Influenza Update

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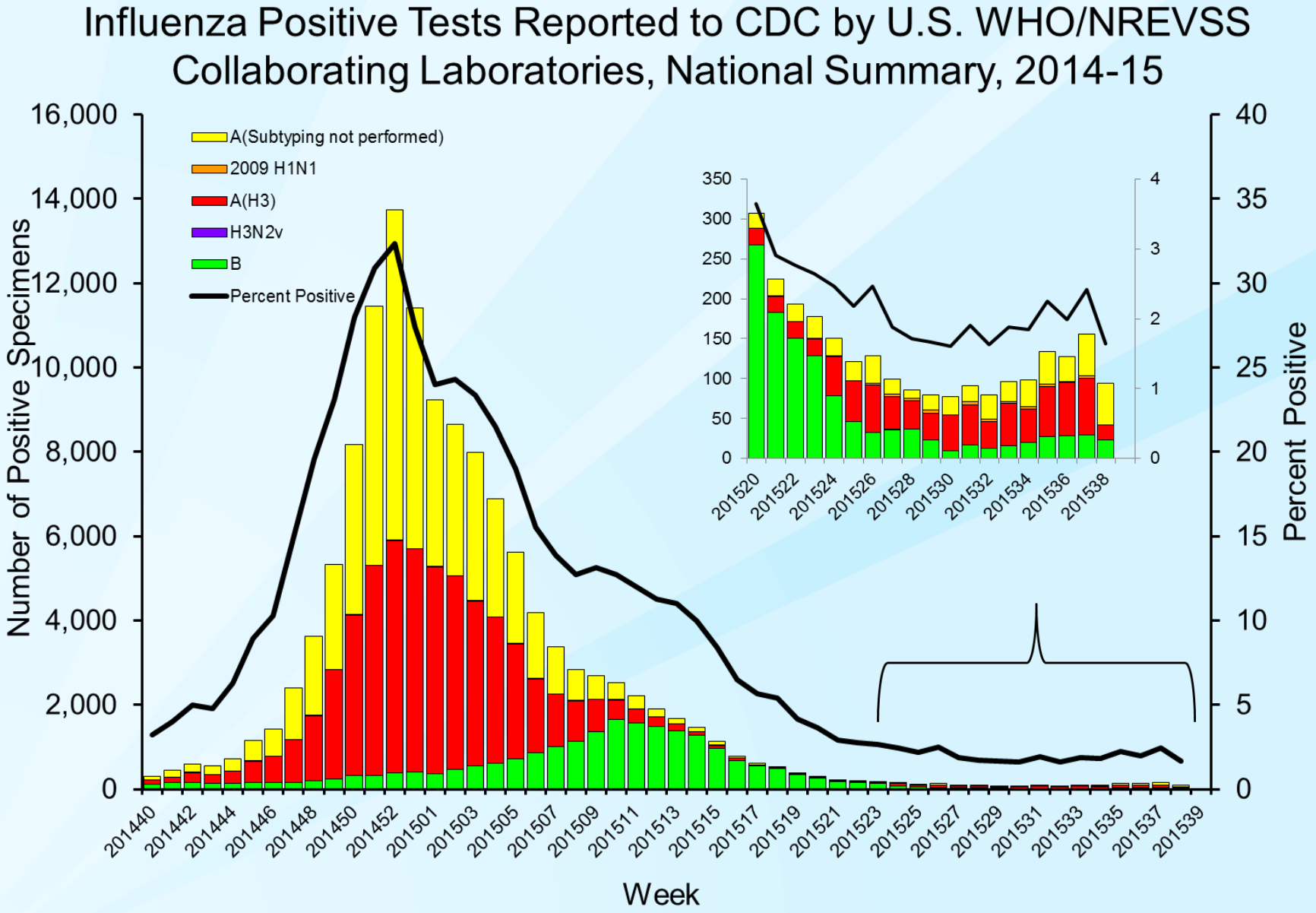
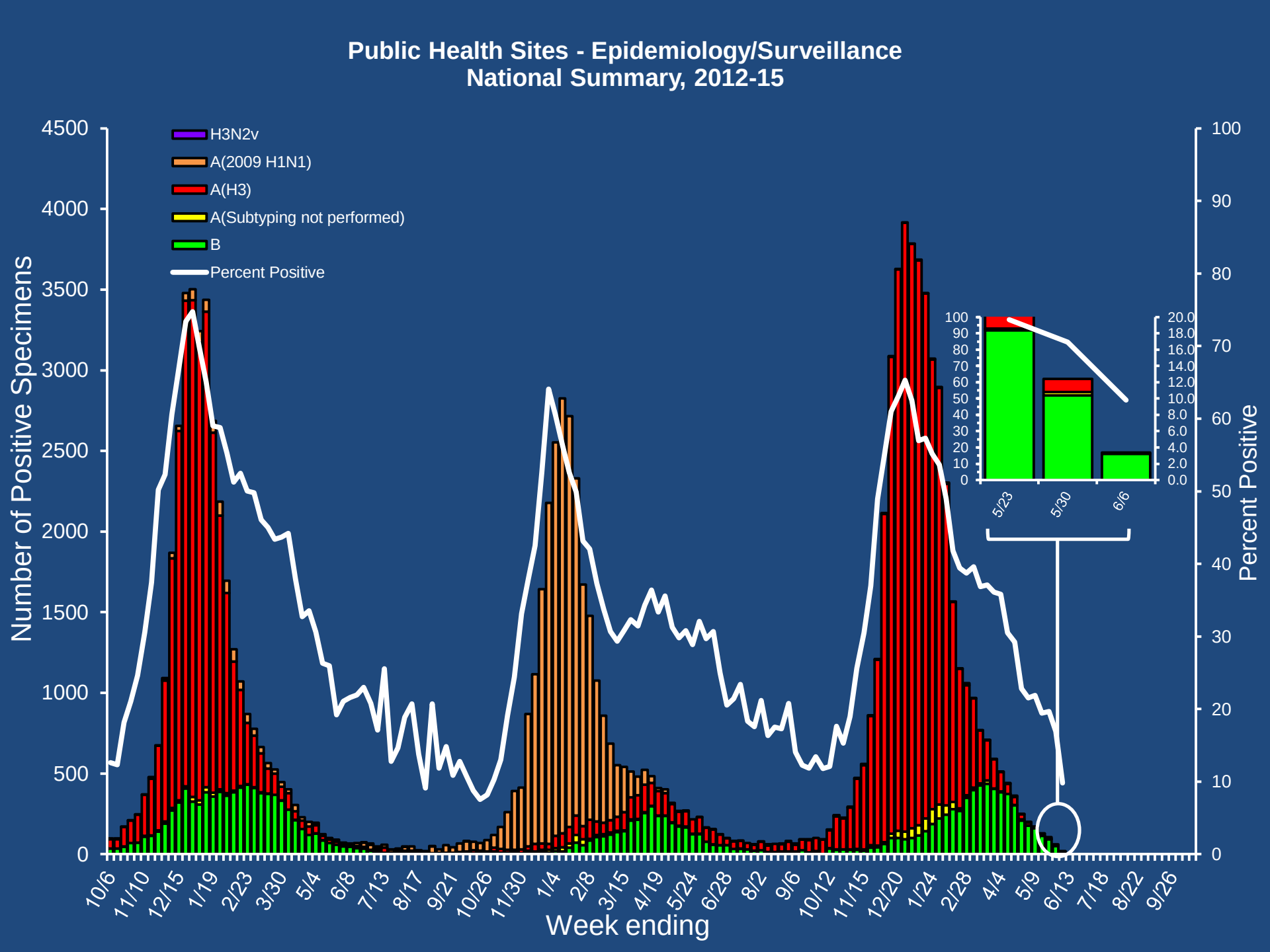
NAICP Call
6 October 2015

Overview

- *Surveillance update*
- *ACIP recommendations update*



CDC, Fluview, 2015 week 38 (September 15, 2015)


Public Health Sites - Epidemiology/Surveillance
National Summary, 2012-15
H3N2v
A(2009 H1N1)
A(H3)
A(Subtyping not performed)
B
Percent Positive
Number of Positive Specimens
Percent Positive
Week ending
4500
4000
3500
3000
2500
2000
1500
1000
500
0
100
90
80
70
60
50
40
30
20
10
0
10/6
11/10
12/15
1/19
2/23
3/30
5/4
6/8
7/13
8/17
9/21
10/26
11/30
1/4
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4/19
5/24
6/28
8/2
9/6
10/12
11/15
12/20
1/24
2/28
4/4
5/9
6/13
7/18
8/22
9/26
5/23
5/30
6/6

2014-15 U.S. Season Summary

- *Predominantly antigenically drifted influenza A (H3N2) viruses early on through late February*
  - *18.6% of 1,324 (H3N2) viruses characterized at CDC were A/Texas/50/2012-like (the virus include din the 2014-15 vaccine)*
  - *81.4% showed reduced titers with antiserum produced against A/Texas/50/2012 or belonged to a genetic group that typically does*
- *B viruses predominated beginning late February*
  - *71.9% of 810 influenza B viruses characterized at CDC were B/Yamagata lineage; 98.1% of these were B/Massachusetts/2/2012-like (included the 2014-15 trivalent and quadrivalent vaccines)*
- *Overall reduced VE for 2014-15*
  - *US Flu VE Network results, June 2015 ACIP: overall 23% across age groups (13% for A(H3N2); 55% for B(Yamagata)*

MMWR (2015) 64;21:583-590

2014-15 U.S. Season Summary

- *Moderately severe season, particularly severe among persons 65 years of age and older*
  - *H3N2-predominant seasons more severe for those at extremes of age (<5 years, ≥65 years) then non-H3N2 predominant seasons*
  - *Influenza activity similar to that of 2012-13, but even higher hospitalization rates among those ≥65 years*
    - *2012-13: 183.2 per 100,000*
    - *2014-15: 319.2 per 100,000*
  - *79% of pneumonia and influenza deaths for 2014-15 occurred in adults ≥65 years (similar to 2012-13)*
- *Cumulative hospitalization rate among children aged <5 years 57.1 per 100,000*
  - *Slightly less than that observed in 2012–13 season (66.2 per 100,000)*

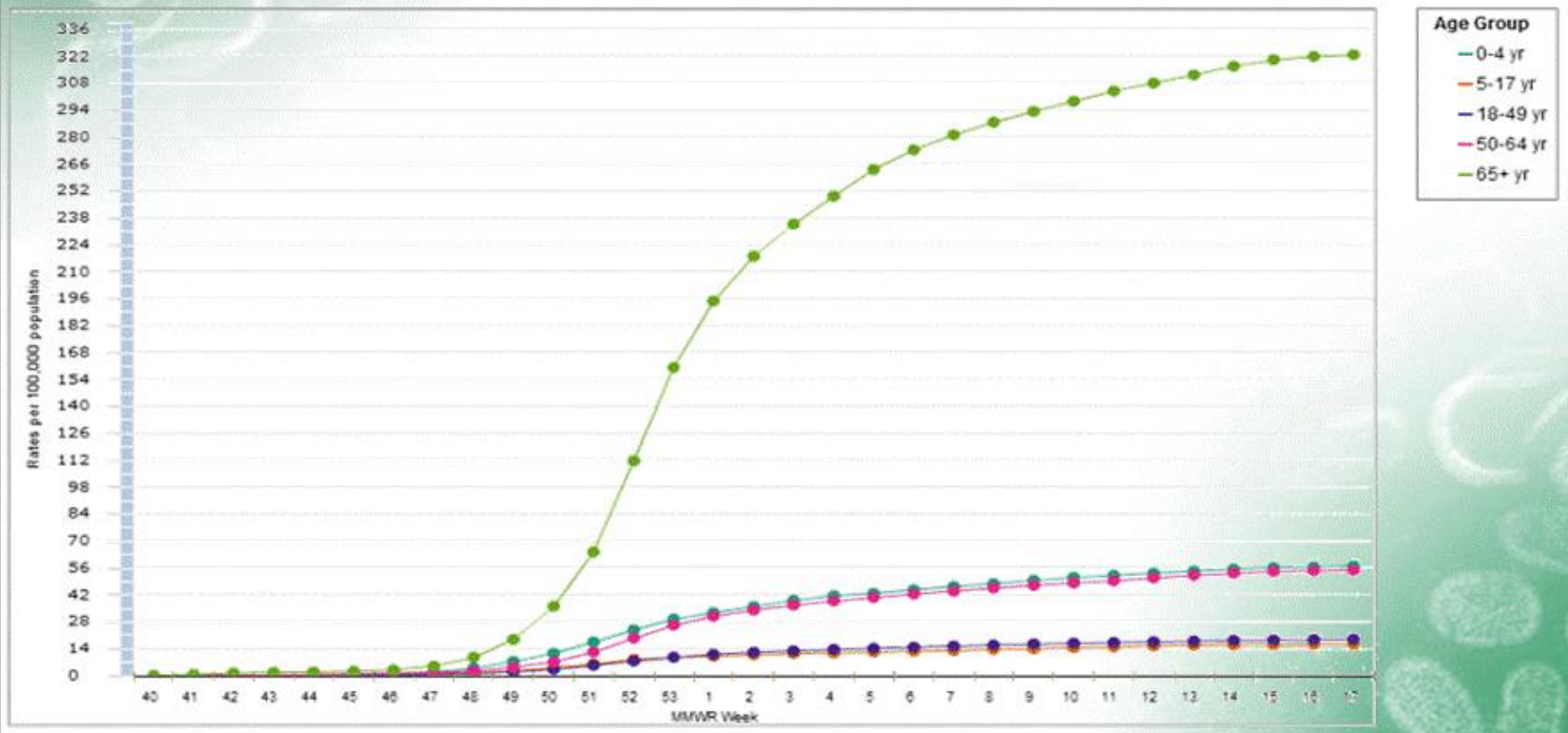
FLUVIEW

A Weekly Influenza Surveillance Report Prepared by the Influenza Division

CDC
Centers for Disease Control and Prevention

Laboratory-Confirmed Influenza Hospitalizations

Preliminary rates as of May 23, 2015

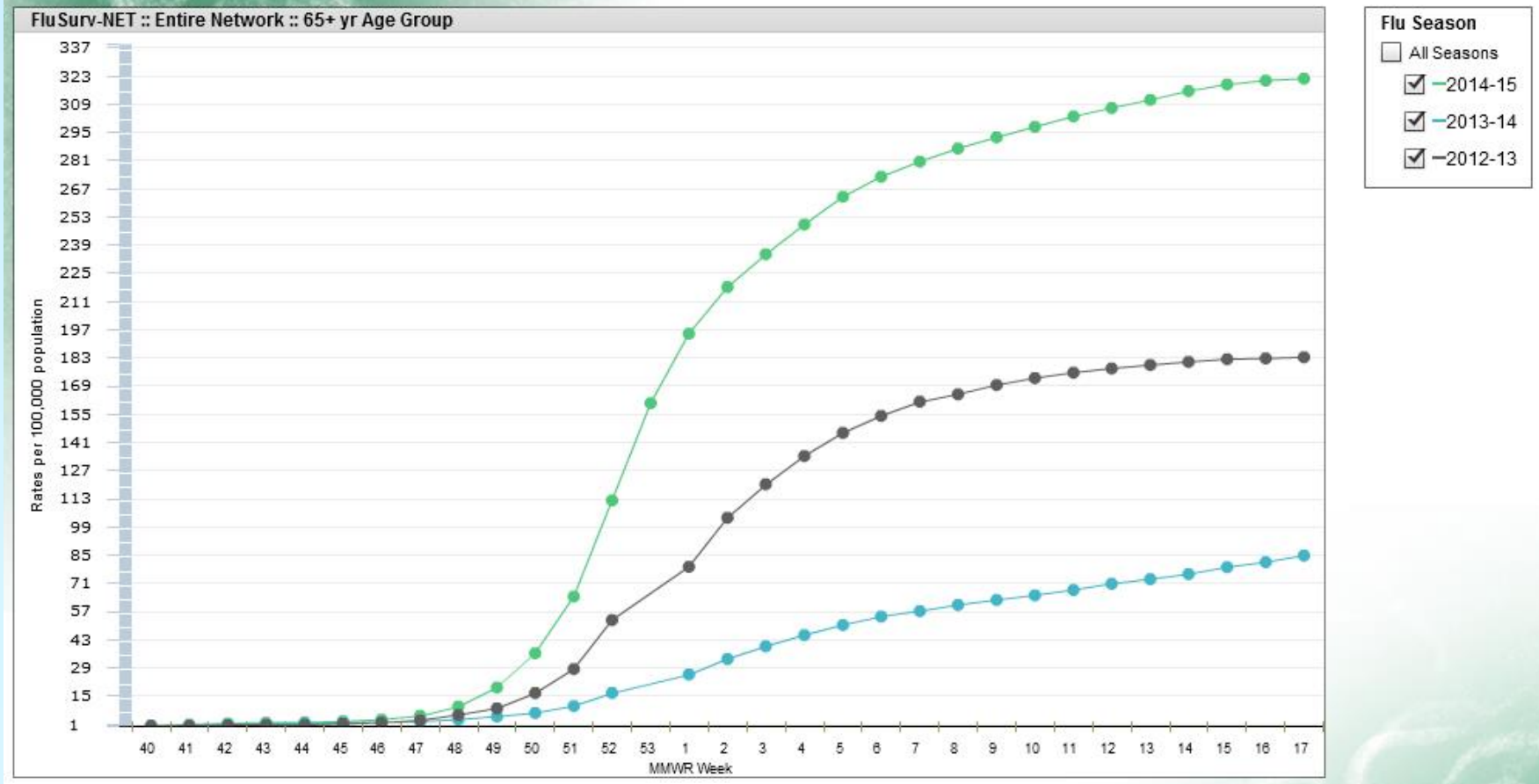


FLUVIEW

Laboratory-Confirmed Influenza Hospitalizations

Preliminary rates as of Sep 26, 2015

CDC



The Influenza Hospitalization Surveillance Network (FluSurv-NET) conducts population-based surveillance for laboratory-confirmed influenza-associated hospitalizations in children (persons younger than 18 years) and adults. The current network covers over 70 counties in the 10 Emerging Infections Program (EIP) states (CA, CO, CT, GA, MD, MN, NM, NY, OR, and TN) and three additional states (MI, OH, and UT). The network represents approximately 9% of US population (~27 million people). Cases are identified by reviewing hospital, laboratory, and admission databases and infection control logs for patients hospitalized during the influenza season with a documented positive influenza test (i.e., viral culture, direct/indirect fluorescent antibody assay (DFA/IFA), rapid influenza diagnostic test (RIDT), or molecular assays including reverse transcription-polymerase chain reaction (RT-PCR)). Data gathered are used to estimate age-specific hospitalization rates on a weekly basis, and describe characteristics of persons hospitalized with severe influenza illness. Laboratory-confirmation is dependent on clinician-ordered influenza testing. Therefore, the rates provided are likely to be underestimated as influenza-related hospitalizations can be missed, either because testing is not performed, or because cases may be attributed to other causes of pneumonia or other common influenza-related complications.

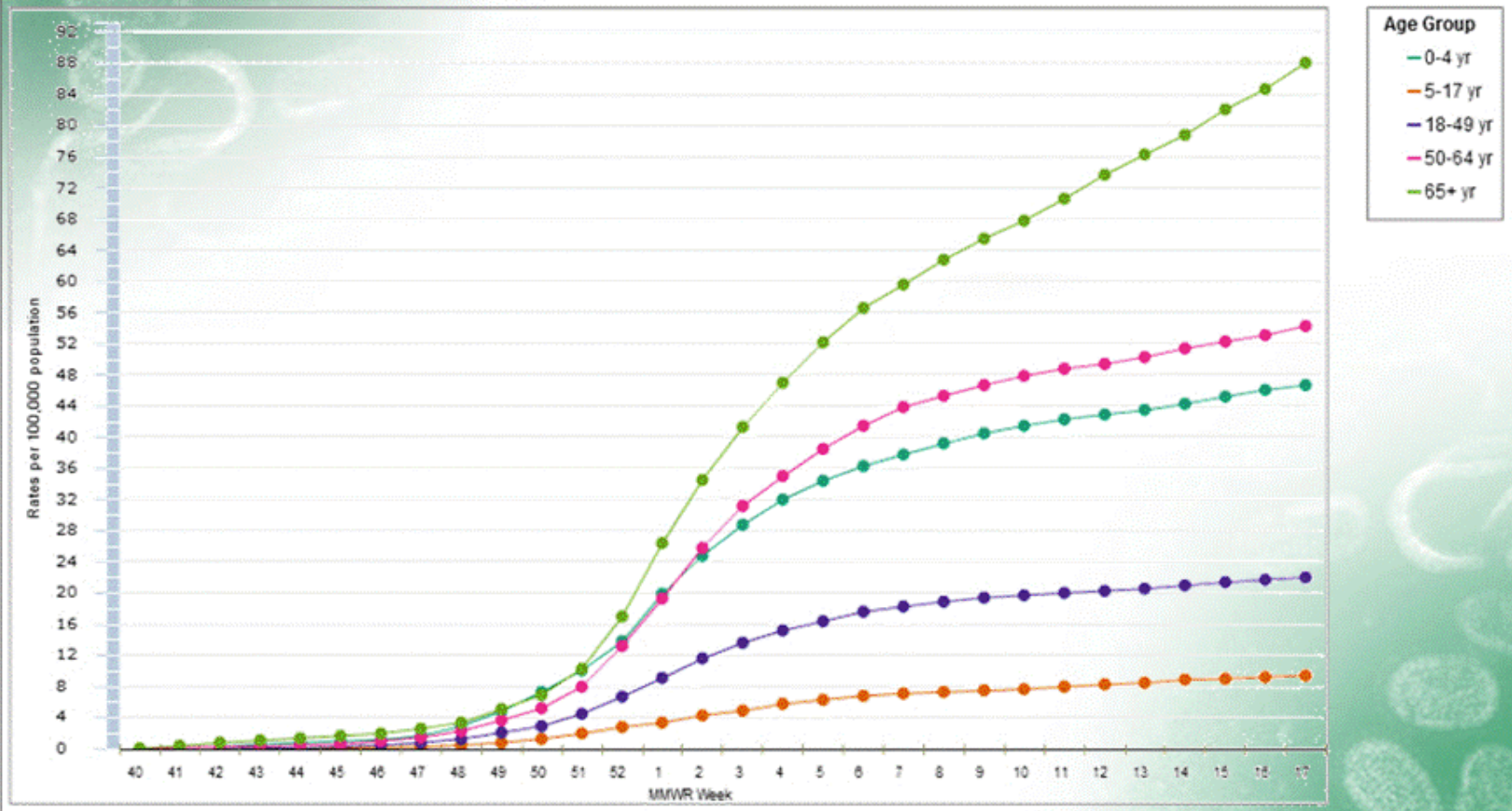
FLUVIEW

A Weekly Influenza Surveillance Report Prepared by the Influenza Division

CDC Centers for Disease Control and Prevention

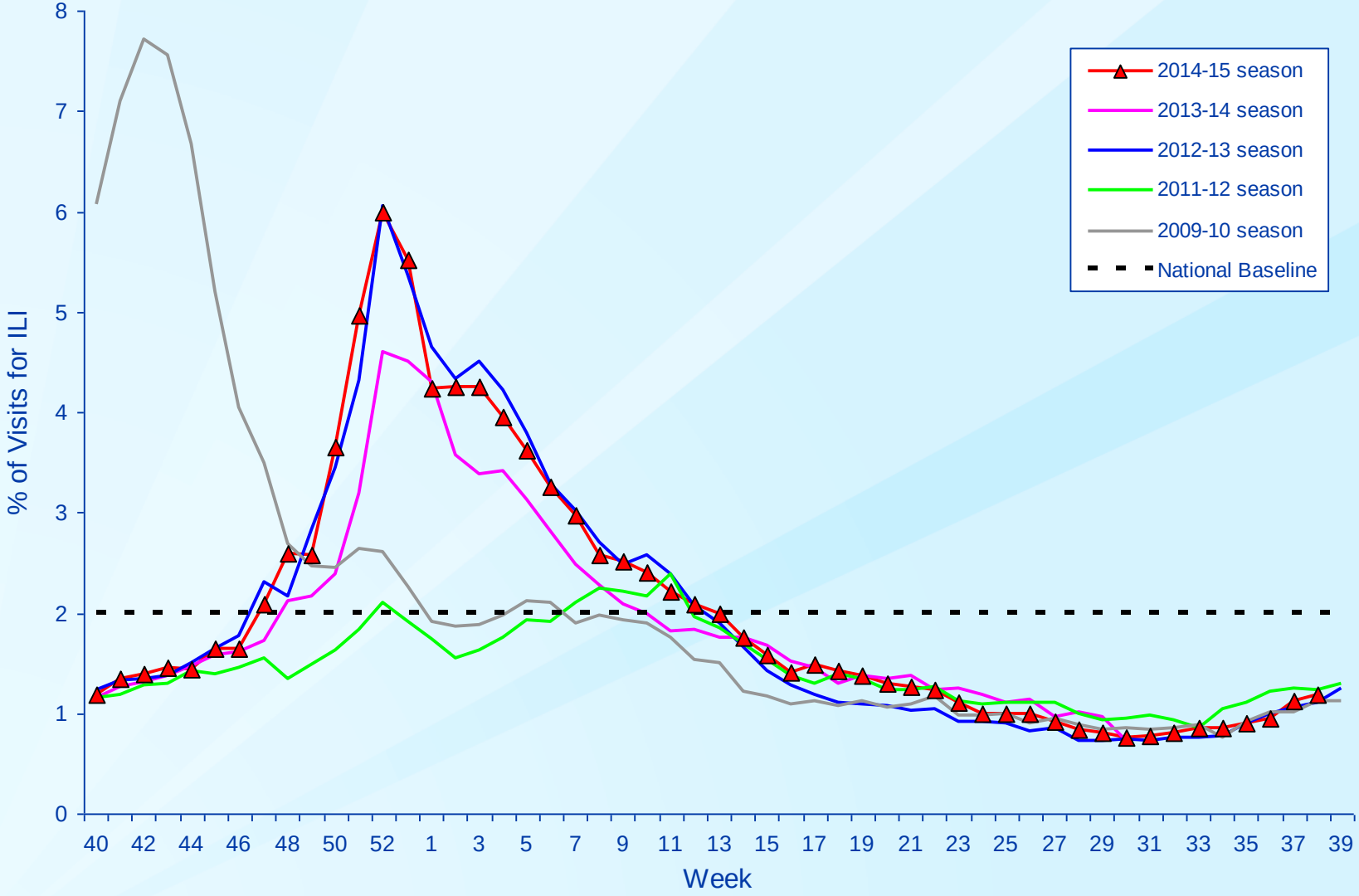
Laboratory-Confirmed Influenza Hospitalizations

Preliminary rates as of May 17, 2014



Data from the Influenza Hospitalization Surveillance Network (FluSurv-NET), a population-based surveillance for influenza related hospitalizations in children and adults in 13 US states. Incidence rates are calculated using the National Center for Health Statistics' (NCHS) population estimates for the counties included in the surveillance catchment area.

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2014-15 and Selected Previous Seasons



*There was no week 53 in the previous influenza seasons displayed above; therefore the week 53 data point for those seasons is an average of weeks 52 and 1.

CDC, Fluview, 2015 week 38 (September 15, 2015)

2015-16 ACIP Influenza Vaccination Statement

- *2015-16 ACIP statement published in MMWR August 7, 2015*
- *Annual influenza vaccination is recommended for all persons aged 6 months and older*
- *Topics discussed:*
  - *Influenza vaccine virus composition for 2015-16*
  - *New FDA-approvals since the 2014-15 statement*
  - *Update in dosing algorithm for children aged 6 mos. through 8 yrs.*
  - *Updated recommendations regarding use of LAIV and IIV for healthy 2 through 8 year olds, including removal of LAIV preference*
- *For topics not addressed, refer to 2013-14 statement*

Vaccine Composition for 2015-16

Two strain changes compared with the 2014-15:

- *For trivalent vaccines,*
  - *an A/California/7/2009 (H1N1)pdm09-like virus (same as 2014-15);*
  - *An A/Switzerland/9715293/2013 (H3N2)-like virus (replaces A/Texas/50/2012 (H3N2)-like)*
  - *A B/Phuket/3073/2013-like virus (Yamagata lineage; replaces previous B/Massachusetts/2/2012-like Yamagata lineage virus)*

- *For quadrivalent vaccines,*
  - *The above three viruses and a B/Brisbane/60/2008-like virus (Victoria lineage; same as 2014-15)*

Influenza Vaccine Product Updates for 2015-16

New licensures, labeling information, and other changes:

- *Fluzone® Intradermal Quadrivalent IIV*
  - *Replaces previous trivalent formulation of Fluzone Intradermal*
  - *Non-inferior immunogenicity, similar adverse event profile to trivalent*
  - *Licensed for persons 18 through 64 years of age*
- *Expanded age indication for Flublok® (now 18 and older)*
  - *Previously licensed for 18 through 49 years*
  - *Similar immunogenicity and safety among persons 50 years and over*
- *Approval of administration of Afluria® by Stratis® jet injector for persons 18 through 64 years of age*
  - *Ages 9 through 17 years, 65 years and over—needle/syringe only*
  - *ACIP does not recommend Afluria under 9 years*
  - *No other influenza vaccines currently licensed for use with a jet injector*

MMWR (2015) 64;30: 618-625

Licensed Seasonal Influenza Vaccines, United States, 2015-16 Season

MMWR (2015) 64;30: 818-825

TABLE. Influenza vaccines — United States, 2015–16 influenza season*

Trade name	Manufacturer	Presentation	Mercury (from thimerosal) µg/0.5 mL	Ovalbumin µg/0.5 mL	Age indications	Latex	Route
Inactivated influenza vaccine, quadrivalent (IIV4), standard dose							
Contraindications: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.*							
Precautions: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Fluarix Quadrivalent	GlaxoSmithKline	0.5 mL single-dose prefilled syringe	—	≤0.05	≥3 yrs	No	IM†
FluLaval Quadrivalent	ID Biomedical Corp. of Quebec (distributed by GlaxoSmithKline)	5.0 mL multi-dose vial	<25	≤0.3	≥3 yrs	No	IM†
Fluzone Quadrivalent	Sanofi Pasteur	0.25 mL single-dose prefilled syringe	—	§	6 through 35 mos	No	IM†
		0.5 mL single-dose prefilled syringe	—	§	≥36 mos	No	IM†
		0.5 mL single-dose vial	—	§	≥36 mos	No	IM†
		5.0 mL multi-dose vial	25	§	≥6 mos	No	IM†
Fluzone Intradermal¶ Quadrivalent	Sanofi Pasteur	0.1 mL single-dose prefilled microinjection system	—	§	18 through 64 yrs	No	ID**
Inactivated influenza vaccine, trivalent (IIV3), standard dose							
Contraindications: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.*							
Precautions: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Afluria	bioCSL	0.5 mL single-dose prefilled syringe	—	<1	≥9 yrs††	No	IM†
		5.0 mL multi-dose vial	24.5	<1	≥9 yrs†† via needle;18 through 64 yrs via jet injector	No	IM†
Fluvirin	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	≤1	≤1	≥4 yrs	Yes§§	IM†
		5.0 mL multi-dose vial	25	≤1	≥4 yrs	No	IM†
Fluzone	Sanofi Pasteur	5.0 mL multi-dose vial	25	§	≥6 mos	No	IM†
Inactivated influenza vaccine, cell-culture-based (ccIIV3), standard dose							
Contraindications: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.*							
Precautions: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Flucelvax	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	—	¶¶	≥18 yrs	Yes§§	IM†
Inactivated influenza vaccine, trivalent (IIV3), high dose							
Contraindications: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.*							
Precautions: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Fluzone High-Dose***	Sanofi Pasteur	0.5 mL single-dose prefilled syringe	—	§	≥65 yrs	No	IM†
Recombinant influenza vaccine, trivalent (RIV3), standard dose							
Contraindications: Severe allergic reaction to any vaccine component.*							
Precautions: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Flublok	Protein Sciences	0.5 mL single-dose vial	—	0	≥18 yrs	No	IM†
Live attenuated influenza vaccine, quadrivalent (LAIV4)							
Contraindications: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Concomitant use of aspirin or aspirin-containing medications in children and adolescents.*							
In addition, ACIP recommends LAIV4 not be used for pregnant women, immunosuppressed persons, persons with egg allergy, and children aged 2 through 4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months.							
LAIV4 should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours.							
Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV4, or should avoid contact with such persons for 7 days after receipt.							
Precautions: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine; asthma in persons aged 5 years and older; medical conditions which might predispose to higher risk for complications attributable to influenza.*							
FluMist Quadrivalent†††	MedImmune	0.2 mL single-dose prefilled intranasal sprayer	—	<0.24 (per 0.2 mL)	2 through 49 yrs	No	IN

See table footnotes on page next page.

Available Influenza Vaccine Products, 2015-16
General Characteristics

- *Live virus vs. not*
- *Trivalent vs. quadrivalent*
- *Standard-dose vs. high-dose*
- *Egg-based vs. non-egg based*
- *Intramuscular vs. intradermal vs. intranasal*

Available Influenza Vaccine Products, 2015-16
(11 Branded Products)

- **9 inactivated vaccine products (IIVs)**
  - *4 quadrivalent*
    - *All standard dose, all egg-based*
    - *3 intramuscular, 1 intradermal*
  - *3 trivalent, standard dose, egg-based (IIV3)—intramuscular*
  - *1 trivalent, standard dose, cell culture-based (ccIIV3)—intramuscular*
  - *1 trivalent, high dose, egg based (high dose IIV3)—intramuscular*

- **1 live attenuated vaccine product (LAIV)**
  - *Quadrivalent only (LAIV4)—intranasal*

- **1 recombinant vaccine product (RIV)**
  - *Trivalent only (RIV3)—intramuscular*

Trivalent Inactivated Influenza Vaccines (IIV3s)

- **Have different age indications; need to check package insert**
  - *An age-appropriate product should be used*
  - *Products available for persons as young as 6 months*
- **All are egg-based EXCEPT Flucelvax® (Novartis)—MDCK cells**
- **All contain 15µg of HA per virus EXCEPT Fluzone® High-Dose**
  - *Contains 60µg HA per virus*
  - *Approved for persons aged 65 years and older*
  - *24.2% more effective than standard dose IIV3 in preventing lab confirmed influenza among persons 65 and older in one RCT*
- **All are administered intramuscularly (needle/syringe)**
- **One (Afluria®, bioCSL) approved for administration via jet injector**
  - *May be administered by sterile needle and syringe (ages 9 and older),*
  - *OR by Stratis® (PharmaJet) jet injector (ages 18 through 64 years ONLY)*

Quadrivalent Inactivated Influenza Vaccines (IIV4s)

- **Provide broader protection against Influenza B viruses**
  - *There are two Influenza B lineages: Victoria and Yamagata*
  - *Immunization against virus from one lineage provides only limited cross-protection against viruses in the other*
  - *Predominant lineage difficult to predict ahead of each season*
  - *Trivalent vaccines contain only one B vaccine virus*
  - *Quadrivalents contain two B viruses (one from each lineage)*
- **All contain 15µg of HA per virus EXCEPT Fluzone® Intradermal Quadrivalent**
- **All are administered intramuscularly EXCEPT Fluzone Intradermal Quadrivalent (intradermal)**
  - *Administered with device included in packaging*
  - *9 mcg per HA virus*
- **Three different products; one approved for as young as 6 mos**

Recombinant Influenza Vaccine (RIV3)

- **FluBlok® (Protein Sciences)**
- **Approved for persons aged 18 years and over**
- **Currently available only in trivalent formulation**
- **Considered egg-free**
- **Vaccine contains recombinant influenza virus HA**
  - *HA produced via introduction of the gene sequence into an insect cell line (Fall Armyworm) using a baculovirus vector*
  - *Contains 45 mcg HA derived from each vaccine virus (135 mcg total)*
- **Per ACIP recs, is an option for persons with egg allergy of any severity (for those within the indicated age range)**

Live Attenuated Influenza Vaccine (LAIV4)

- **FluMist® (MedImmune)**
- **Administered intranasally**
- **Quadrivalent only since 2013-14**
- **Approved for persons aged 2 through 49 years**
  - *ACIP recommends only for certain populations*

Persons for Whom LAIV Should Not Be Used (1)

LAIV should not be used in the following populations:

- *Persons aged <2 years or >49 years;*
- *Those with contraindications listed in the package insert:*
  - *Children and adolescents receiving aspirin or aspirin-containing products;*
  - *Persons who have experienced severe allergic reactions to the vaccine or any of its components, or to a previous dose of any influenza vaccine;*
- *Pregnant women;*
- *Immunosuppressed persons;*
- *Persons with a history of egg allergy;*
- *Children aged 2 through 4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months;*

Persons for Whom LAIV Should Not Be Used (2)

In addition to those on the previous slide, LAIV should not be used in the following populations (continued):

- *Persons who have taken influenza antiviral medications within the previous 48 hours.*
- *Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV, or should avoid contact with such persons for 7 days after receipt.*

Precautions for the Use of LAIV

In addition to groups for whom LAIV is not recommended, the following are precautions for use of LAIV:

- *Medical conditions that predispose to high risk of complications due to influenza (labeled precaution per the package insert);*
- *Asthma in persons aged ≥5 years (package insert notes potential increased risk of wheezing).*
- *Guillain-Barré Syndrome within 6 weeks of a prior dose of influenza vaccine (a precaution for all influenza vaccines)*
- *Moderate to severe illness with or without fever (a precaution for all influenza vaccines)*

Currently Available Influenza Vaccines (N=11)

- **For many people, more than one option—examples:**
  - *Healthy 2 through 49 year olds—LAIV or IIV?*
  - *65 years and older—standard dose or high dose IIV?*
  - *Pretty much anyone—quadrivalent or trivalent?*

- **ACIP makes no preferential recommendations for one product over another in situations where more than one is appropriate for a given individual**

Thank You!

For more information please contact Centers for Disease Control and Prevention

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Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
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