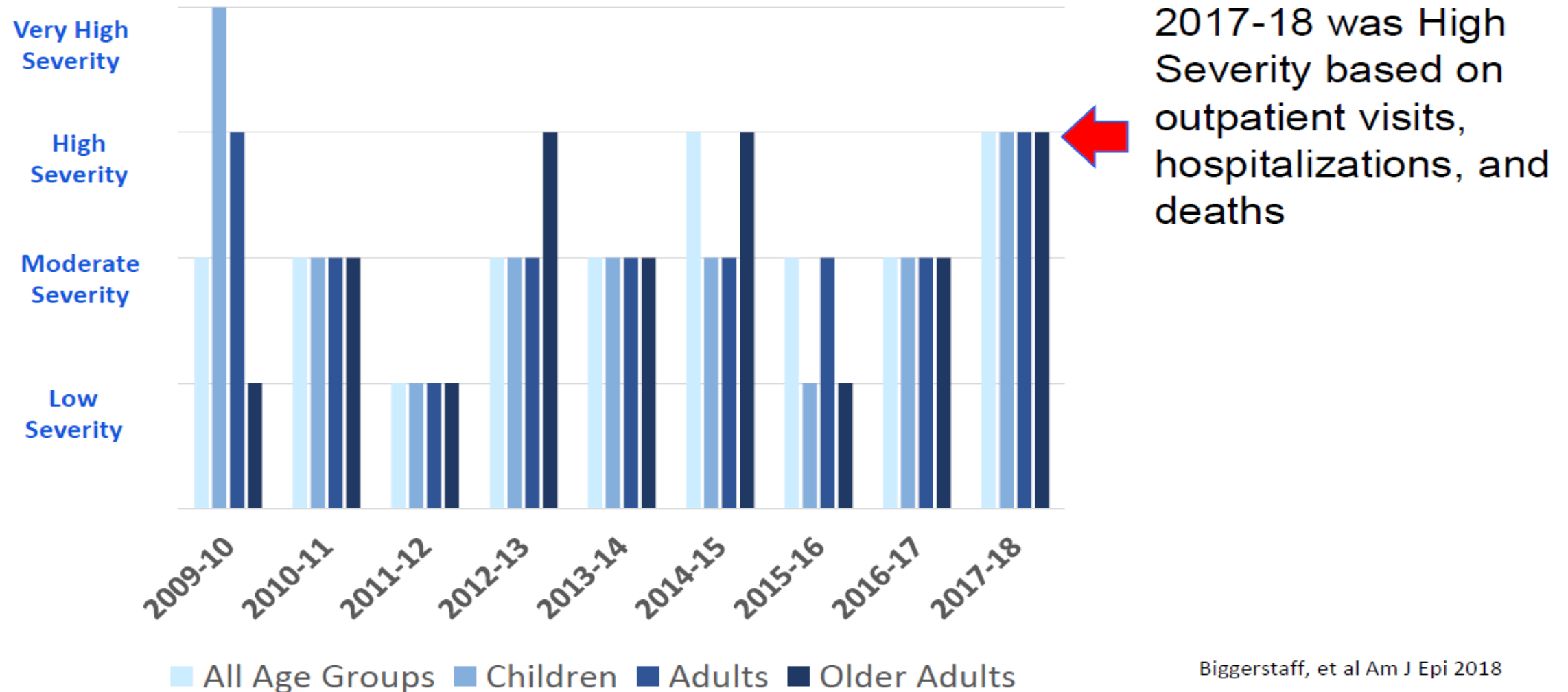
- Pneumonia and Influenza Mortality, National Center for Health Statistics



- Deaths in Children with Laboratory Confirmed Influenza



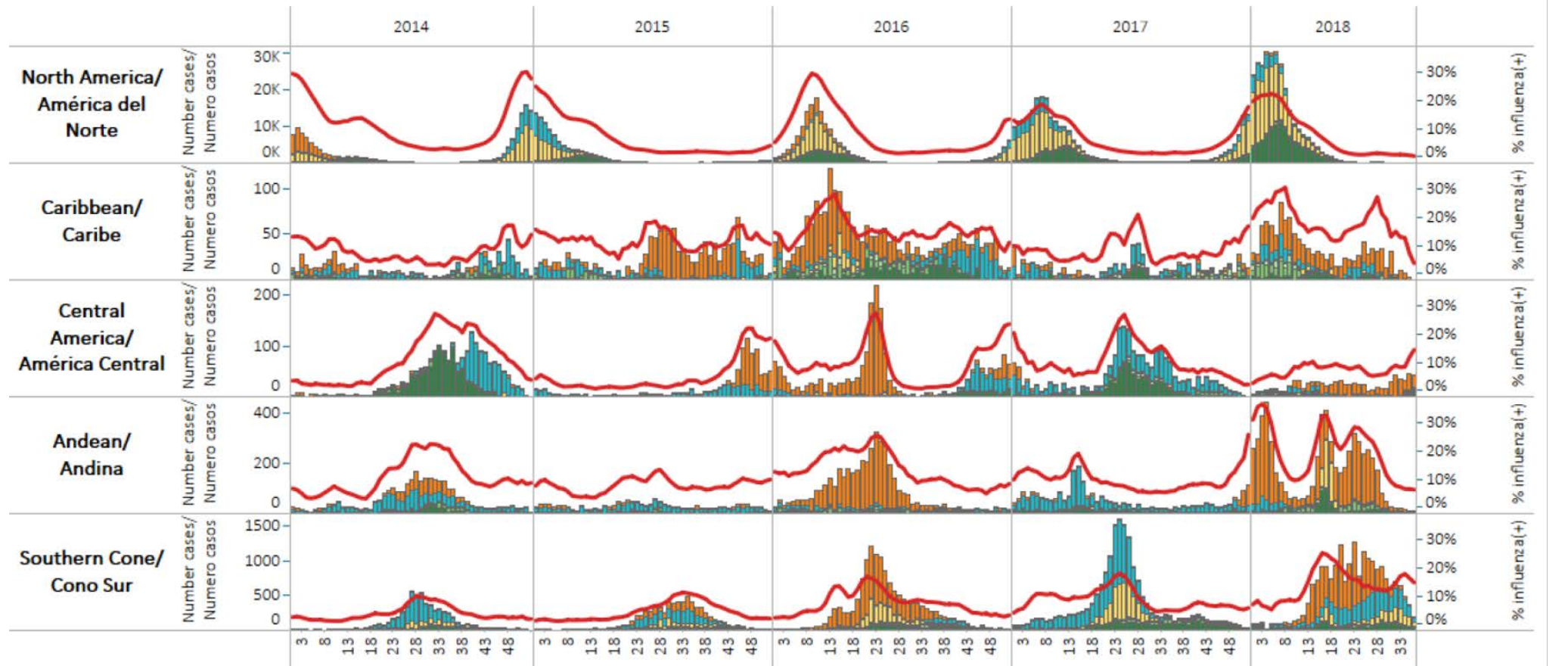
# Season Severity Assessment – By Age Group and Season, 2009-10 through 2017-18



# 2018: Southern Hemisphere

## Influenza circulation by subregion, 2014-18

Distribution of influenza viruses by subregion, 2012-18  
Distribución de virus de influenza por subregión, 2012-18



Data as of September 10, 2018

[https://www.paho.org/hq/index.php?option=com\\_content&view=article&id=3352:influenza-situation-report&Itemid=2469&lang=pt](https://www.paho.org/hq/index.php?option=com_content&view=article&id=3352:influenza-situation-report&Itemid=2469&lang=pt)

# Sources of 2018–19 Influenza Season Data

- Updated surveillance information is available each Friday
  - FluView, static report: <https://www.cdc.gov/flu/weekly/>
  - FluView Interactive, online application:  
<https://www.cdc.gov/flu/weekly/fluviewinteractive.htm>
  
- Vaccine effectiveness estimates
  - Morbidity and Mortality Week Report (MMWR) updates:  
<https://www.cdc.gov/mmwr/index.html>
  - Advisory Committee on Immunization Practices (ACIP) meetings:  
<https://www.cdc.gov/vaccines/acip/meetings/index.html>

# CDC Antiviral Treatment Recommendations

- Antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who is:
  - Hospitalized
  - Has severe, complicated, or progressive illness
  - Is at high risk for influenza complications

# People at High Risk for Influenza Complications for Whom Antiviral Treatment is Recommended

- Children <2 years old (although all children <5 years old are considered at high risk for complications, highest risk is for children <2 years old)
- Adults age 65 years and over
- Pregnant/postpartum women
- Children  $\leq 18$  years old receiving long-term aspirin therapy
- American Indians/Alaska Natives
- People with underlying medical conditions (e.g., pulmonary, cardiac, immunosuppression, neurologic and neurodevelopment conditions)
- Residents of nursing homes/chronic care facilities

# CDC Antiviral Treatment Recommendations

- Antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who is:
  - Hospitalized
  - Has severe, complicated, or progressive illness
  - Is at high risk for influenza complications
- Antiviral treatment can be considered for any previously healthy, symptomatic outpatient not at high risk with confirmed or suspected influenza on the basis of clinical judgment, if treatment can be initiated within 48 hours of illness onset
- Clinical benefit is greatest when antiviral treatment is administered early
- Three FDA-approved antivirals are recommended for use in the United States: oral oseltamivir, inhaled zanamivir, and intravenous peramivir



# 2018-19 ACIP Influenza Vaccination Recommendations Update

# Groups Recommended for Vaccination

- Routine annual influenza vaccination is recommended for all persons **≥6 months of age** who do not have contraindications
- While vaccination is recommended for everyone in this age group, there are some for whom it is particularly important—
  - People aged ≥6 months who are at increased risk of complications and severe illness due to influenza
  - Contacts and caregivers of persons
    - <5 years of age
    - ≥50 years of age
    - with medical conditions that put them at higher risk for severe complications from influenza

# Groups at Increased Risk for Influenza Complications and Severe Illness

- Children aged 6 through 59 months and adults aged  $\geq 50$  years (children under 6 months of age are also at high risk, but cannot be vaccinated);
- Persons with chronic pulmonary (including asthma) or cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
- Immunosuppressed persons;
- Women who are or will be pregnant during the influenza season;
- Children and adolescents (aged 6 months–18 years) who are receiving aspirin- or salicylate-containing medications (who might be at risk for Reye syndrome after influenza virus infection);
- Residents of nursing homes and other long-term care facilities;
- American Indians/Alaska Natives; and
- Persons who are extremely obese (BMI  $\geq 40$ ).

# 2018-19 ACIP Influenza Statement—Updates

- Principal changes and updates for 2018-19
  - Influenza vaccine composition for 2018-19
  - LAIV4 an option for 2018-19
  - Vaccines for egg-allergic persons
  - Two labeling changes for existing vaccines

# 2018-19 Influenza Vaccine Composition

- Trivalent vaccines:
  - an A/Michigan/45/2015 (H1N1)pdm09-like virus;
  - an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus--*updated*;
  - a B/Colorado/06/2017-like virus (Victoria lineage)--*updated*.
- Quadrivalent vaccines:
  - The above three viruses, and
  - a B/Phuket/3073/2013-like virus (Yamagata lineage).

# ACIP LAIV4 Recommendations for 2018-19 (1)

- Can choose any appropriate vaccine (IIV, RIV4\*, or LAIV4)  
(\*RIV4 not licensed for children <18 years)
- LAIV had not been recommended for 2016-17 or 2017-18
  - Low effectiveness vs. influenza A(H1N1)pdm09 among children 2 through 17 yrs during 2013-14 and 2015-16
  - Thought due to poor fitness of the H1N1pdm09 virus in the vaccine
- In February 2018, ACIP reviewed additional data
  - Two analyses of previous seasons' data from observational studies
  - Manufacturer data on shedding and immunogenicity of new H1N1pdm09 vaccine virus indicating improved fitness
- For 2018-19, LAIV4 is an option for those for whom it is appropriate
  - No U.S. VE data yet on new formulation with the new H1N1pdm09

# ACIP LAIV4 Recommendations for 2018-19 (2)

- Difference in ACIP and American Academy of Pediatrics (AAP) recommendations:
  - ACIP makes no preferential recommendations for any one vaccine type when more than one is appropriate;
  - AAP recommends IIV as the primary choice for children.
- Recommendations share the same principle that influenza vaccination is an important preventive strategy for children

# Who Shouldn't Receive LAIV4

- Persons aged <2 years or >49 years (for whom not licensed by FDA)
- Labeled contraindications in package insert:
  - History of severe allergic reaction to any vaccine component\* or to a previous dose of influenza vaccine (like other influenza flu vaccines)  
*\*Note though* that ACIP recommends vaccination of persons with egg allergy: this differs from FDA-approved labeling for most influenza vaccines)
  - Concomitant aspirin- or salicylate-containing therapy in children or adolescents (risk of Reye syndrome)
- ACIP also recommends LAIV not be used in these situations:
  - Pregnancy
  - Immunocompromised persons
  - Children <5 with a history of asthma or wheezing
  - Caregivers and contacts of persons requirement a protected environment
  - Persons who have received influenza antivirals within previous 48 hours

# Precautions to use of LAIV4

- **Some similar to other influenza vaccines:**
  - Moderate or severe illness with or without fever
  - Guillain-Barré syndrome within 6 weeks following a previous dose of influenza vaccine
- **Additional precautions specific to LAIV4**
  - Asthma in persons aged 5 and older
  - Other medical conditions that predispose to increased risk of severe influenza illness e.g., other chronic pulmonary diseases; cardiovascular disease (excluding isolated hypertension); renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);

# Influenza Vaccination of Persons with Egg Allergy

- Mostly unchanged, except that LAIV4 is an option
- Egg allergic persons can receive any licensed, recommended vaccine that is otherwise appropriate (IIV, RIV4, or LAIV4)—for children, IIV or LAIV4
- With history of severe allergic reaction to egg (any symptom other than hives), vaccine should be administered in an inpatient or outpatient medical setting, supervised by a health care provider able to recognize and manage severe allergic conditions.
  - **NOTE:** *Here ACIP differs from FDA-approved labeling for most IIVs and LAIV, for which severe egg allergy is a contraindication*
- No specific post-vaccination observation period recommended
  - ACIP General Best Practices guidelines: providers should consider observing recipients of any vaccine for 15 minutes to avoid injury due to syncope

# Licensure Changes Since Publication of 2017-18 ACIP Statement

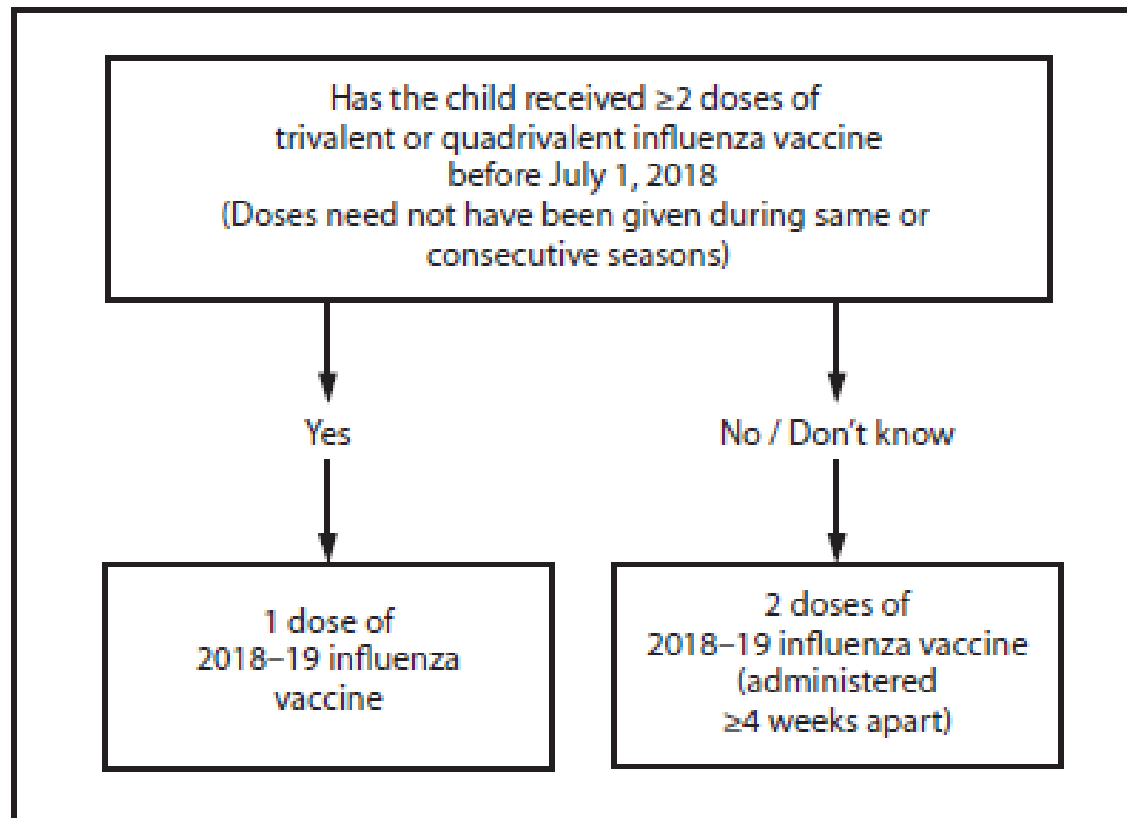
- **Afluria Quadrivalent (Standard-dose IIV4, Seqirus)**
  - Licensed in August 2016, for  $\geq 18$  years
  - In August 2017, expanded to  $\geq 5$  years
  - Like Afluria (IIV3, also available this season), can be administered via jet injector (the Pharmajet Stratis), but only for ages 18 through 64 years
- **Fluarix Quadrivalent (Standard-dose IIV4, GSK)**
  - Previously licensed for  $\geq 3$  years; in January 2018 expanded to  $\geq 6$  months
  - One of three IIVs approved for children 6 through 35 months of age
  - Dose volume is same for all ages (0.5mL)

# Inactivated Influenza Vaccines (IIVs) for 6- through 35-month-olds

- Two potential points of confusion
  - Three licensed products, but the **dose volumes differ**:
    - Fluarix Quadrivalent: 0.5mL
    - FluLaval Quadrivalent: 0.5 mL
    - Fluzone Quadrivalent: 0.25 mL
  - **Dose volume** is distinct from **number of doses** needed:
    - For example, a first time vaccine who is 1 year old
    - and who gets 0.5mL FluLaval Quadrivalent for a first dose—
    - *Still* needs a second dose of influenza vaccine,  $\geq 4$  weeks later

# Number of Doses for Ages 6 Months through 8 Years

FIGURE. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2018–19 influenza season



- Approach is same as last season
- Children in this age group who have not had  $\geq 2$  doses of trivalent or quadrivalent vaccine before July 1, 2018 need two doses in 2018-19.
- Previous doses can be from different/non-consecutive seasons.
- If two doses needed for 2018-19, should be given  $\geq 4$  weeks apart.

# Additional CDC Resources

- CDC Influenza homepage: <https://www.cdc.gov/flu/>
- Influenza surveillance: <https://www.cdc.gov/flu/weekly/fluactivitysurv.htm>
- Influenza vaccination coverage: <https://www.cdc.gov/flu/fluview/index.htm>
- For Professionals: <https://www.cdc.gov/flu/professionals/index.htm>
  - Vaccination homepage: <https://www.cdc.gov/flu/professionals/vaccination/index.htm>
  - 2017-18 ACIP Influenza Recommendations:
    - <https://www.cdc.gov/mmwr/volumes/66/rr/rr6602a1.htm>
    - Antiviral homepage: <https://www.cdc.gov/flu/professionals/antivirals/index.htm>
- For Children (created by CDC and endorsed by the AAP): activity book
  - [https://www.cdc.gov/phpr/readyrigley/documents/readyrigley\\_flu.pdf](https://www.cdc.gov/phpr/readyrigley/documents/readyrigley_flu.pdf)



# Thank You!

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



# IHS Influenza Awareness System (IIAS) 2017-2018 Recap

**GREAT PLAINS TRIBAL CHAIRMEN'S HEALTH BOARD**

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

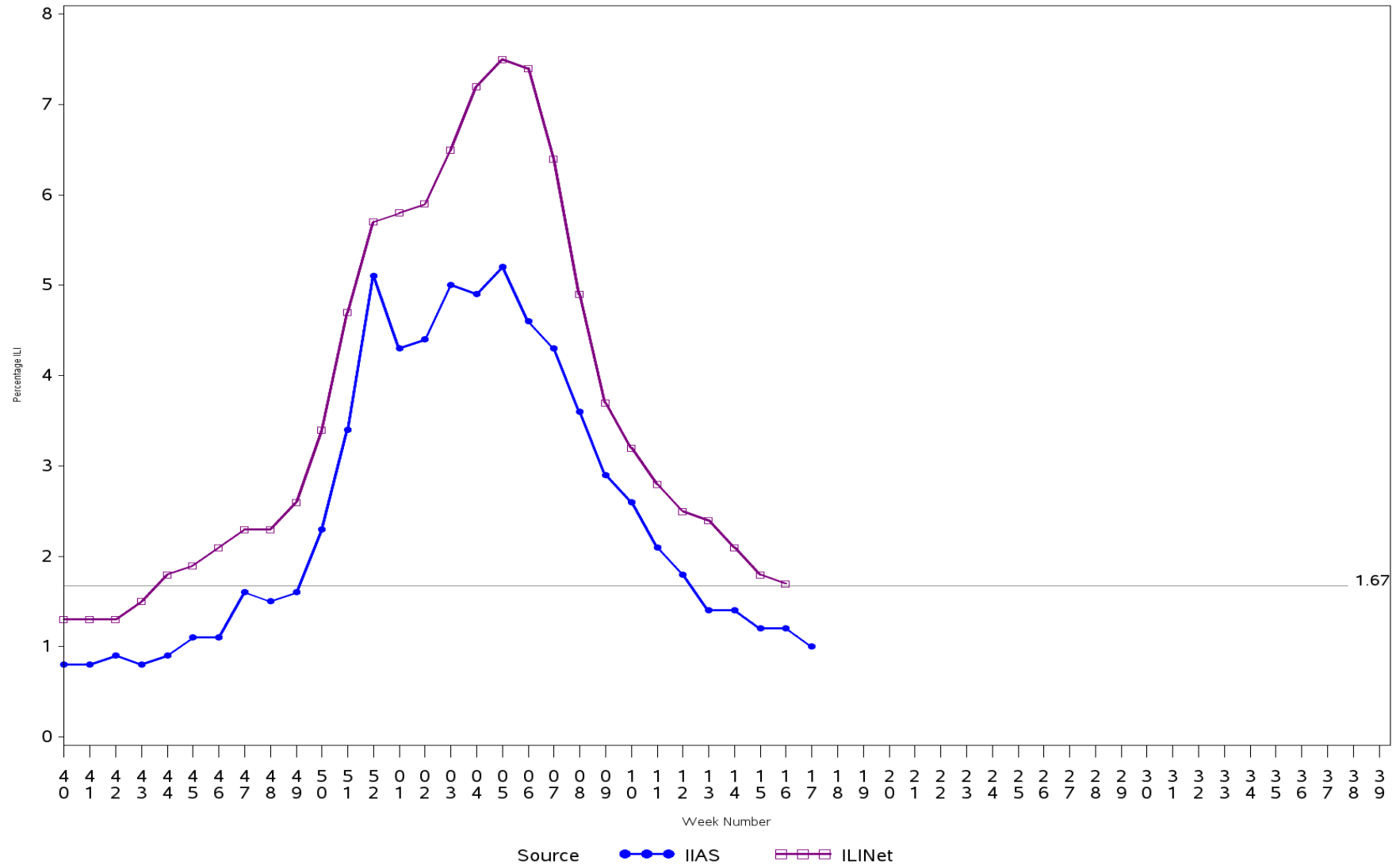
As Native American people, we need to keep our circle protected and strong.  
It is up to **EACH AND EVERY ONE OF US** to make sure that our loved ones are protected from the dangers of the flu.  
**GET YOUR FLU VACCINE TODAY.**  
Check out [cdc.gov/flu](http://cdc.gov/flu) for more information.

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.

**GREAT PLAINS TRIBAL CHAIRMEN'S HEALTH BOARD**  
NORTHERN PLAINS TRIBAL EPIDEMIOLOGY CENTER

1779 Broad Road, Rapid City, SD 57702—(7) 606.721.1923—(7) 606.721.1930—[www.gpchb.org](http://www.gpchb.org)

Percentage of Outpatient Visits for Influenza-Like Illness (ILI)  
IIAS vs. ILINet  
10/01/17 to 04/28/2018

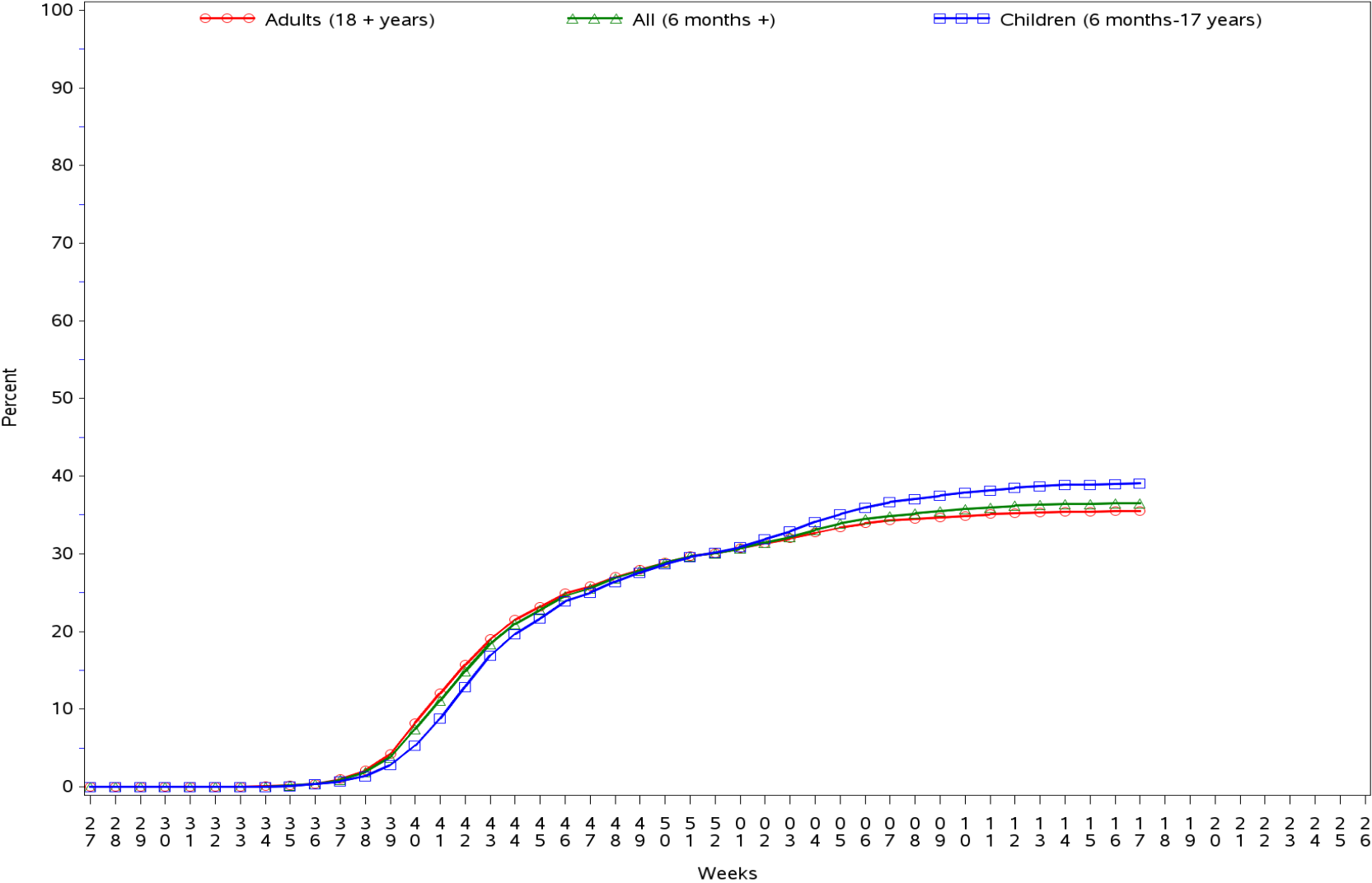


All IHS Areas

Cumulative One-Dose Seasonal Influenza Vaccine Coverage

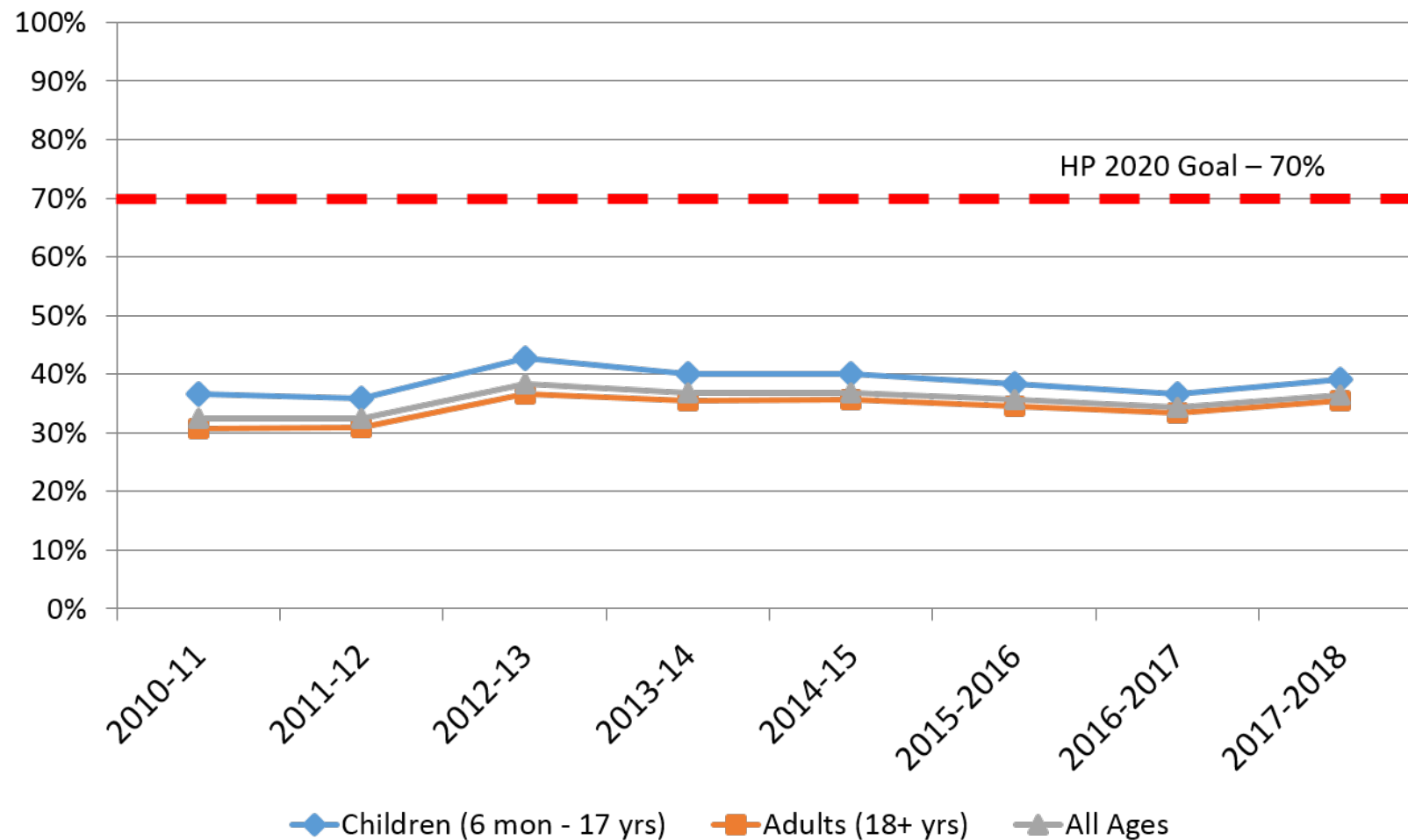
07/02/17 to 04/28/18

Active Clinical Population

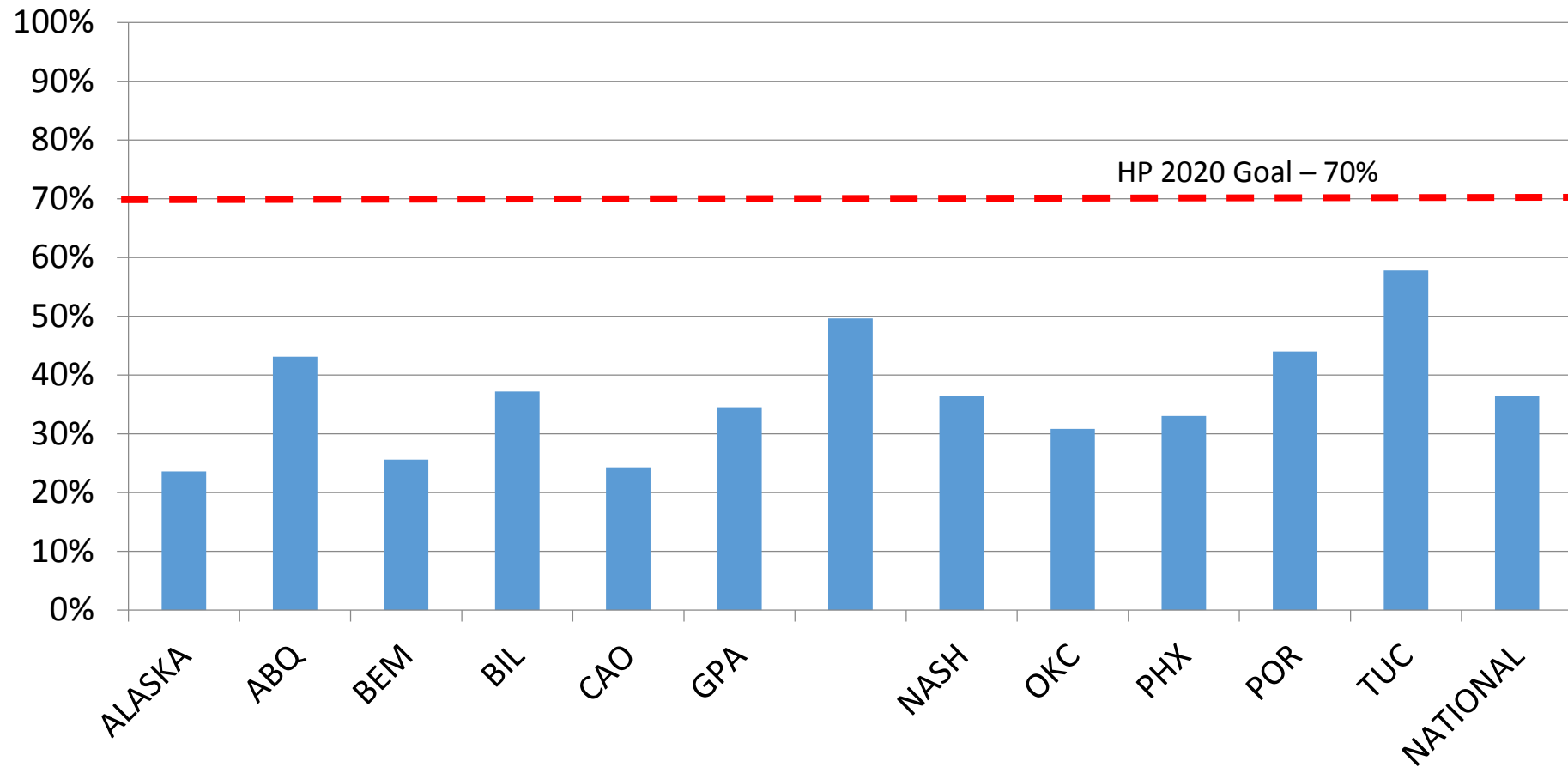


Data Source: IHS Influenza Awareness System, Data as of April 28, 2018

# IHS Influenza Vaccine Coverage 1 dose, All Ages ( $\geq 6$ months)



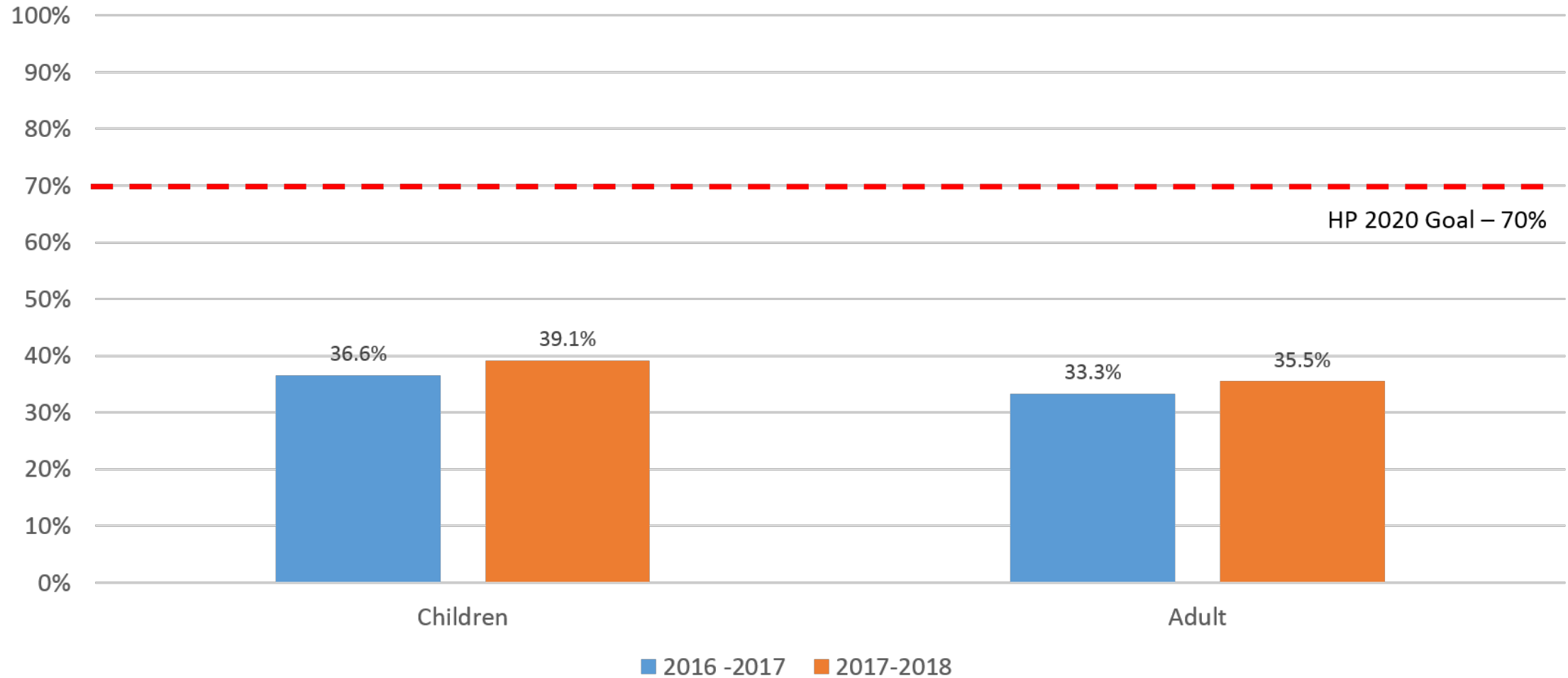
# Seasonal Influenza Vaccine Coverage All Ages (6 Months and older) 2017-2018 flu season



Data Source:  
IHS Influenza Awareness System; Data as of April 28, 2018

N = IAS: 942,889 patients (231 facilities)  
NIRS: 584,008 patients (146 facilities)

# IIAS IHS Influenza Vaccine Coverage Children and Adults 2017-2018

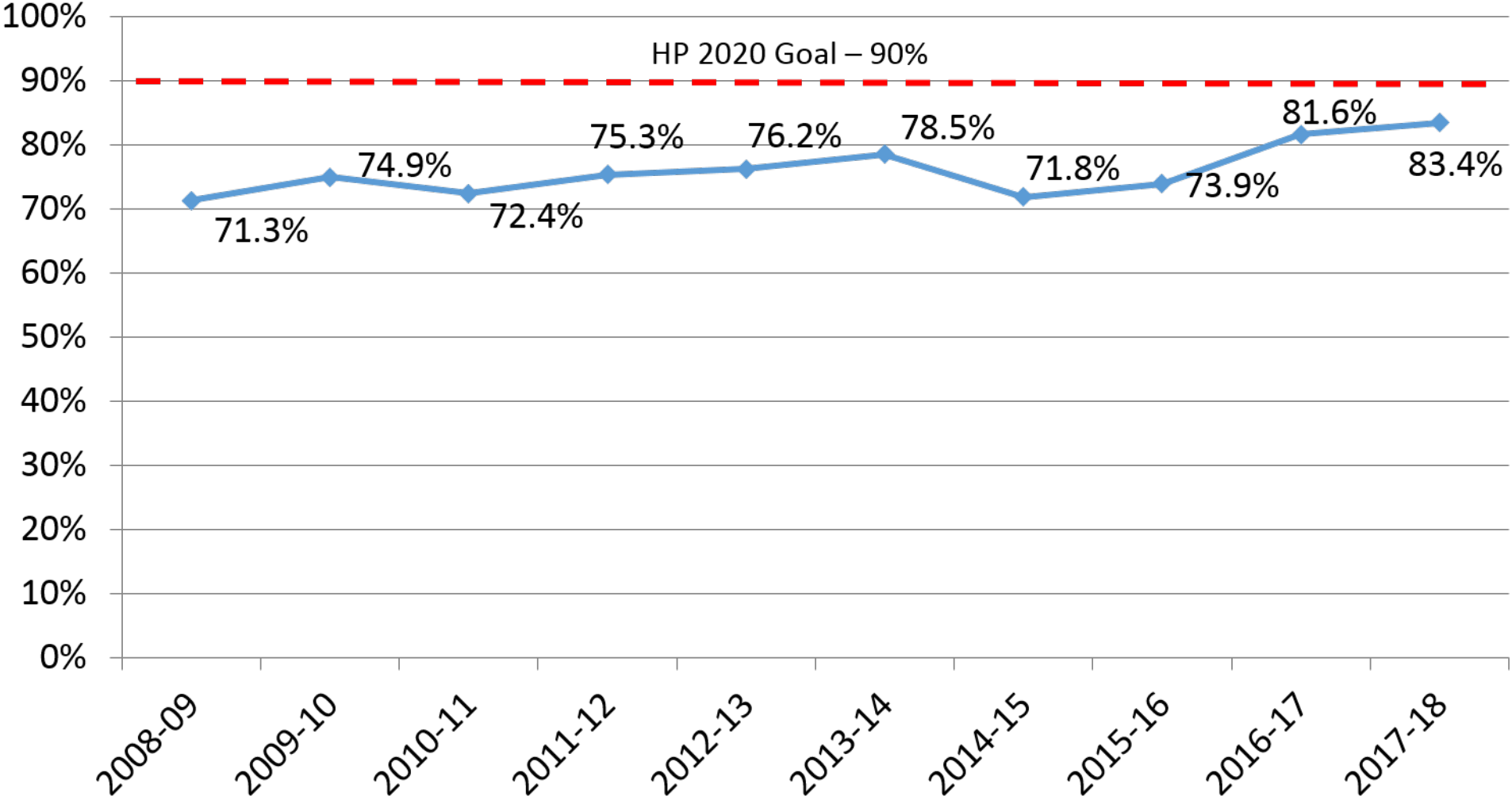


# IHS Mandatory Seasonal Influenza Immunizations for Health Care Personnel Policy

- “All Civil Service employees, contract staff, temporary employees, students, and volunteers who work in an IHS health care facility, must receive a seasonal influenza vaccination by October 31 of each year or have on file a valid medical or religious exemption.”
  - Applies to all bargaining unit employees (BUE) in the LIUNA and NFFE unions, and to all non-bargaining unit IHS employees working in IHS facilities.
  - Indian Health Service Circular 2016-04 - [https://www.ihs.gov/ihtm/index.cfm?module=dsp\\_ihtm\\_circ\\_main&circ=ihtm\\_circ\\_1604](https://www.ihs.gov/ihtm/index.cfm?module=dsp_ihtm_circ_main&circ=ihtm_circ_1604).

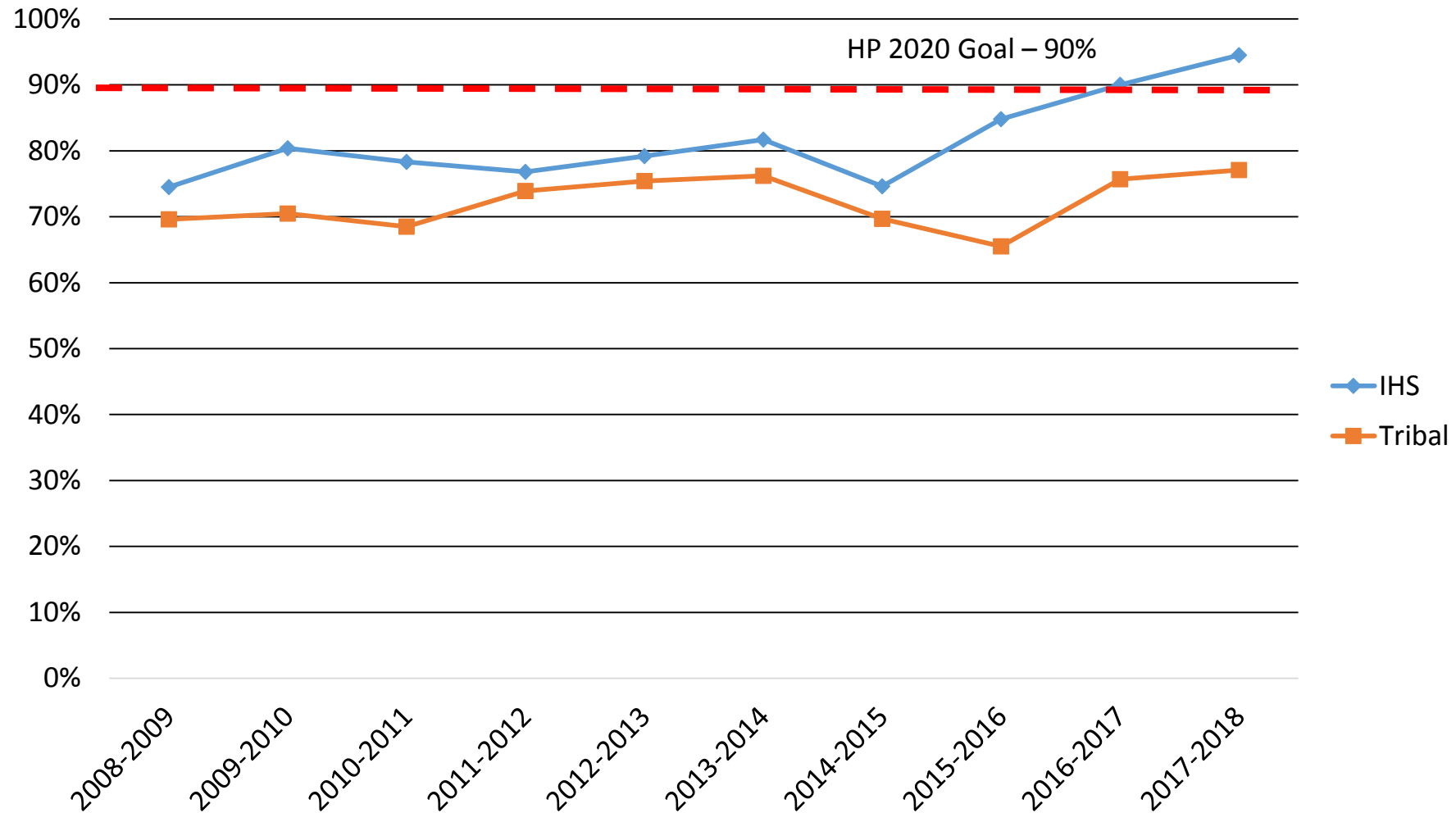
# IHS Health Care Personnel Influenza Vaccine Coverage

## All IHS/Tribal/Urban Facilities



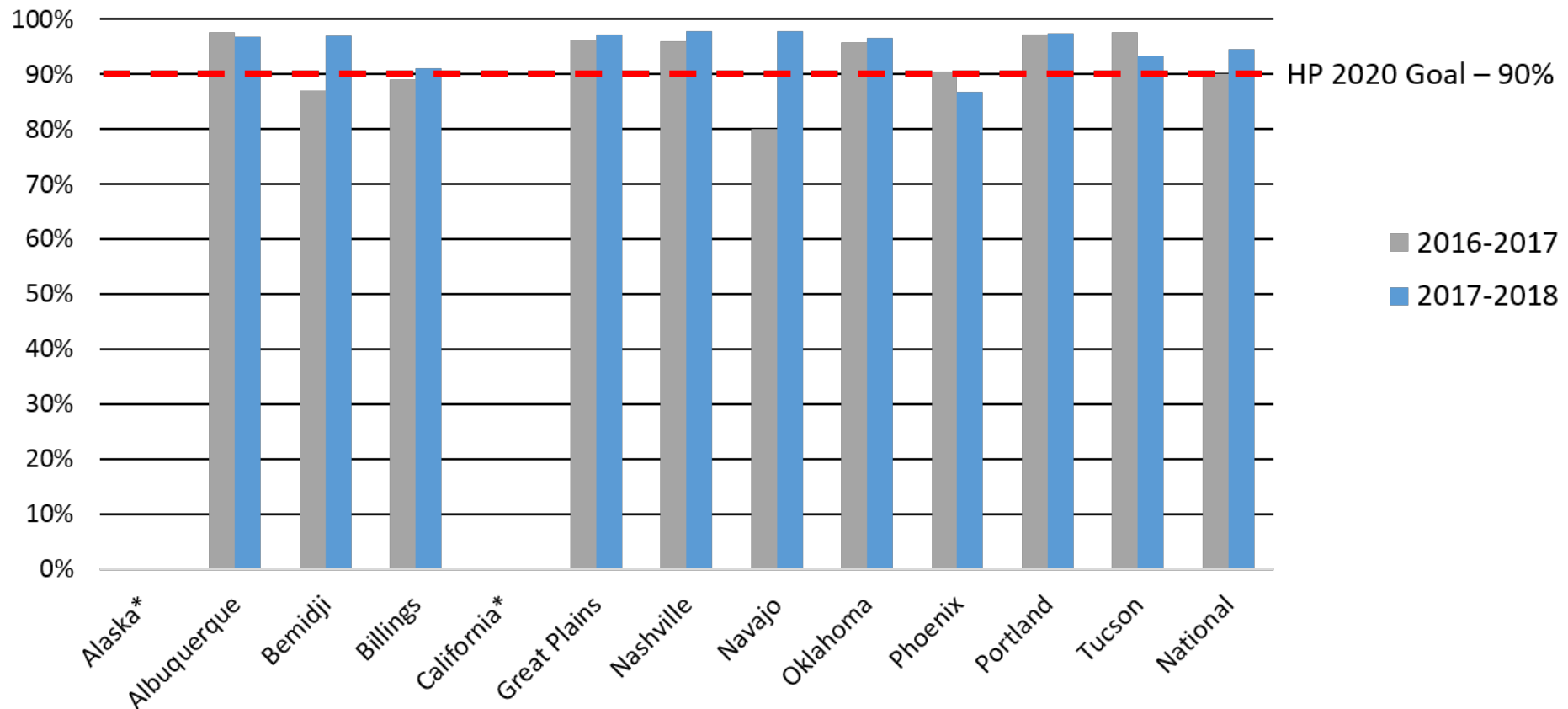
Data as of March 31<sup>st</sup>, 2017; IHS National Immunization Reporting System

# Health Care Personnel Influenza Vaccine Coverage IHS and Tribal Facilities



Data Source: National Immunization Reporting System, Data as of March 31, 2018

# HCP Influenza Vaccine Coverage IHS Facilities Only



\* No IHS facilities

Data Source: National Immunization Reporting System  
Data as of March 31, 2018

N = 2016-2017; 16,220 HCP (64 facilities)  
2017-2018; 14,486 HCP (56 facilities)

# Influenza Vaccine Coverage Summary

- Little change in influenza vaccine coverage
  - IHS patients
- Influenza vaccine coverage remains below Healthy People 2020 goal for children and adults
  - HP 2020 goal: 70% for children and adults
- Health Care Personnel working in IHS facilities
  - HP 2020 Goal of 90% MET!
  - 9 IHS Areas achieved 90% coverage in their IHS facilities!
  - Mandatory policy may have helped

RPMS Updates

# 2018-2019 Influenza Vaccine Codes in RPMS

CVX Code	Full vaccine name (CDC abbreviation)	RPMS Short Name	Brand	Manufacturer	Presentation	Age Indication	Dose
<b>Trivalent Inactivated Vaccines (IIV3) Available for 2018-2019 Season</b>							
135	Influenza, high dose seasonal, preservative-free	FLU-HIGH	Fluzone® High Dose	Sanofi Pasteur	0.5 ml prefilled syringe	≥65yrs	0.5 ml
140	Influenza, seasonal, injectable, preservative free, trivalent	FLU-IIV3pf	Afluria®	Seqirus	0.5 ml prefilled syringe	≥5yrs	0.5 ml
141	Influenza, seasonal, injectable, trivalent	FLU-IIV3	Afluria®	Seqirus	5.0 ml multidose vial	≥5 yrs	0.5 ml
168	influenza, trivalent, adjuvanted	FLU-IIV3ad	Fluad®	Seqirus	0.5 ml prefilled Syringe	≥65yrs	0.5 ml
<b>Quadrivalent Inactivated Vaccines (IIV4) Available for 2018-2019 Season</b>							
150	Influenza, injectable, quadrivalent, preservative free	FLU-IIV4pf	Fluarix® Quadrivalent	GSK	0.5 ml prefilled syringe	≥6 mos	0.5 ml
			FluLaval® Quadrivalent	ID Biomedical Corp. of Quebec	0.5 ml prefilled syringe	≥6 mos	0.5 ml
			Fluzone® Quadrivalent	Sanofi Pasteur	0.5 ml prefilled syringe or single dose vial	≥3 yrs	0.5 ml
			Afluria® Quadrivalent	Seqirus	0.5 ml Prefilled syringe	≥5 yrs	0.5 ml
158	Influenza, injectable, quadrivalent	FLU-IIV4	FluLaval® Quadrivalent	ID Biomedical Corp. of Quebec	5.0 ml multidose vial	≥6 mos	0.5 ml
			Fluzone® Quadrivalent	Sanofi Pasteur	5.0 ml multidose vial	≥6 mos	0.25 ml or 0.5 ml
			Afluria® Quadrivalent	Seqirus	5.0 ml multidose vial	≥5 yrs	0.5 ml
161	Influenza, injectable, quadrivalent, preservative free, pediatric, 0.25 ml	FLU-PEDIV4	Fluzone® Quadrivalent	Sanofi Pasteur	0.25 ml prefilled Syringe	6-35 mos	0.25 ml
171	Influenza, injectable, MDCK, preservative free, quadrivalent	FLU-ccl4pf	Flucelvax® Quadrivalent	Seqirus	0.5 ml prefilled syringe	≥4 yrs	0.5 ml
185	influenza, recombinant, quadrivalent, injectable, preservative free	FLU-RIV4	FluBlok® Quadrivalent	Protein Sciences	0.5 ml prefilled syringe	≥18 yrs	0.5 ml
186	Influenza, injectable, MDCK, quadrivalent	FLU-ccl4	Flucelvax® Quadrivalent	Seqirus	5.0 ml multidose vial	≥4 yrs	0.5 ml
<b>Quadrivalent Live Attenuated Virus Vaccines (LAIV4)</b>							
149	influenza, live, intranasal, quadrivalent (LAIV4)	FLU-LAIV4	FluMist®	MedImmune	0.2 ml Single dose prefilled nasal spray	2-49 yrs	0.2 ml
<b>Codes that should ONLY be used to record vaccines given elsewhere, if formulation is unknown</b>							
88	influenza virus vaccine, unspecified formulation	FLU-NOS	None	None			
<b>Codes that should not be used this influenza season - Inactivate them in your vaccine table</b>							
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) (cclIV3)	FLU-cclIV3					
155	Seasonal, trivalent, recombinant, injectable influenza vaccine, preservative free (RIV)	FLU-RIV3	FluBlok®				
160	Influenza A monovalent (H5N1), ADJUVANTED-2013	H5N1, adj	Influenza A (H5N1) -2013				
166	Influenza, intradermal, quadrivalent, preservative free	FLU-DERM4	Fluzone® Intradermal Quadrivalent				

Available at [www.ih.gov/flu](http://www.ih.gov/flu), under ‘Provider Resources’

# 2018-2019 Seasonal Influenza Vaccine and Antiviral Procurement

IHS National Supply Service Center  
Pharmacy Support Branch  
Karsten T. Smith, PharmD  
[Karsten.Smith@ihs.gov](mailto:Karsten.Smith@ihs.gov)

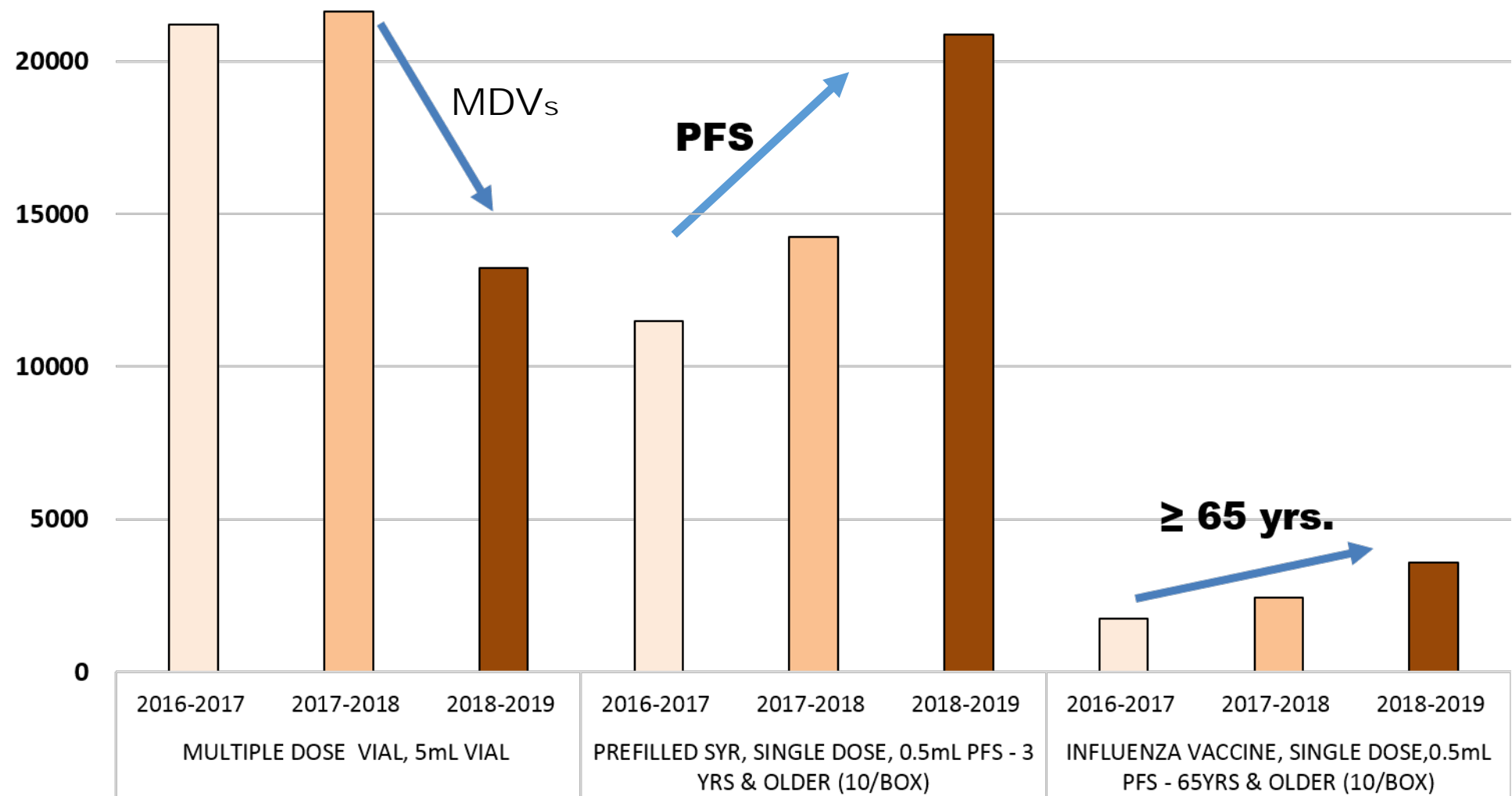
# NSSC—2018-2019 Influenza Vaccines

Product Name	Dosage Form	NDC	Price/dose
<b>Afluria® MDV</b> Quadrivalent	Multi-Dose Vial (MDV) -10 doses/vial Peds/Adult (5 years & older)	33332-0418-10	<b>\$10.83</b>
<b>Fluzone®</b> Quadrivalent	PFS - 0.25mL - 10 doses/package Pediatric (6-35 months)	49281-0518-25	\$12.00
<b>Fluzone®</b> Quadrivalent	PFS – 0.5mL – 10 doses/package Peds/Adult (3 years & older)	49281-0418-50	\$12.00
<b>Fluad®</b> adjuvanted vaccine	PFS – 65 yrs. & older - 10 doses/package	70461-0018-01	\$25.27
*			
<b>Flublok®‡</b>	Single Dose Vial – 0.5mL—10 doses/box	42874-	\$32.04

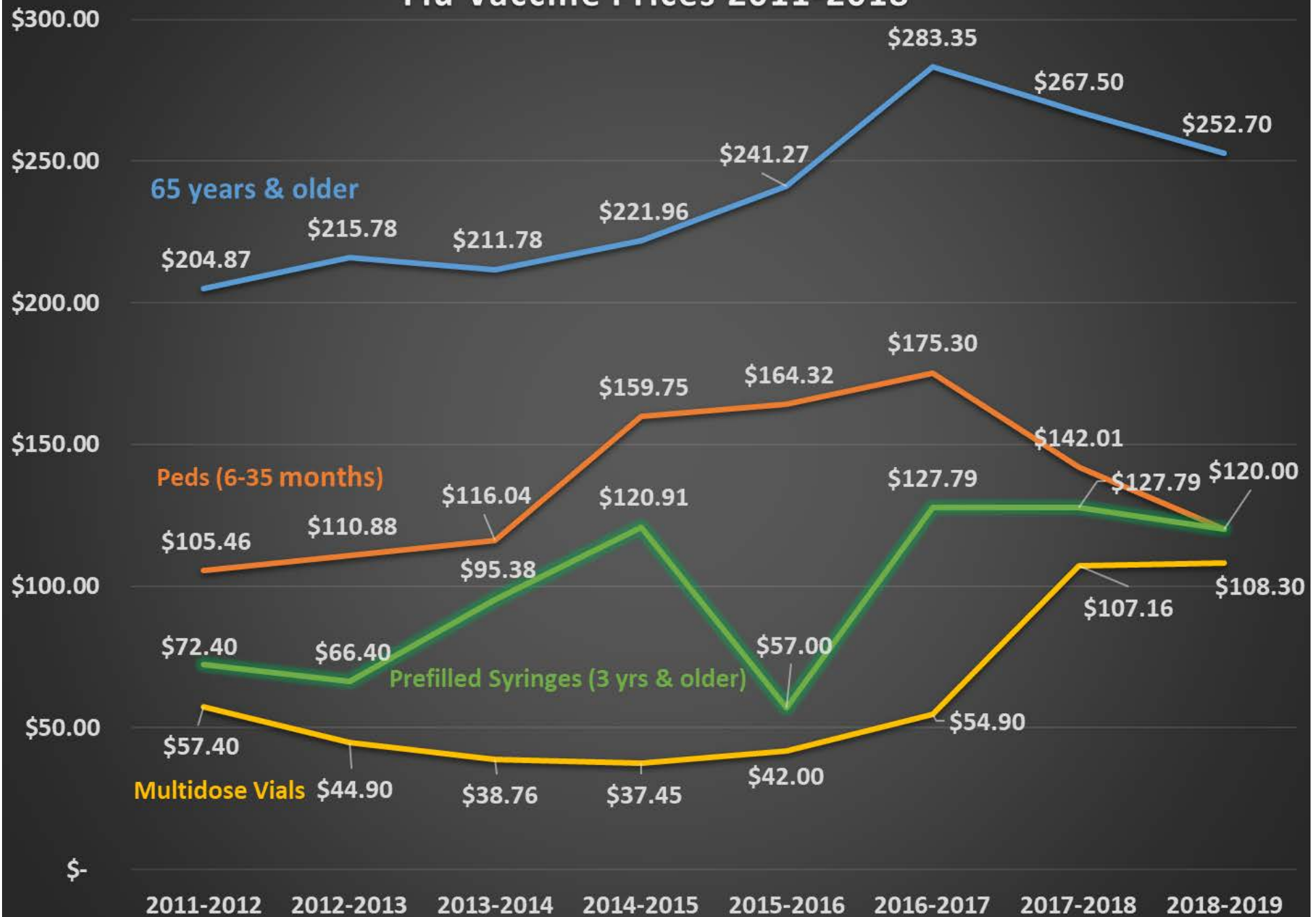
‡ Vaccine is supplemental to the four contract vaccines and IHS receiving FSS pricing

✓ Delivery: 50% by **September 15<sup>th</sup>**, remaining 50% by October 15<sup>th</sup>

# Trends in Influenza Vaccine Purchases by NSSC customers



## Flu Vaccine Prices 2011-2018



# Flu Vaccine Ordering Post-Solicitation

- Contact “Gabe” Wyatt [aaron.wyatt@ihs.gov](mailto: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 receive free from NSSC just pay shipping. Contact: “Gabe” Wyatt ([Aaron.Wyatt@ihs.gov](mailto: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 \$0.00 per bottle – Expires June 2019 (part of the Shelf Life Extension Program (SLEP) for on hand Please contact NSSC for details.**

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

# Thank you!

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