What's New for the 2016-2017 Flu Season: Recommendations for Children

Clinician Outreach and Communication Activity (COCA) Call

October 27, 2016

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Objectives

At the conclusion of this session, the participant will be able to:

- Describe strategies to prepare for the 2016-2017 influenza season
- Identify key recommendations in the AAP influenza policy statement
- Discuss vaccine effectiveness
- Clarify recommendations related to live attenuated influenza vaccine
- Explain the importance of antiviral medications in the control of influenza
- Discuss flu vaccine and egg allergic children

Today's First Presenter

Lisa Grohskopf, MD, MPH
Medical Officer
National Center for Immunization and Respiratory Diseases – Influenza Division
Centers for Disease Control and Prevention

Today's Second Presenter

Henry (Hank) Bernstein, DO, MHCM, FAAP
Professor of Pediatrics
Influenza Division
Hofstra Northwell - LIJ School of Medicine

2016-17 ACIP Influenza Vaccination Recommendations Update

Lisa Grohskopf

Influenza Division, CDC

October 27, 2016

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
    - Fluad
    - Flucelvax Quadrivalent
  - Changes to egg allergy recommendations

- **Some new product licensures since publication**
  - Afluria Quadrivalent
  - Flublok Quadrivalent

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."

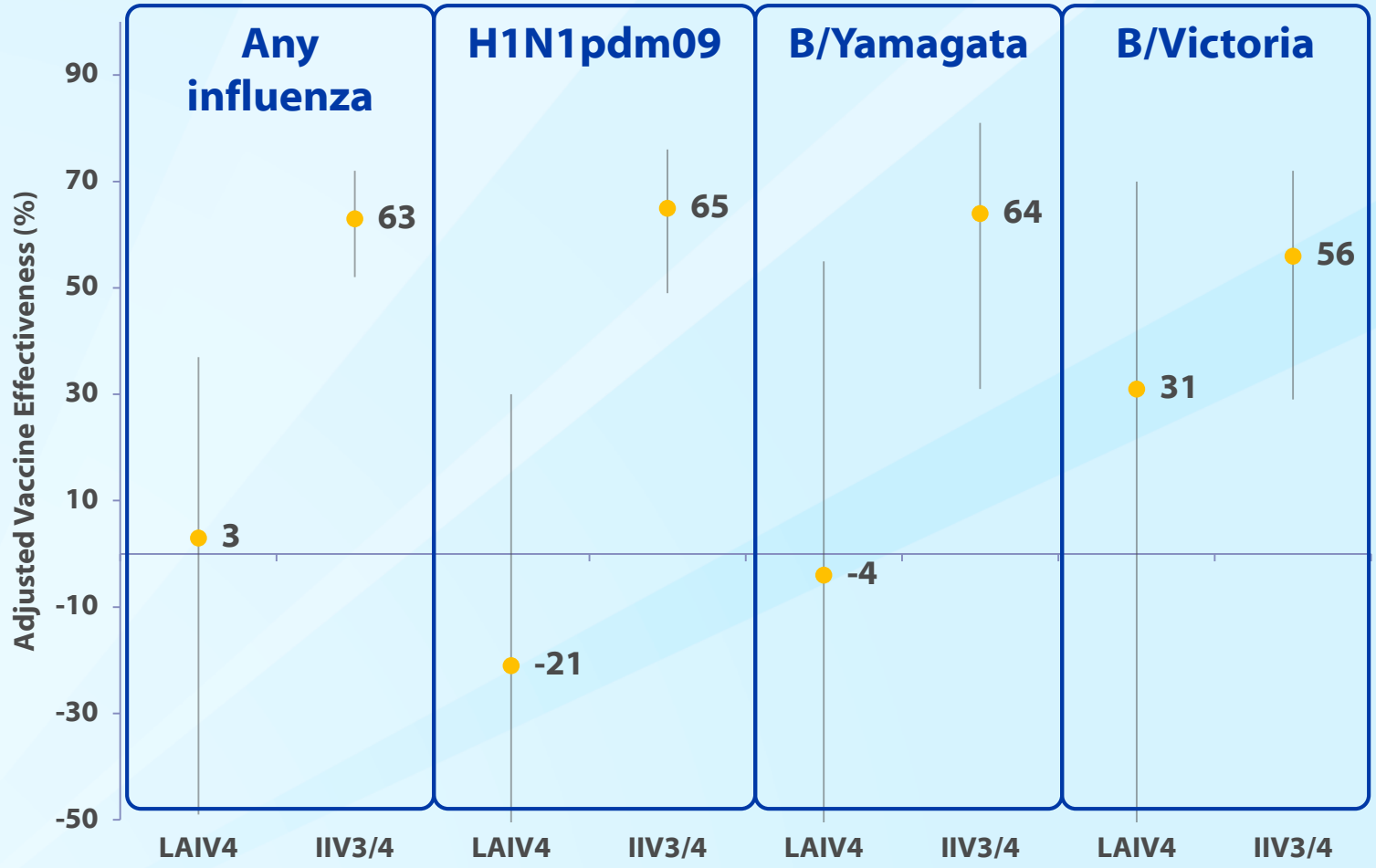
Change in LAIV Recommendations—History (1)

- **LAIV licensed in 2003**
- **Early randomized comparative trials of LAIV vs. IIV**
  - Conducted pre-pandemic (2002-03 and 2004-05 seasons) demonstrated superior efficacy of LAIV among young children
  - Lead to ACIP 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)

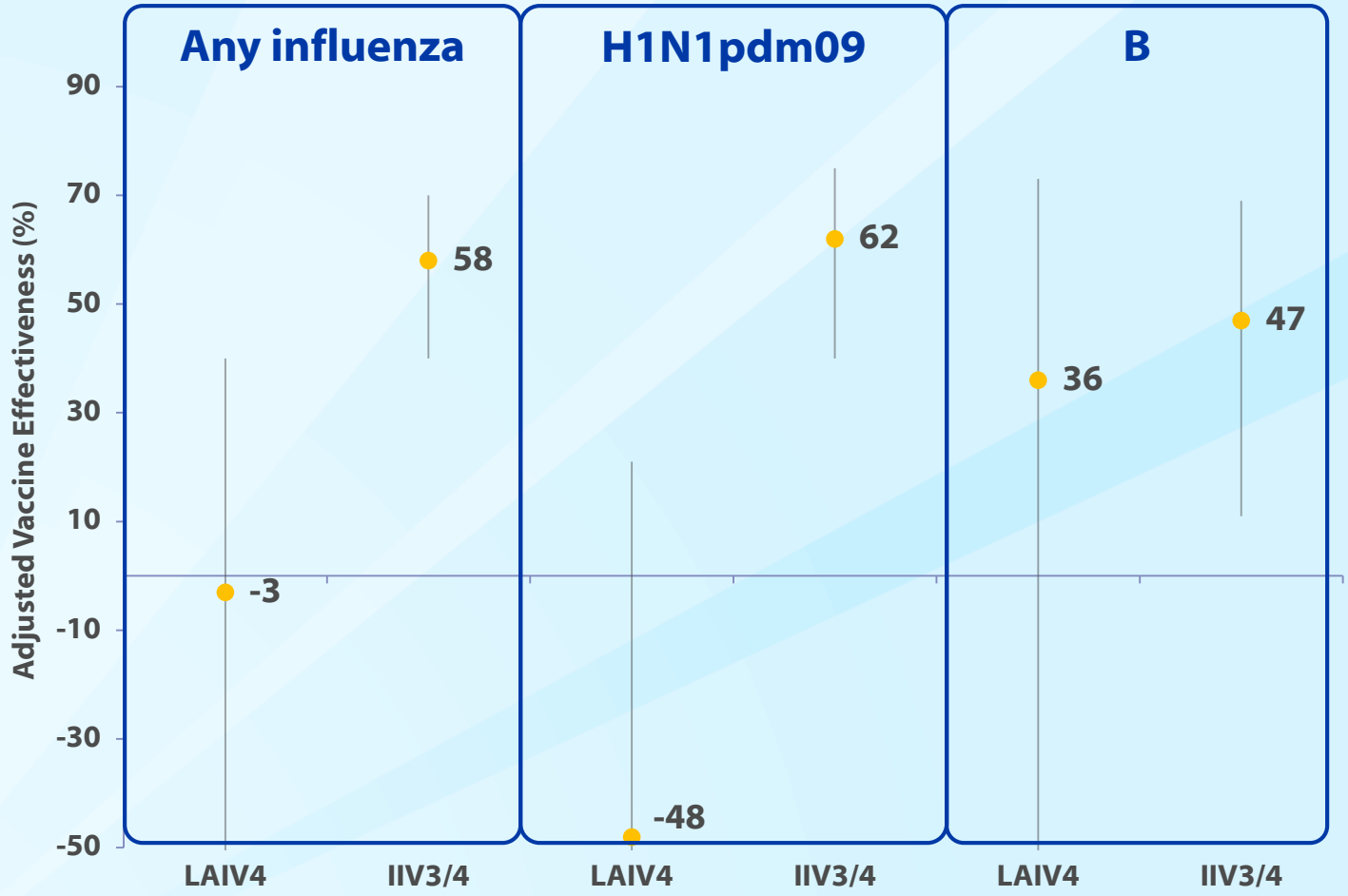
- **In June 2016, ACIP reviewed LAIV VE data for children 2 through 17 years of age, for the 2015-16 season, from three U.S. observational studies.**
- **VE against all influenza A and B**
  - US Flu VE Network: 3%, not statistically significant
  - MedImmune: 46%, statistically significant
  - US Department 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



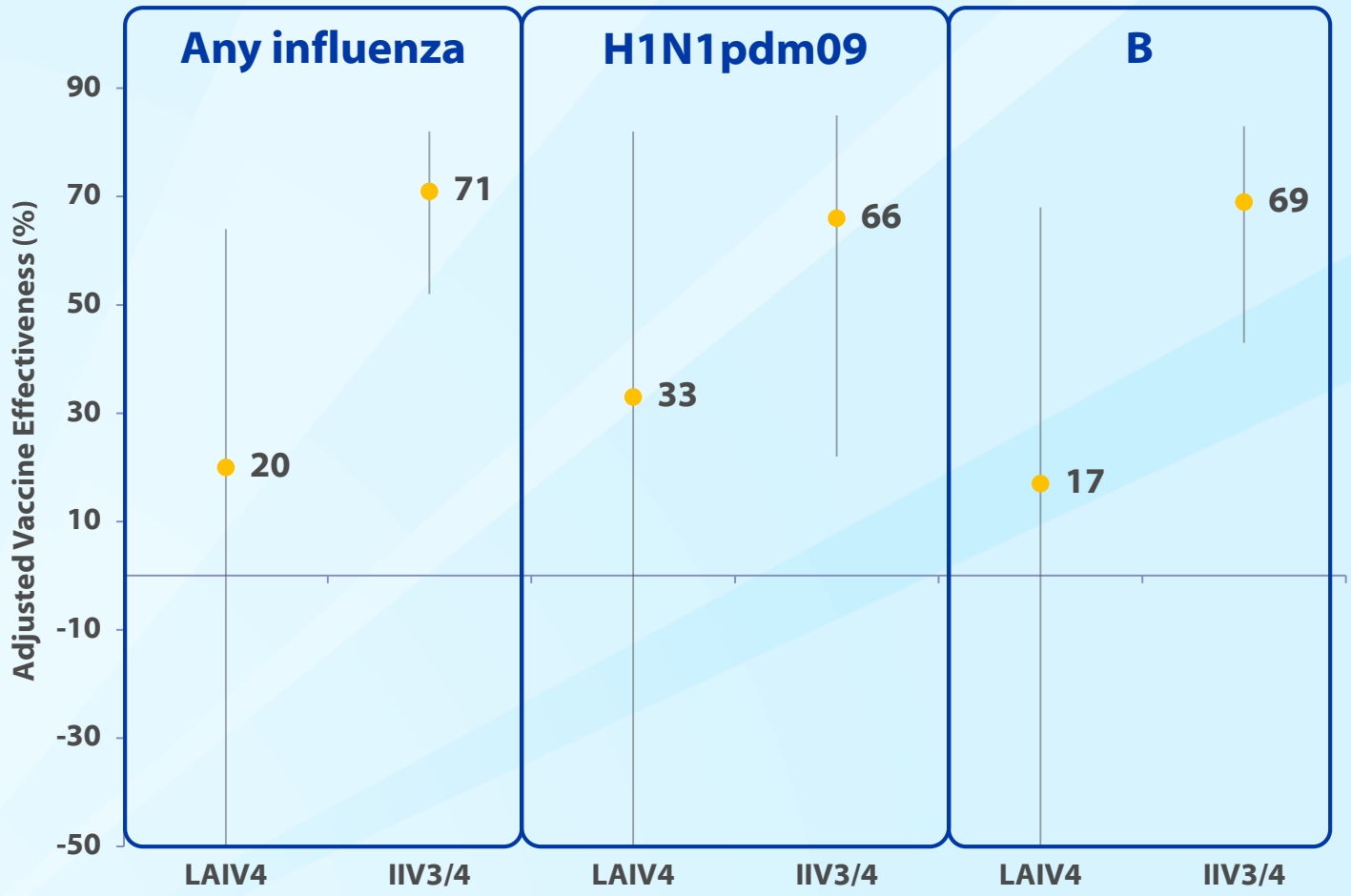
Total, Flu +	324	367	156	174	59	63	100	121
Vaccinated, Flu +	38	81	23	41	8	12	7	28

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



Total, Flu +	183	213	113	126	66	83
Vaccinated, Flu +	28	58	20	33	8	25

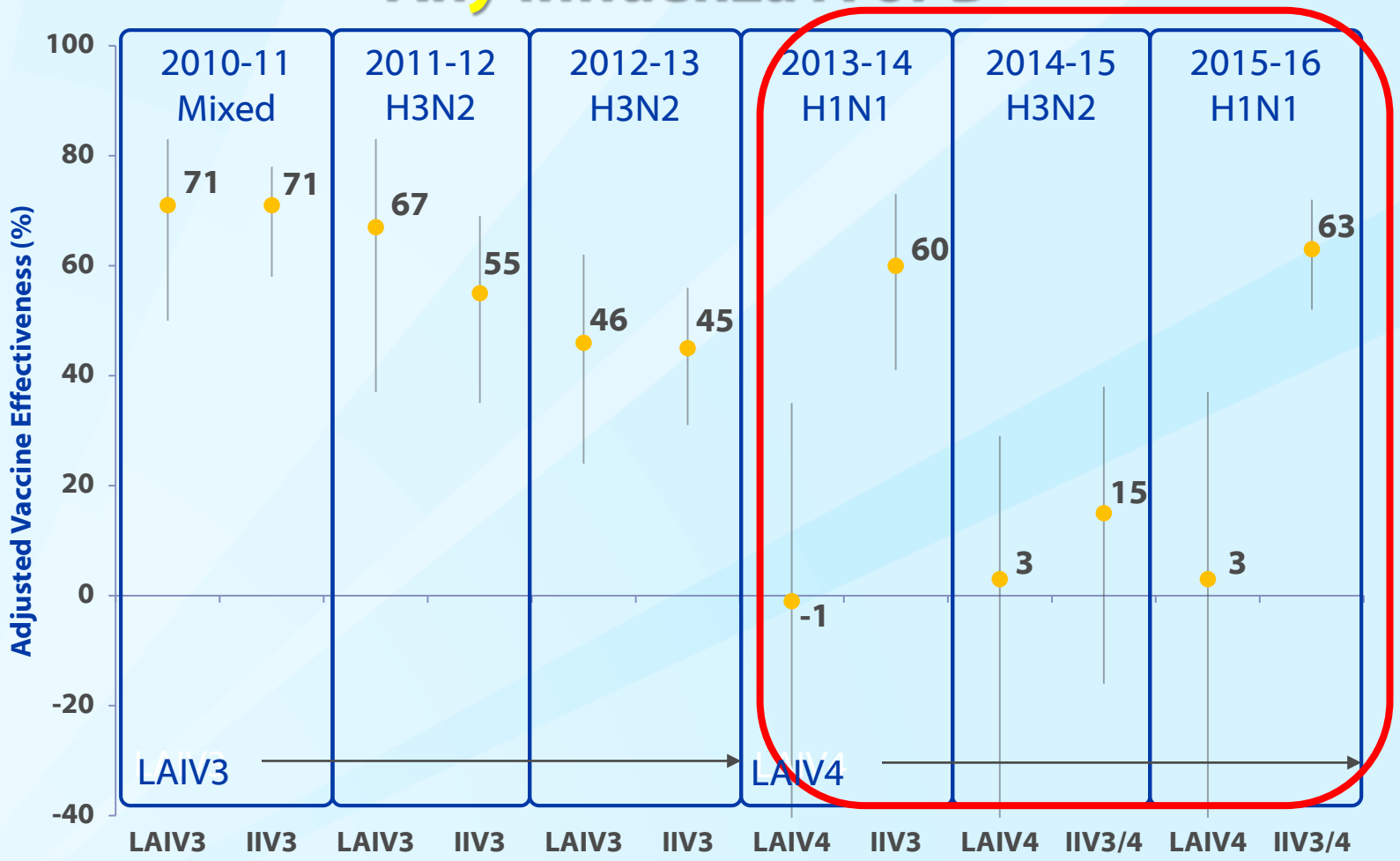
LAIV and IIV vaccine effectiveness ages 9–17 years, by influenza type/subtype, 2015-16



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



	LAIV3	IIV3	LAIV3	IIV3	LAIV3	IIV3	LAIV4	IIV3	LAIV4	IIV3/4	LAIV4	IIV3/4
Total, Flu +	267	314	225	264	722	859	220	222	588	562	324	367
Vaccinated, Flu +	21	66	12	51	61	198	34	36	106	180	38	81

New Vaccines for 2016-17

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

Other Recent Licensures

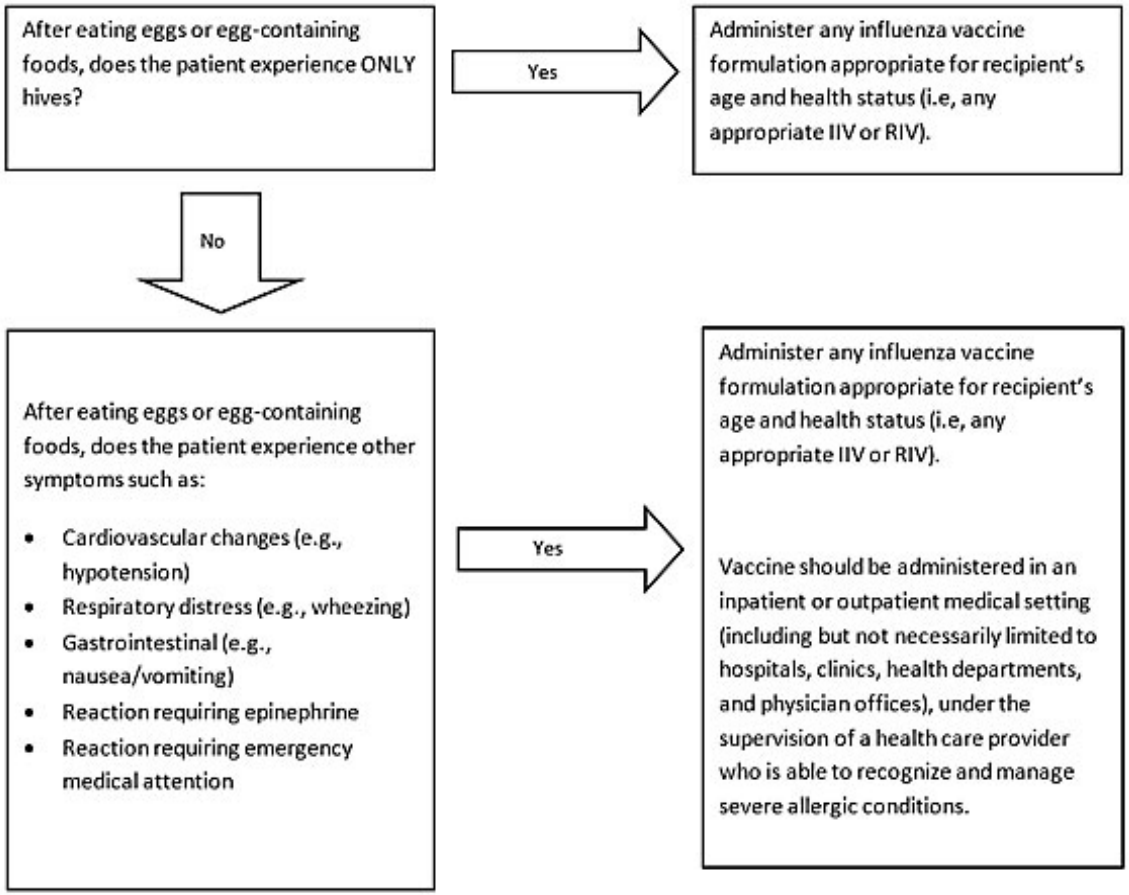
- **Afluria Quadrivalent**
  - Standard-dose quadrivalent IIV
  - Indicated for persons aged 18 years and older
  - Immunogenically noninferior to trivalent formulation
  - Will be available alongside trivalent formulation of Afluria this season
    - **Note**: trivlalent licensed for 5 years and older; but recommended by ACIP only for 9 years and older due to febrile reactions with 2010 Southern Hemisphere formulation)
- **Flublok Quadrivalent**
  - Recombinant quadrivalent influenza vaccine
  - Indicated for persons aged 18 years and older
  - Hemagglutinin produced in insect cell line using a viral vector
  - Immunogenically noninferior to trivalent formulation
  - Currently not anticipated to be available for 2016-17

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 RIV—however, RIV not licensed for persons under 18 years of age)**
- **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."

Recommendations regarding influenza vaccination of persons who report allergy to eggs: Advisory Committee on Immunization Practices, United States, 2016-17 Influenza season.

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

Acknowledgements

ACIP Influenza Work Group

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Thank You!

Questions?

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Intranasal FluMISSED Its Target: Influenza Prevention and Treatment for 2016-2017

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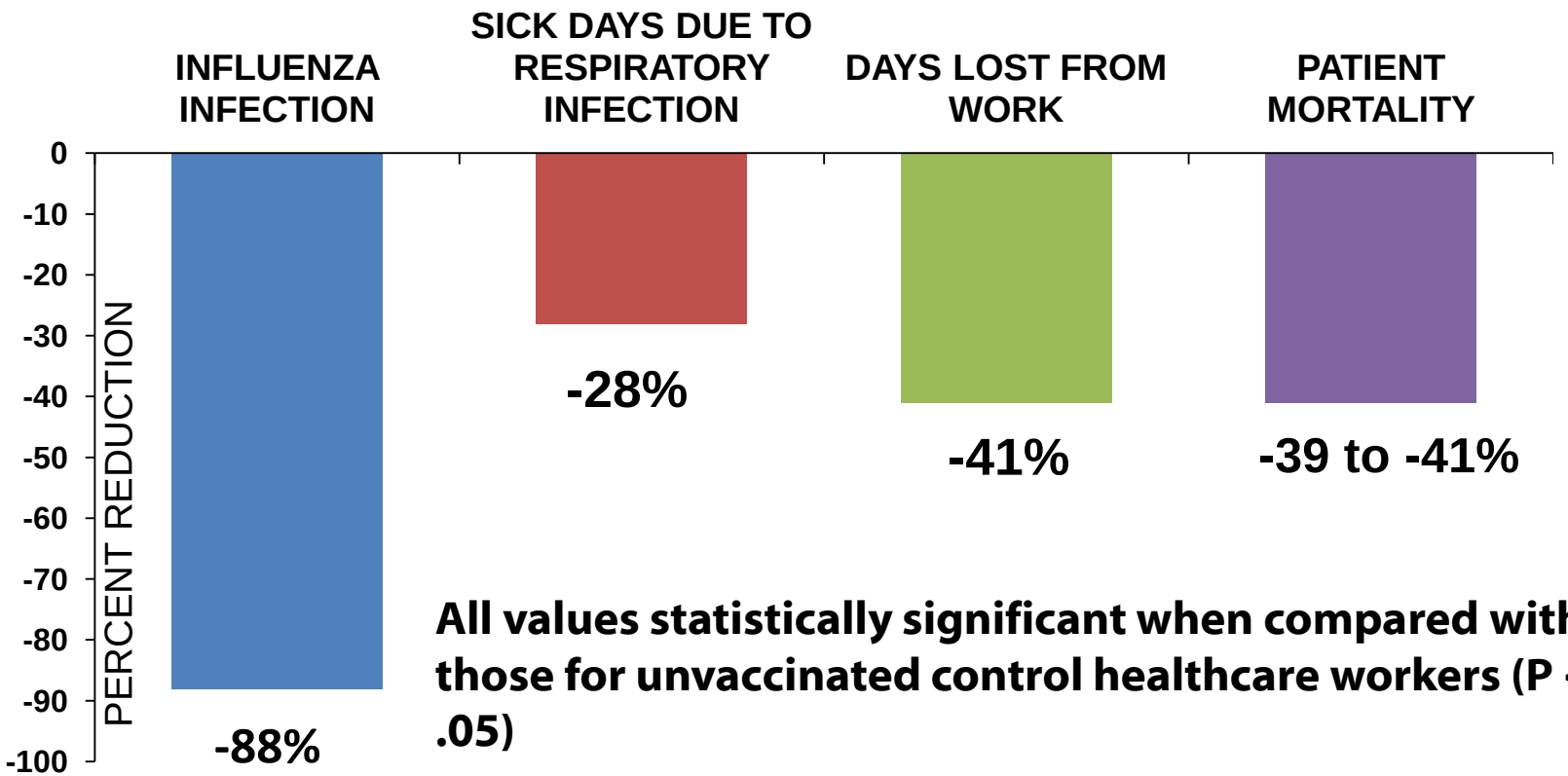
HOFSTRA NORTHWELL
SCHOOL of MEDICINE
AT HOFSTRA UNIVERSITY

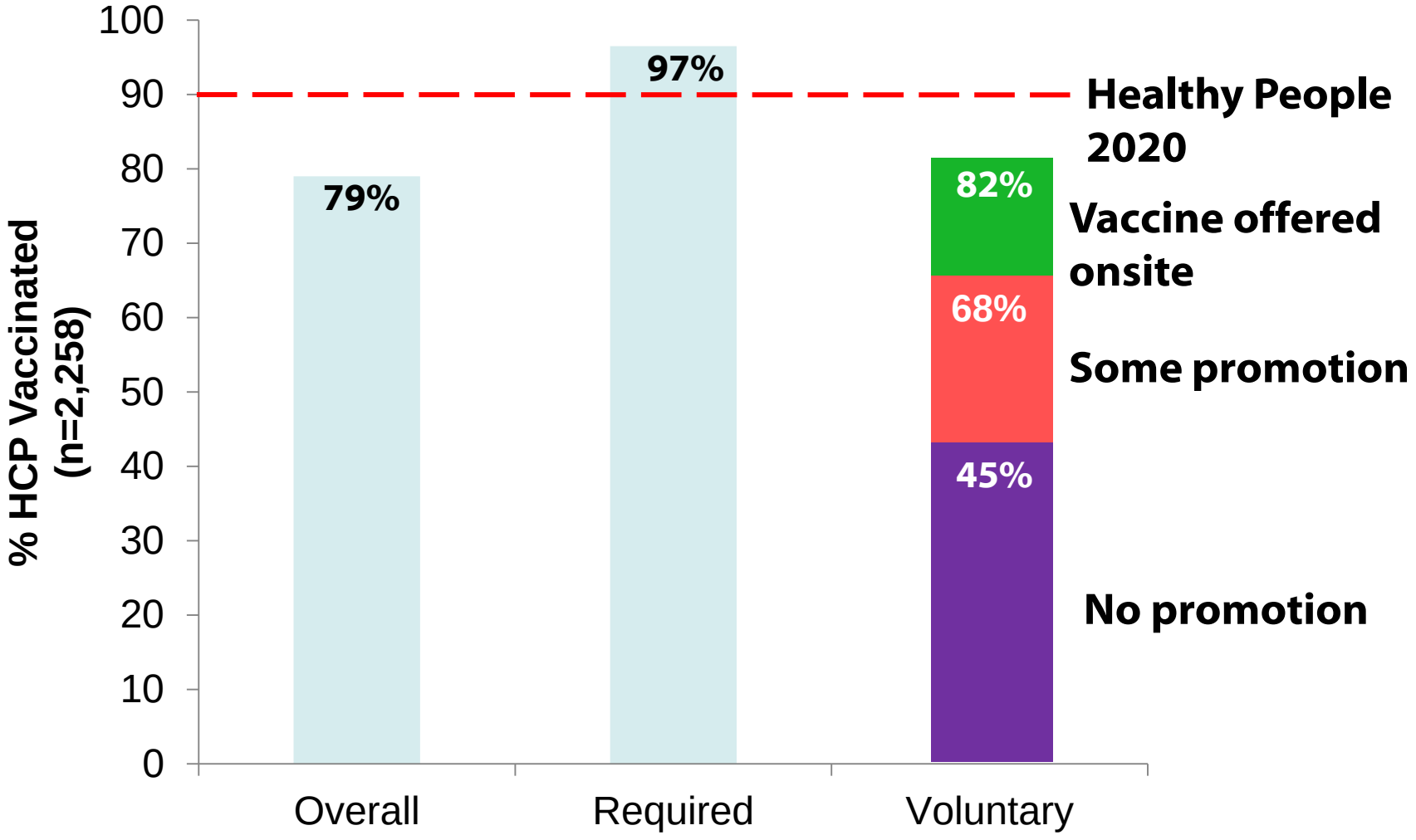
Percent Reduction in Outcomes for HCP Receiving Influenza Vaccine



Adapted from: Talbot TR, Bradley SF, Cosgrove SE, et al. Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. *Infect Control Hosp Epidemiol* 2005;26:882–890.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
MMWR Weekly
Vol. 65, No. 38
September 30, 2016

HCP Flu Vaccine Coverage United States, 2015-2016



Adapted from Black CL, Yue X, Ball SW, et al. Influenza Vaccination Coverage Among Health Care Personnel — United States, 2015–16 Influenza Season. MMWR Morb Mortal Wkly Rep 2016;65:1026–1031. DOI: http://dx.doi.org/10.15585/mmwr.mm6538a2

FLUVIEW

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

Epidemiology

Vaccine Effectiveness

Egg Allergy

PEDIATRICS

Recommendations for Prevention and Control of Influenza in Children, 2016–2017

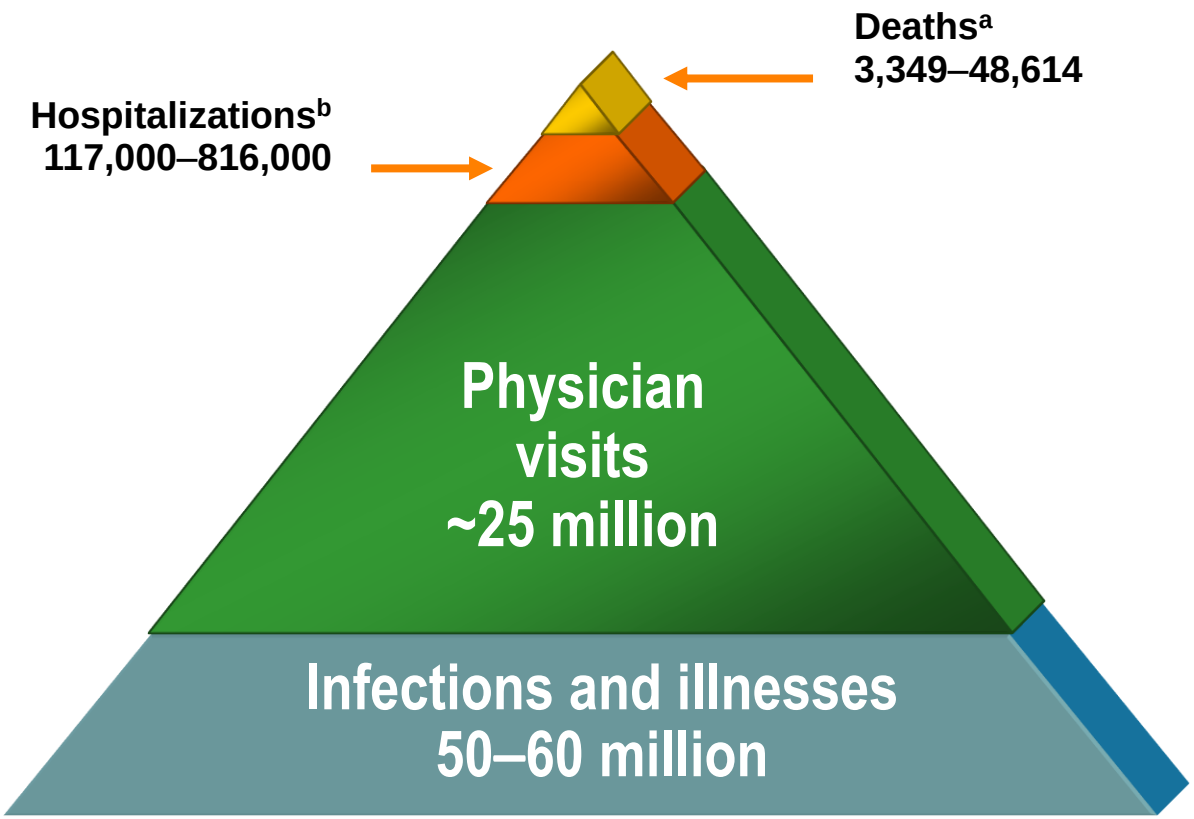
COMMITTEE ON INFECTIOUS DISEASES

THE AMERICAN ACADEMY OF PEDIATRICS

Policy Statement

Treatment

Influenza Disease Burden in the US in an Average Year

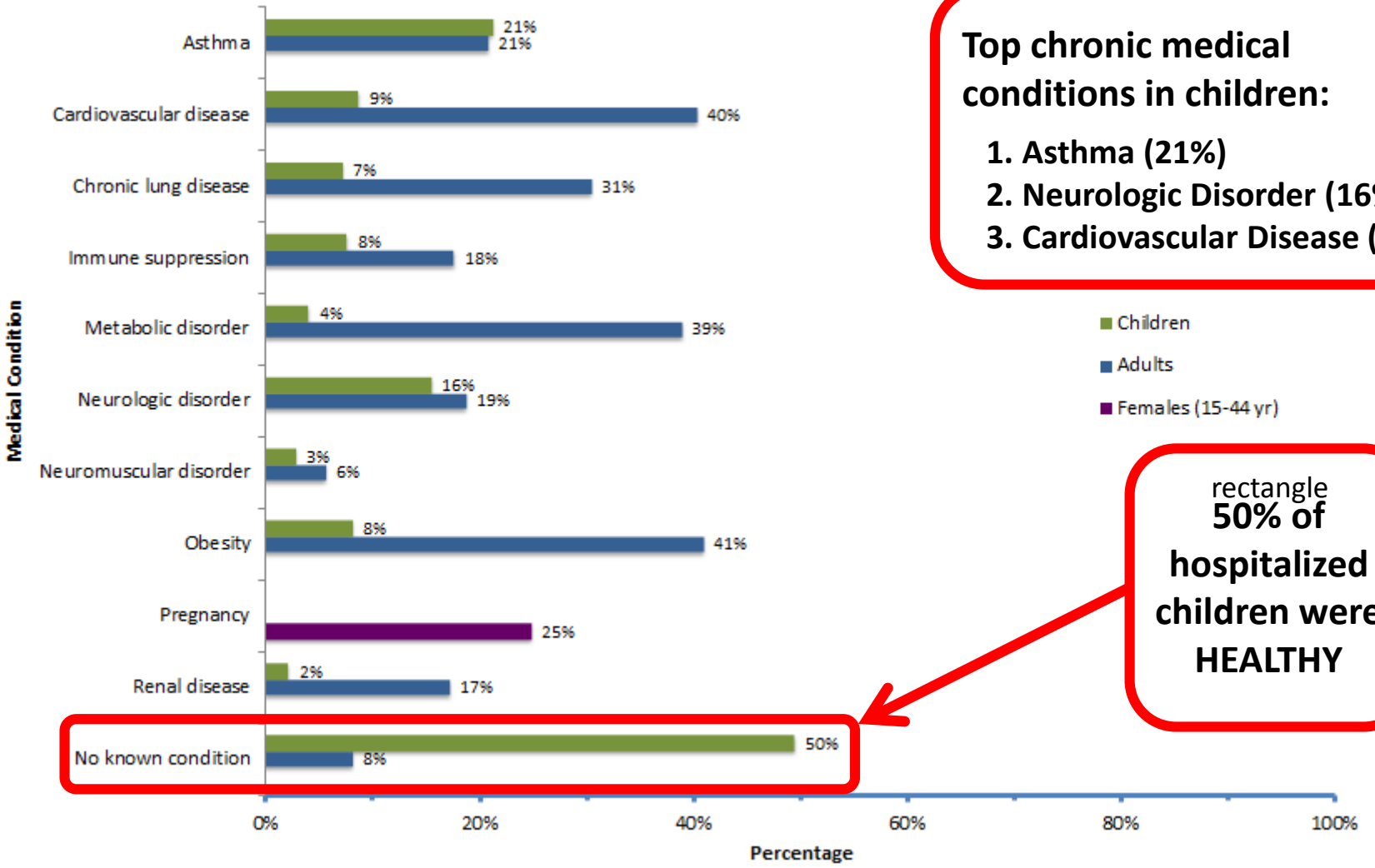


[a] *MMWR*. 2010: 59(22):1057–1062.; Reed C, Chaves SS, Daily Kirley P, et al. (2015) Estimating Influenza Disease Burden from Population-Based Surveillance Data in the United States. PLoS ONE 10(3): e0118369.

[B] All-cause hospitalization and mortality associated with influenza virus infection.

Thompson WW, et al. *JAMA*. 2003;289:179; Thompson WW, et al. *JAMA*. 2004;292:1333; Couch RB. *Ann Intern Med*. 2000;133:992; Patriarca PA. *JAMA*. 1999;282:75;ACIP. *MMWR*. 2004;53(RR06):1.; Reed C, Chaves SS, Daily Kirley P, et al. (2015) Estimating Influenza Disease Burden from Population-Based Surveillance Data in the United States. PLoS ONE 10(3): e0118369.

Selected Underlying Medical Conditions in Patients Hospitalized w/ Influenza 2015-2016



Top chronic medical conditions in children:

1. **Asthma (21%)**
2. **Neurologic Disorder (16%)**
3. **Cardiovascular Disease (9%)**

rectangle

50% of hospitalized children were HEALTHY

Influenza Vaccination Rates for Adults 2015-2016 (trends from 2014-2015 season)

Adults 18-64 years[a]

Adults ≥ 65 years[a]

Pregnant Women[b]

Health Care Personnel[c]

[a] http://www.cdc.gov/flu/fluvaxview/coverage-1516estimates.htm
[b] CDC Internet Panel Surveys. http://www.cdc.gov/mmwr/volumes/65/wr/mm6538a2.htm
[c] CDC Internet Panel Surveys: http://www.cdc.gov/flu/fluvaxview/pregnant-coverage_1516estimates.htm

Pediatric Deaths and Hospitalizations by Season and Predominant Strain

Influenza Season	Predominant Strain	Pediatric Deaths	Hospitalizations (0-4 years old) per 100,000	Hospitalizations (5-17 years old) per 100,000
2015-2016	pH1N1	85	42.5	9.6
2014-2015*	H3N2	148	57.3	16.6
2013-2014	pH1N1	111	47.3	9.4
2012-2013	H3N2	171	67	14.6
2011-2012*	H3N2	37	16	4
2010-2011	H3N2	123	49.5	9.1
2009-2010	pH1N1	288	77.4	27.2
2008-2009	H1N1	137	28	5
2007-2008	H3N2	88	40.3	5.5
2006-2007	H1N1	77	34.6	2.3

2016-2017 Seasonal Influenza Vaccine Strains

Trivalent

- A/California/7/2009 (H1N1)-like virus
- A/Hong Kong/4801/2014 (H3N2)-like virus
- B/Brisbane/60/2008-like virus (B/Victoria lineage)

Quadrivalent*

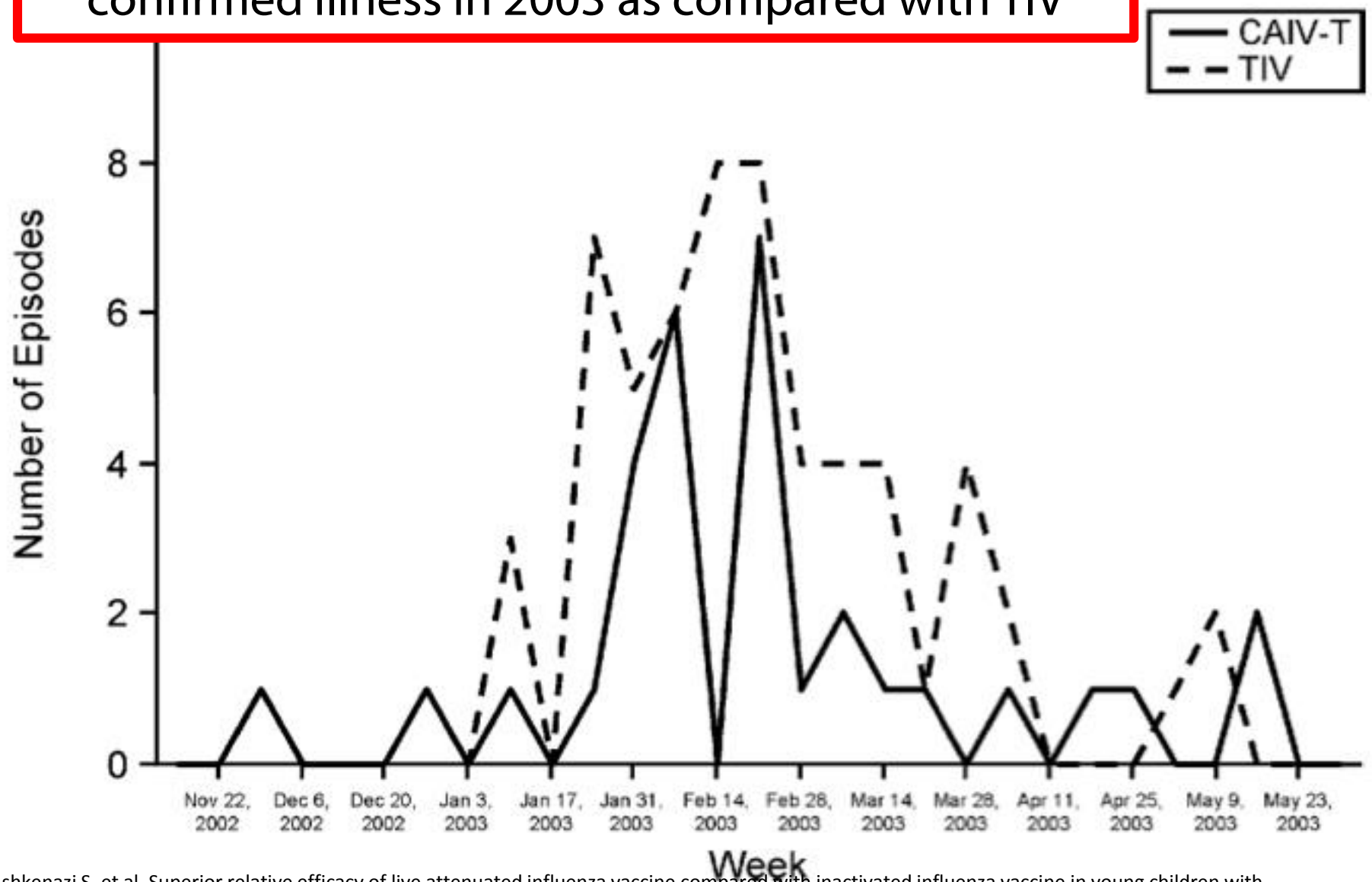
- Adds B/Phuket/3073/2013-like virus (B/Yamagata lineage)

Strains that changed from last season

*** B strains in quadrivalent formulation are the same as 2015-16 vaccine**

LAIV4 should NOT be used in any setting during the 2016-2017 season

LAIV3 had consistently fewer episodes of culture-confirmed illness in 2003 as compared with TIV



Ashkenazi S, et al. Superior relative efficacy of live attenuated influenza vaccine compared with inactivated influenza vaccine in young children with recurrent respiratory tract infections. Pediatr Infect Dis J. 2006 Oct;25(10):870-9.

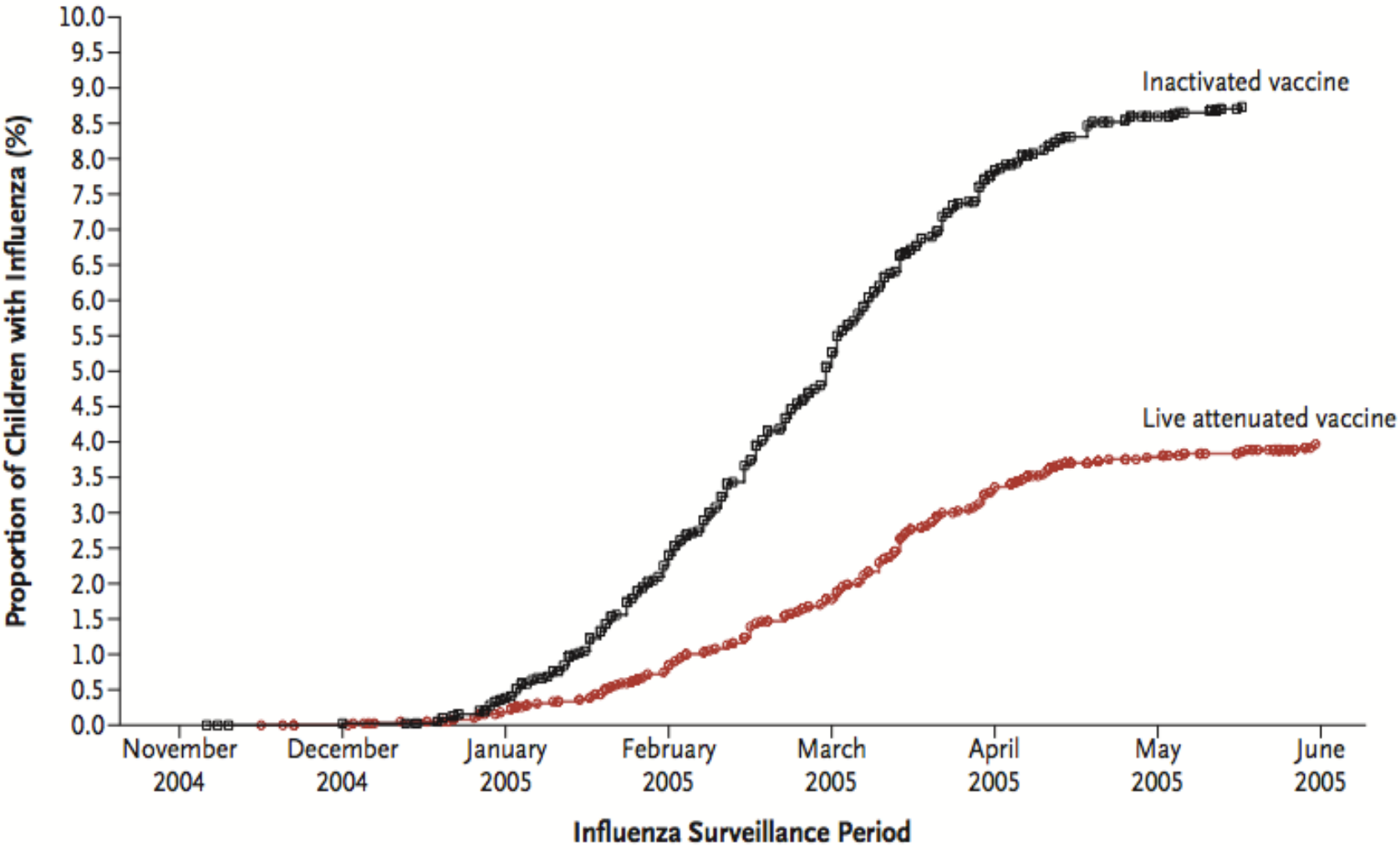


Figure 1. Kaplan–Meier Curves for the Time to the First Culture-Confirmed Report of Influenza in the Two Vaccine Groups.

Belshe RB, et al. Live attenuated versus inactivated influenza vaccine in infants and young children. N Engl J Med. 2007 Feb 15;356(7):685-96.

VS

LAIV 3

LAIV 4

Hypotheses for why LAIV4 wasn't effective vs H1N1pdm09

- Increased susceptibility to thermal degradation
- Viral interference with adding 4th strain
- Pre-existing immunity due to more years of annual influenza vaccination or natural infection
- Poor antigenic match between vaccine and circulating strains
- Waning protection during season
- Manufacturing problem

H. Caspard et al. / Vaccine 34 (2016) 5066–5072

Overall Vaccine Effectiveness LAIV4 vs. IIV Ages 2-17 Years By Season

Season (Predominant Strain)	Age Range (yrs)	Adjusted VE (95% CI)	
		LAIV4	IIV3/IIV4
2013-2014 (H1N1pdm09)	2-17	2% (-53 to 37)	61% (42 to 74)
	2-8	-39% (-156 to 25)	60% (32 to 76)
	9-17	36% (-31 to 69)	62% (30 to 80)
2014-2015 (H3N2)	2-17	9% (-18 to 29)	31% (16 to 44)
	2-8	9% (-28 to 35)	26% (2 to 44)
	9-17	17% (-27 to 46)	33% (9 to 51)
2015-2016 (H1N1pdm09)	2-17	3% (-49 to 37)	63% (52 to 72)
	2-8	-3% (-76 to 40)	58% (40 to 70)
	9-17	20% (-78 to 64)	71% (52 to 82)

LAIV4 Confidence intervals all cross zero

AAP Seasonal Influenza Policy 2016–2017. Pediatrics. 2016;138(4)


LAIV4 has struck out

LAIV3

LAIV4

2003
LAIV3 licensed ages 5-49
FDA

Feb 2007
Belshe et al.
The NEW ENGLAND JOURNAL of MEDICINE

Feb 2012
LAIV4 licensed ages 2-49
FDA

Feb 2015
Rescind preferential recommendation
CDC

What's next for LAIV4?

LAIV Timeline

?

Oct 2006
Ashkenazi et al.
The Pediatric Infectious Disease Journal

Sept 2007
Expand use to ages 2-4
FDA

June 2014
Preferential recommendation
CDC

June 2016
"**LAIV4** should not be used in any setting during the 2016-2017 season."
THE AMERICAN ACADEMY OF PEDIATRICS
CDC

Journal of American Academy of pediatrics: Recommendations for Prevention and Control of Influenza in Children 2016-2017

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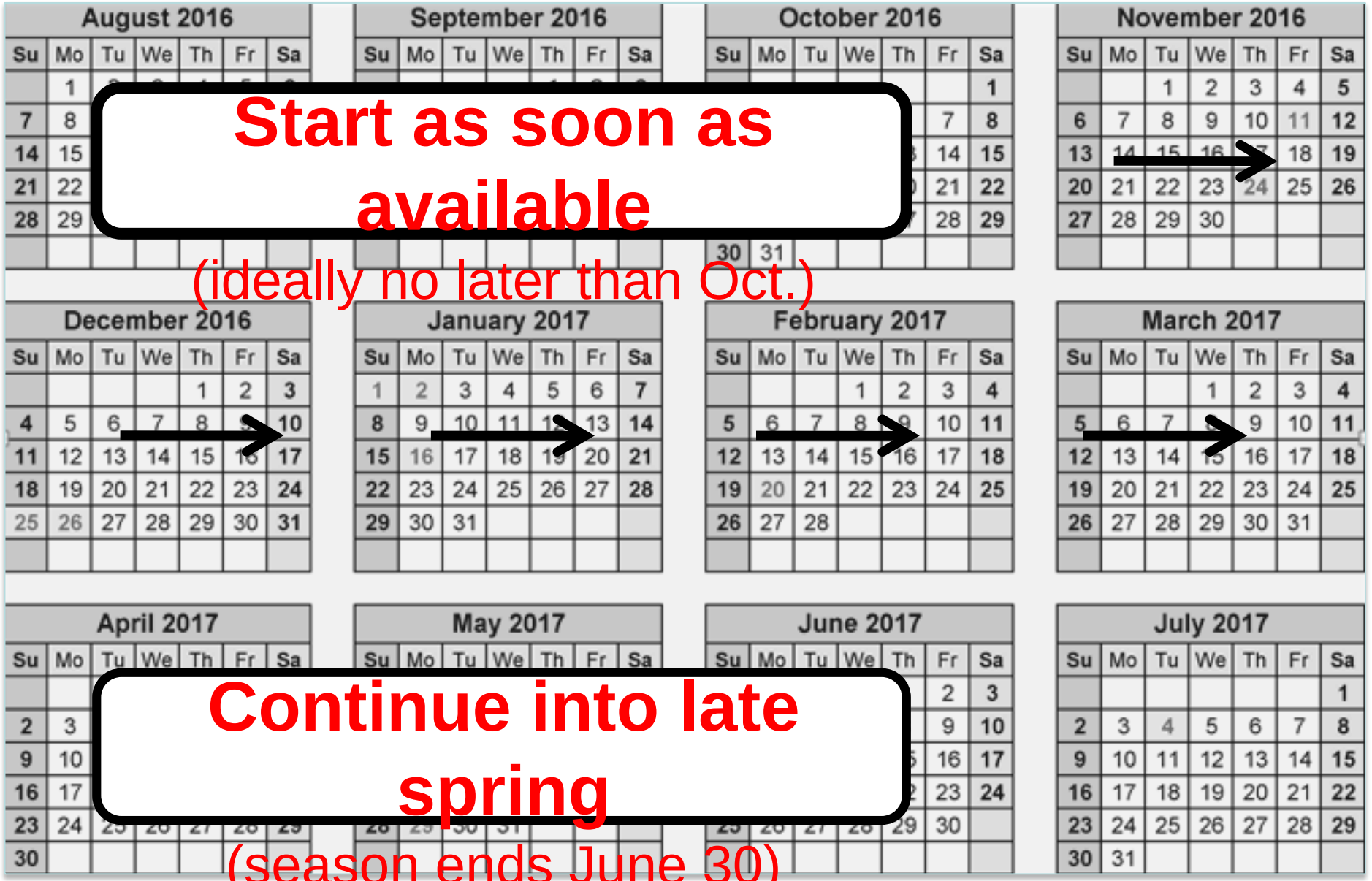
Recommendations for Prevention and Control of Influenza in Children, 2016–2017

COMMITTEE ON INFECTIOUS DISEASES

Everyone 6 months and older should get a flu shot this year

Offer Vaccine Throughout Year



Special Populations to Reach

Children

Health Care Personnel

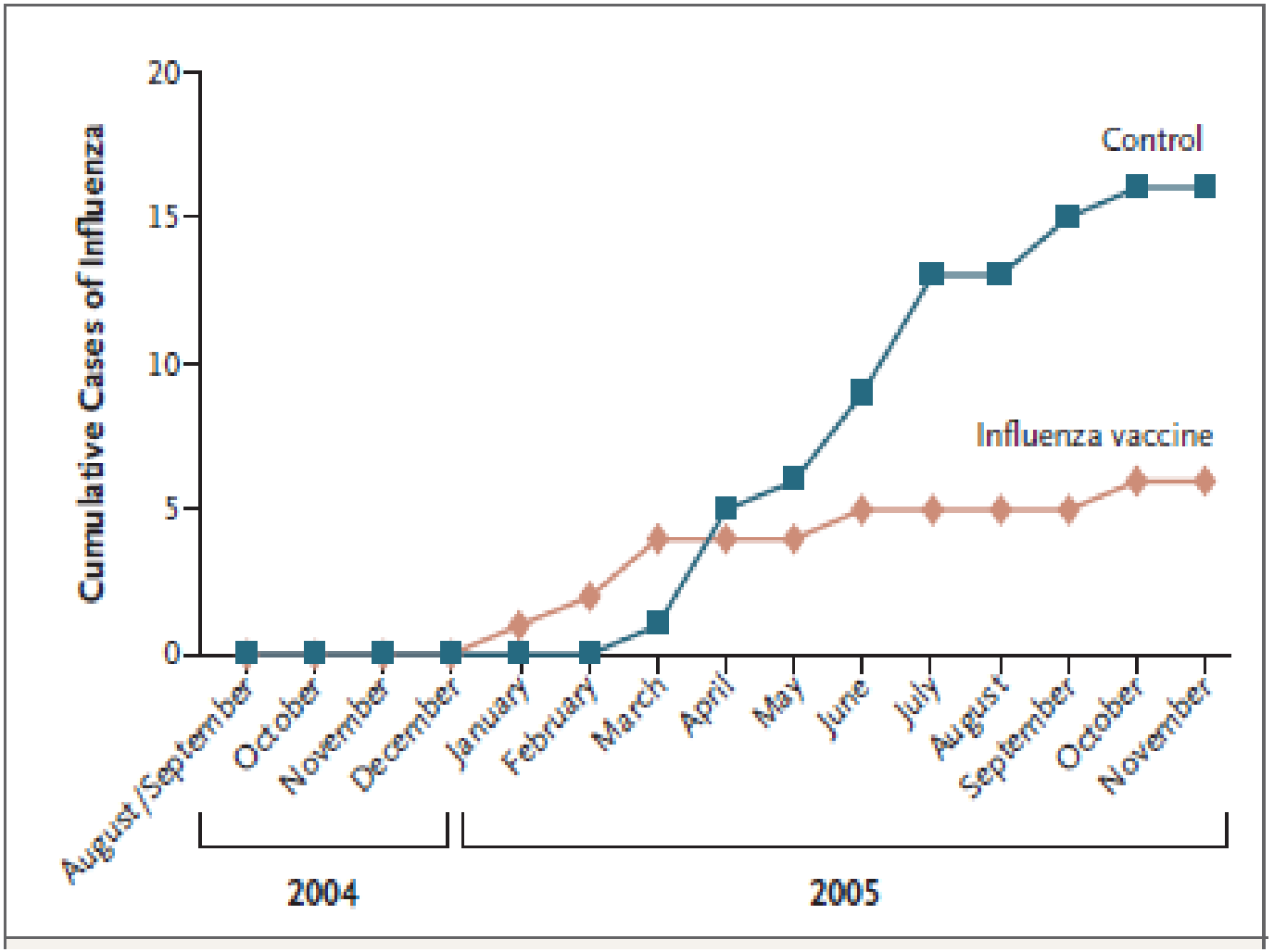
Pregnant Women

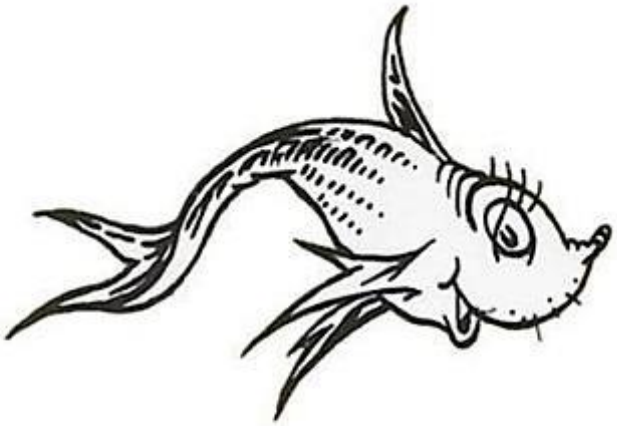
Household Contacts of High Risk Children and All Children <5

The NEW ENGLAND JOURNAL of MEDICINE

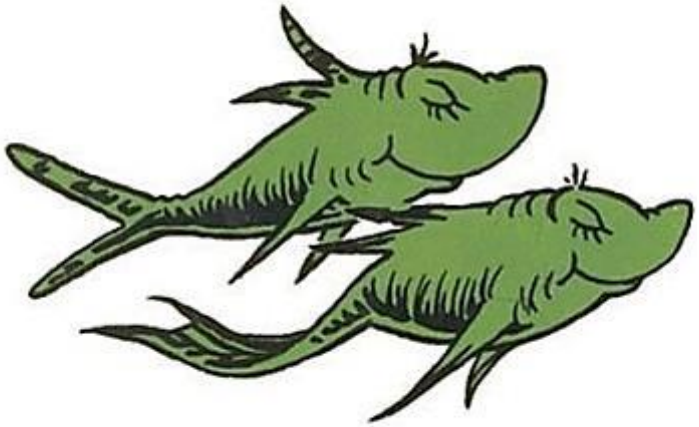
Effectiveness of Maternal Influenza Immunization in Mothers and Infants

Zaman et al.



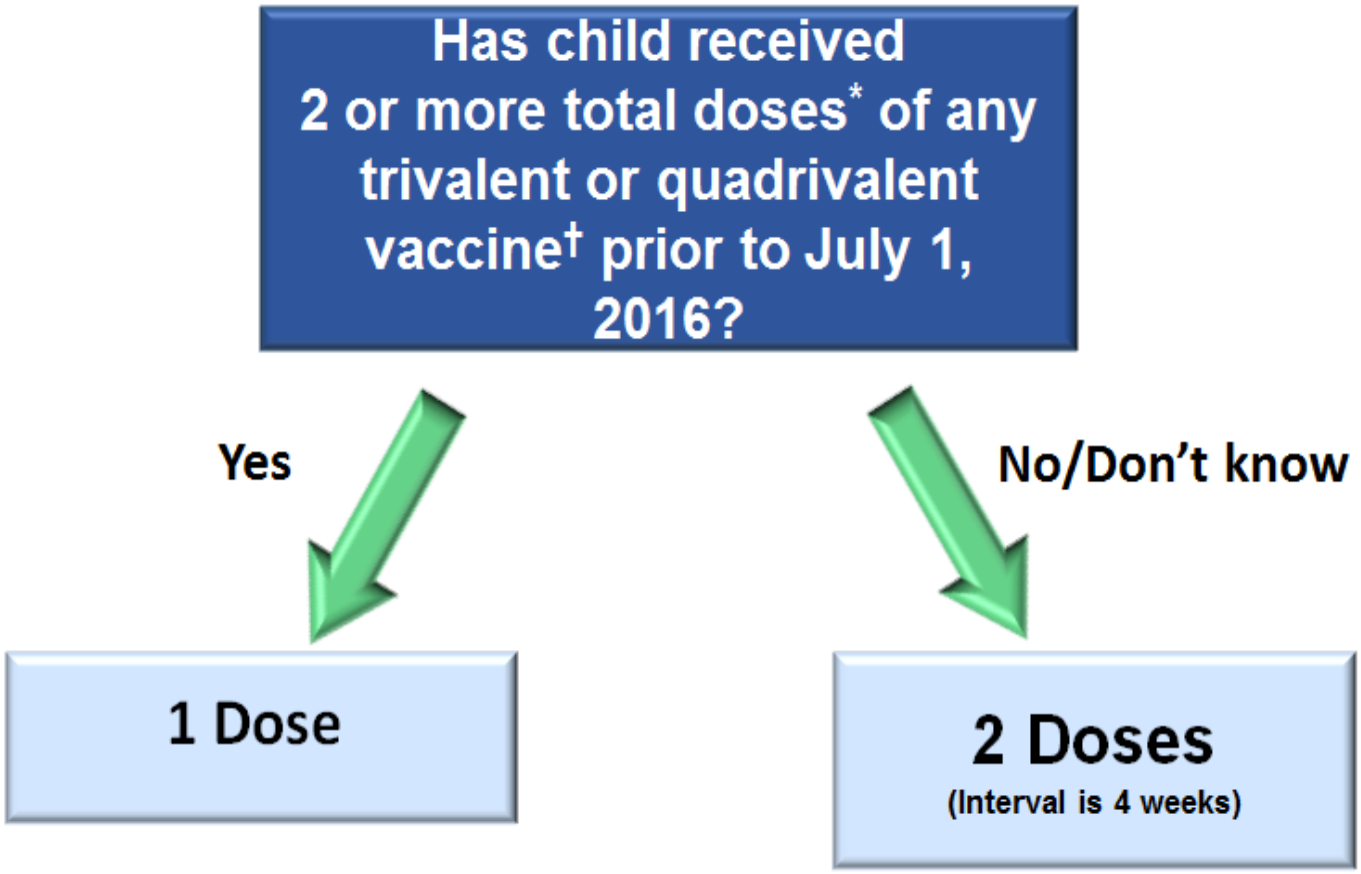


One Dose



Two Dose

Number of Seasonal Influenza Doses for Children 6 Months – 8 Years

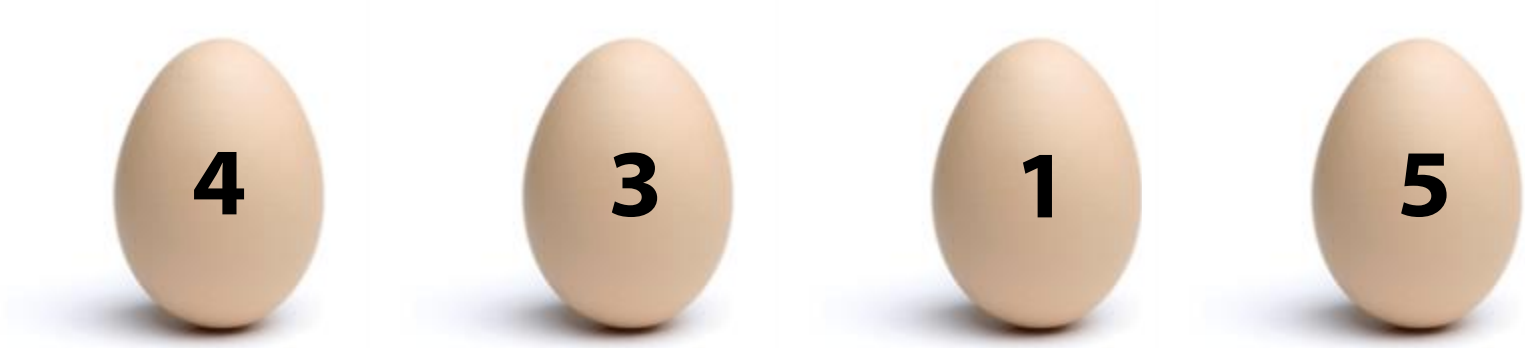


*** 2 doses need not have been received during the same season or consecutive seasons**

† Receipt of LAIV4 in the past is still expected to have primed a child's immune system, despite recent evidence for poor effectiveness. There currently are no data that suggest otherwise.

Evidence-Based Practice

- **28** studies
- **4315** egg-allergic subjects (656 with severe allergies)
- **No** serious allergic reactions (respiratory distress or hypotension) after receiving the influenza vaccine



Des Roches A, et al. Egg-allergic patients can be safely vaccinated against influenza. *J Allergy Clin Immunol* 2012;130:1213-1216.
Greenhawt MJ, Spergel JM, Rank MA, et al. Safe administration of the seasonal trivalent influenza vaccine to children with severe egg allergy. *Ann Allergy Asthma Immunol*. 2012;109:426—430.
Kelso, JM. Influenza Vaccine and Egg Allergy: Nearing the End of an Evidence-Based Journey. *J Allergy Clin Immunol*. 2015;;3:140-1.=

Onset Time of Vaccine-Triggered Anaphylaxis (n=33)

The Journal of Allergy and Clinical Immunology

McNeil et al. Risk of anaphylaxis after vaccination in children and adults. *J Allergy Clin Immunol* 2015

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AAP Policy Recommendation

All children with egg allergies can receive the influenza vaccine with no special precautions than those recommended for routine vaccines

Recommendations for Prevention and Control of Influenza in Children, 2016–2017. COMMITTEE ON INFECTIOUS DISEASES. Pediatrics Sep

Influenza Antiviral Medications

2015–2016 Viruses	Adamantanes (Amantadine/Rimantadine)	Oseltamivir (Tamiflu)	Zanamivir (Relenza)	Peramivir (Rapivab)
Influenza A (H1N1) (derived from 2009 pandemic)	Resistant	Susceptible	Susceptible	Susceptible
Influenza A (H3N2)	Resistant	Susceptible	Susceptible	Susceptible
Influenza B (both lineages)	Resistant	Susceptible	Susceptible	Susceptible

OFFER treatment ASAP to children

- **Hospitalized for:**
  - **presumed influenza**
  - **severe, complicated, or progressive illness attributable to influenza**

- **With influenza (any severity) at high risk of complications**

AAP 2016-17 Seasonal Influenza Policy

CONSIDER treatment for clinical influenza if…

- **Any healthy child with presumed influenza**
- **Siblings at home:**
  - **< 6 months old**
  - **with underlying medical conditions that predispose to flu complications**

AAP 2016-17 Seasonal Influenza Policy

Oseltamivir Treatment Evidence

<48 hrs after onset

Prospective, controlled study in **outpatient** setting[a]

>48 hrs after onset

Retrospective, uncontrolled studies of **hospitalized** patients[b,c,d,e,f]

Reduced morbidity and mortality

[a] FDA. Oseltamivir Package Insert. Available at http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM147992.pdf.
[b] Muthuri SG, Venkatesan S, Myles PR, et al. Effectiveness of neuraminidase inhibitors in reducing mortality in patients admitted to hospital with influenza A H1N1pdm09 virus infection: a meta-analysis of individual participant data. Lancet Respir Med 2014; published online March 19. DOI:10.1016/S2213-2600(14)70041-4.
[c] Hsu J, Santesso N, Mustafa R, et al. Antivirals for treatment of influenza: a systematic review and meta-analysis of observational studies. Ann Intern Med 2012; 156: 512–24.
[d] Louie JK, Yang S, Acosta M, et al. Treatment with neuraminidase inhibitors for critically ill patients with influenza A (H1N1)pdm09. Clin Infect Dis 2012; 55: 1198–204.
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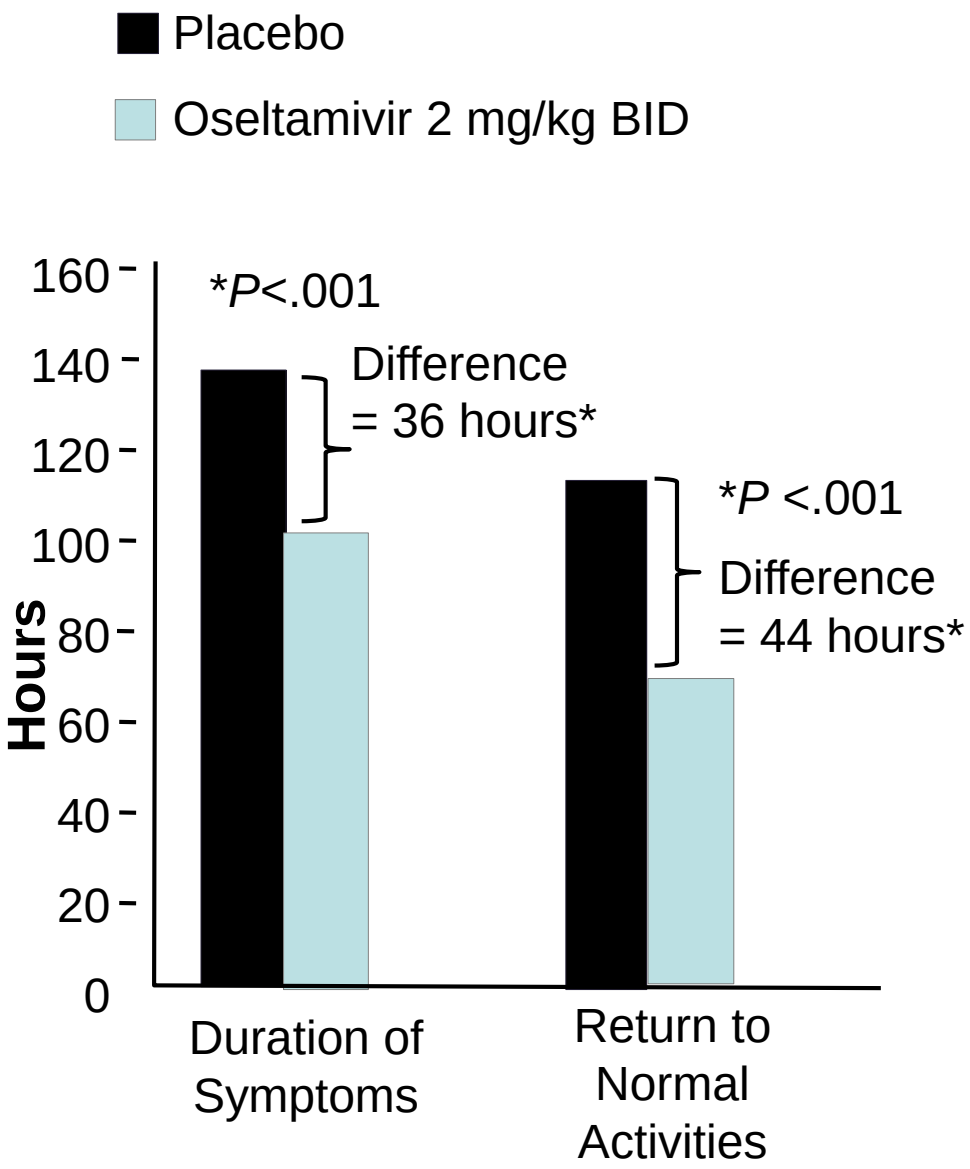
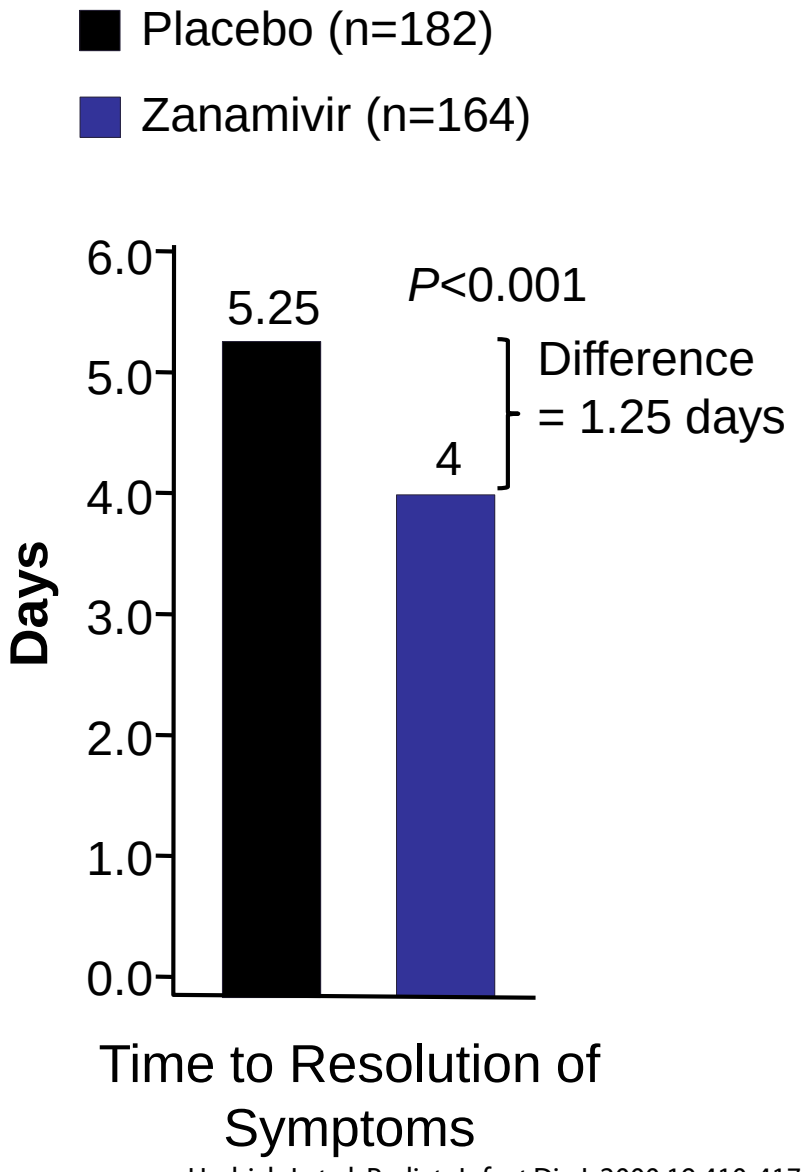
Antiviral Treatment Clinical Efficacy

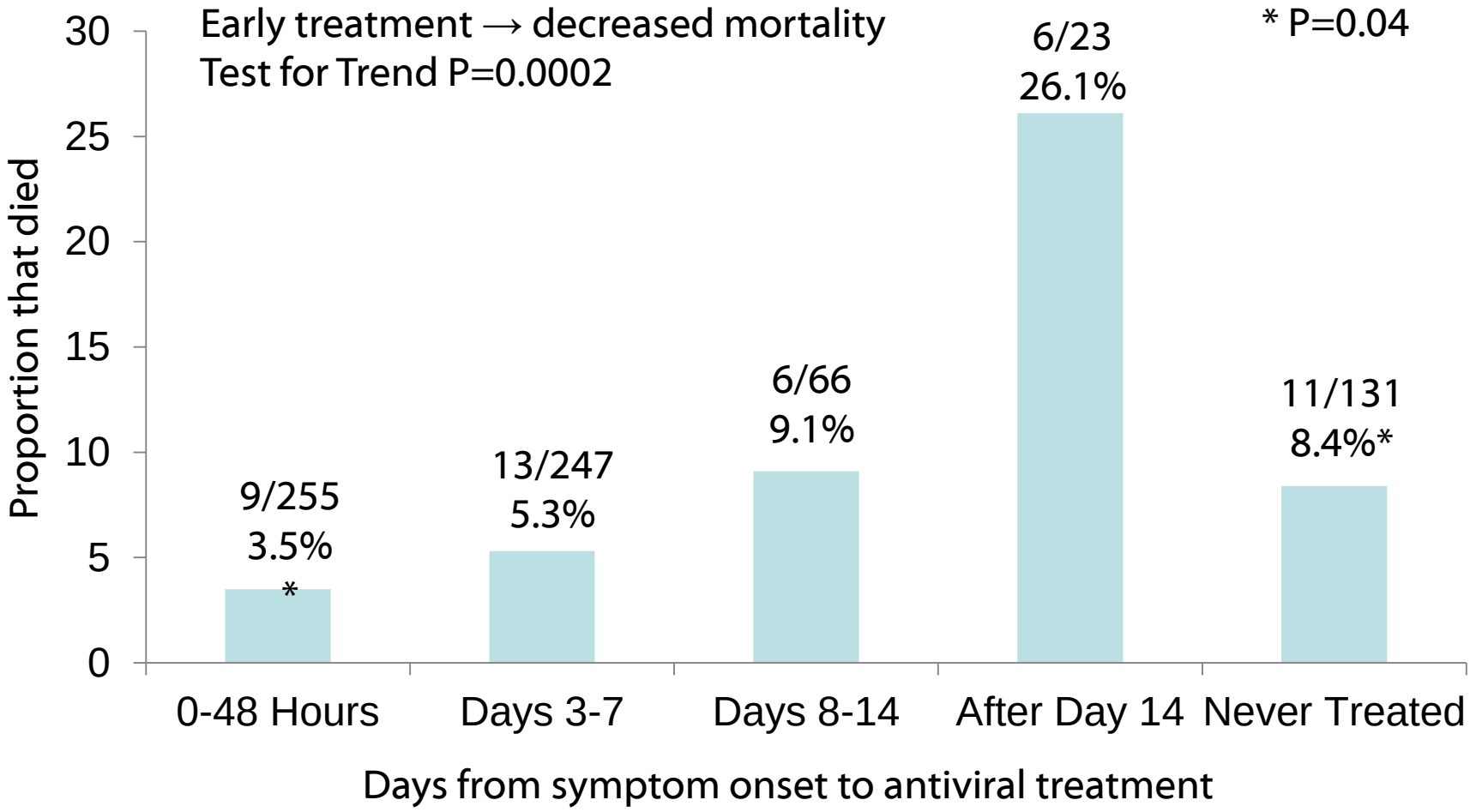


Whitley R et al. Pediatr Infect Dis J. 2001;20:127-133



Hedrick J et al. Pediatr Infect Dis J. 2000;19:410-417

NAIs and Mortality in Children California Surveillance Data (n=784)

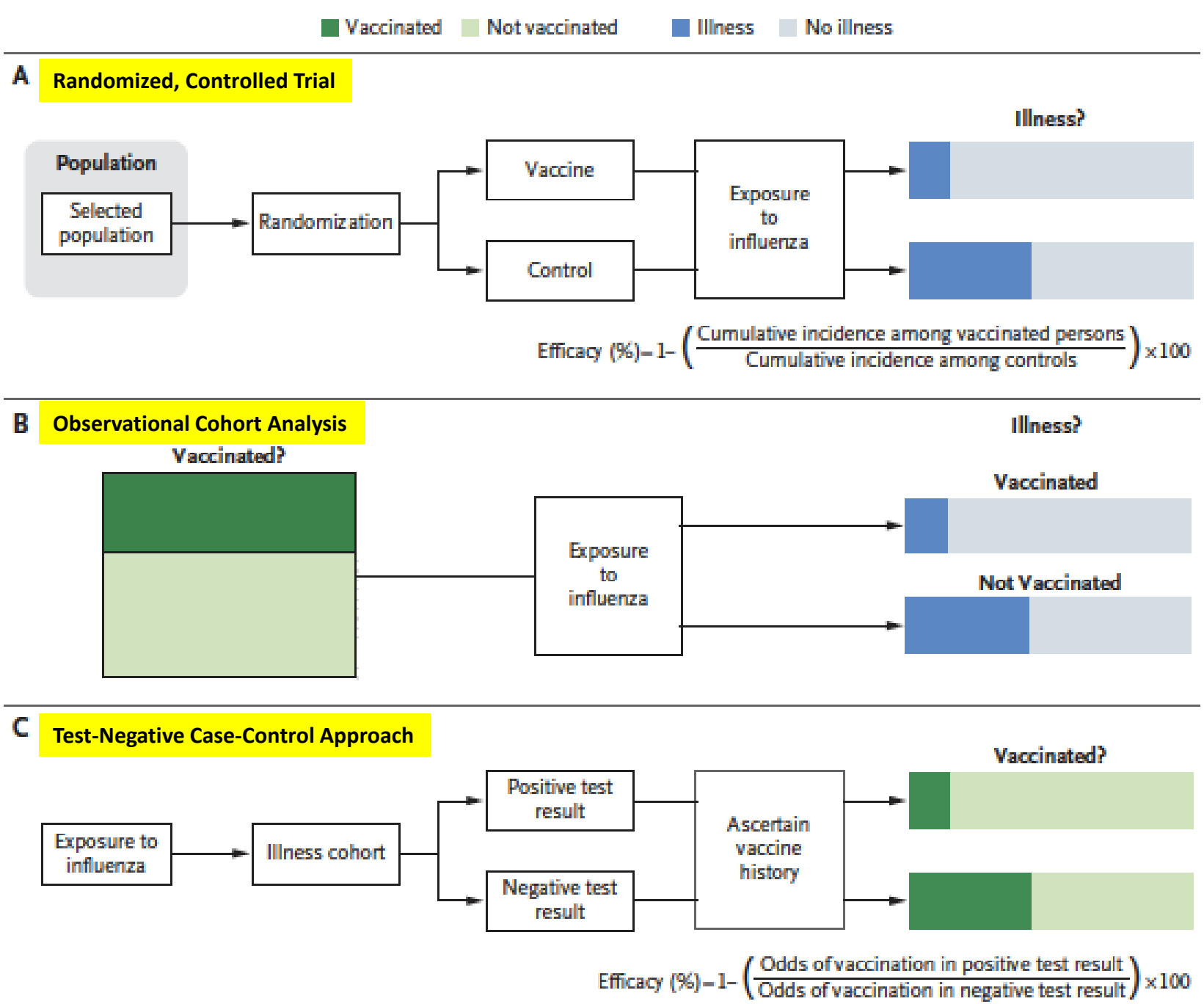


Louie et al., Pediatrics

[Intervention Review]

Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children

First published: 10 April 2014



Treanor JJ. *N Engl J Med.* 2016;375:1261-8.

Commentary and IDSA Support for Influenza Antiviral Treatment

- **No placebo-controlled RCTs available for NAI treatment of hospitalized influenza patients**
- **Challenging to undertake RCTs with mortality and severe morbidity as outcomes**
- **Observational studies consistently report clinically meaningful benefits of NAI treatment that creates large body of evidence for benefit**

Nguyen-Van-Tam et al., Commentary in The Lancet IDSA Statement

FLUVIEW

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

Epidemiology

Vaccine Effectiveness

Egg Allergy

PEDIATRICS

Recommendations for Prevention and Control of Influenza in Children, 2016–2017

COMMITTEE ON INFECTIOUS DISEASES

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Policy Statement

Treatment

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