

ACIP Recommendations

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National Influenza Vaccine Summit
May 16, 2012

National Center for Immunization & Respiratory Diseases
Influenza Division

Disclaimers

- ❑ The findings and conclusions in this presentation have not been formally disseminated by CDC and should not be construed to represent any agency determination or policy.
- ❑ I have no financial conflicts of interest.

ACIP Influenza Statement, 2012-2013

- ❑ **Will be presented at June 20-21 ACIP meeting**
 - Recommendations not final until published
 - Things may happen between now and then
- ❑ **Brief format (MMWR Policy Note)**
- ❑ **Topics:**
 - Vaccines available for 2012-2013
 - Vaccine virus strain changes
 - Vaccine schedule for children 6 mos through 8 yrs
 - Quadrivalent vaccine
- ❑ **At this time, no major changes or expansion of recommendations anticipated**
 - Annual vaccination recommended for all 6 mos. and older

Vaccines Available for 2012-2013

- ❑ **No new vaccines anticipated to be available this season**
- ❑ **Quadrivalent live attenuated influenza vaccine (LAIV; FluMist Quadrivalent, MedImmune) approved by FDA February 2012**
 - Anticipated to be available for 2013-2014 US season
- ❑ **Options similar to last season:**
 - Trivalent inactivated vaccine (TIV)—6 mos and older (**BUT** age indications differ by brand—consult PI)
 - High dose TIV—65 yrs and over
 - Intradermal TIV—18 through 64 yrs
 - LAIV—healthy, non-pregnant persons 2 through 49 yrs
- ❑ **ACIP currently expresses no preferences**

2012-2013 Vaccine Components

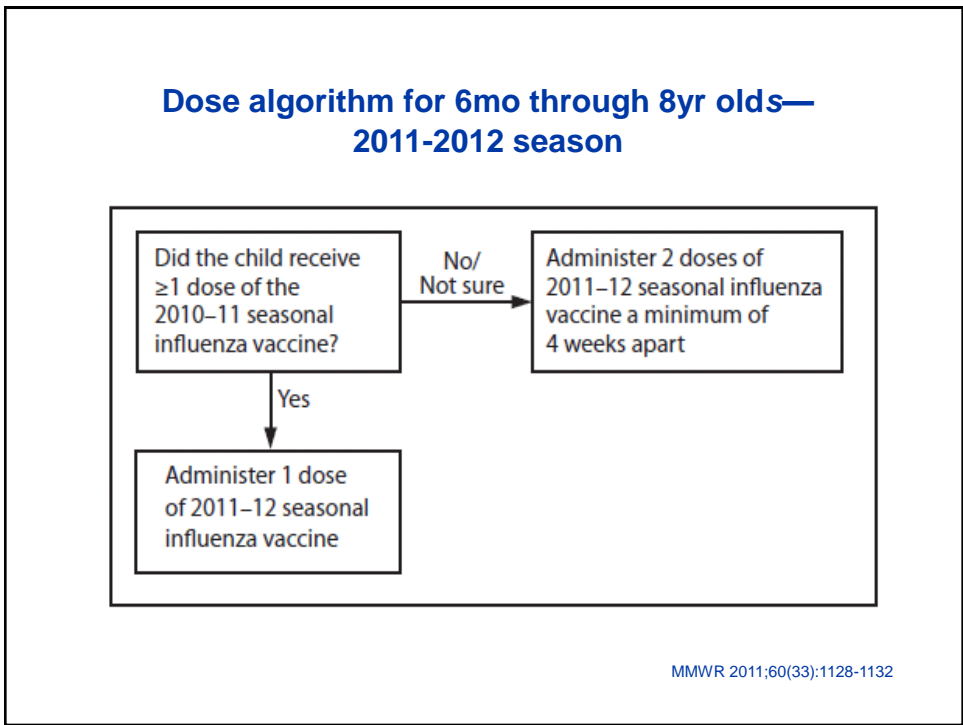
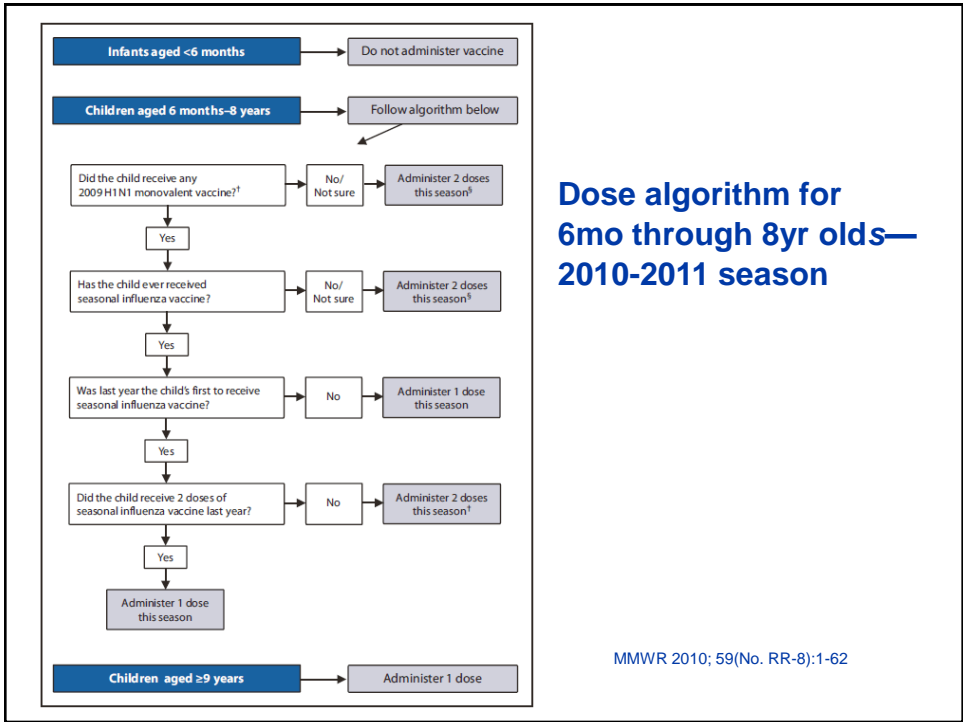
- **Changes in the A(H3N2) and B strains as compared with 2011-2012 vaccine:**
 - A/California/7/2009 (H1N1)pdm09
 - A/Victoria/361/2011 (H3N2)
 - B/Wisconsin/1/2010 (Yamagata lineage; replaces previous Victoria lineage virus)

- **WHO recommended countries considering use of a Victoria-lineage B virus use a strain similar to B/Brisbane/60/2008 (contained in 2011-2012 vaccine)**
 - FDA recommended this be used if quadrivalent vaccines were to be available in 2012-2013

One Dose or Two? Vaccine for Children 6 Months Through 8 Years

- **Children under 9 years of age require 2 doses of influenza vaccine in first season of vaccination.**
 - Doses administered ≥ 4 weeks apart

- **Antigenic novelty of pdm09 (2009 H1N1) necessitated consideration of this additional antigen**
 - Needed to document receipt of seasonal and H1N1 vaccine
 - For 2010-2011 season, 2 doses needed unless child had
 - Received ≥ 1 dose of monovalent 2009(H1N1) vaccine, AND
 - Had received seasonal vaccine previously, AND
 - Had received 2 doses of seasonal vaccine in first season vaccinated



Dose algorithm for 6mo through 8yr olds— 2012-2013 season

- **Algorithm still under discussion**

- **Considerations**
 - Maximize likelihood that children needing two doses receive them
 - Simplicity
 - Optimally, harmonization with American Academy of Pediatrics

Quadrivalent Influenza Vaccines

- **Would contain 4 vaccine virus antigens**
 - A(H1N1), A(H3N2), and **two** B strains (one Victoria lineage, one Yamagata lineage)

- **Potentially advantageous—**
 - Cross-protection conferred against B virus in one lineage by vaccination against a B virus in the other lineage is limited
 - Circulating B strains difficult to predict
 - Recent analysis suggests possible modest reduction in influenza-associated outcomes, depending upon supply, coverage, effectiveness, and incidence of influenza associated with the two B lineages

- **First quadrivalent influenza vaccine approved by FDA in February, 2012**
 - FluMist Quadrivalent (MedImmune)--LAIV

Reed C, et al. Vaccine (2012), doi:10.1016/j.vaccine.2011.12.098

Summary

- **No expansion or major changes in recommendations expected**
 - (however, recommendations not final until published)

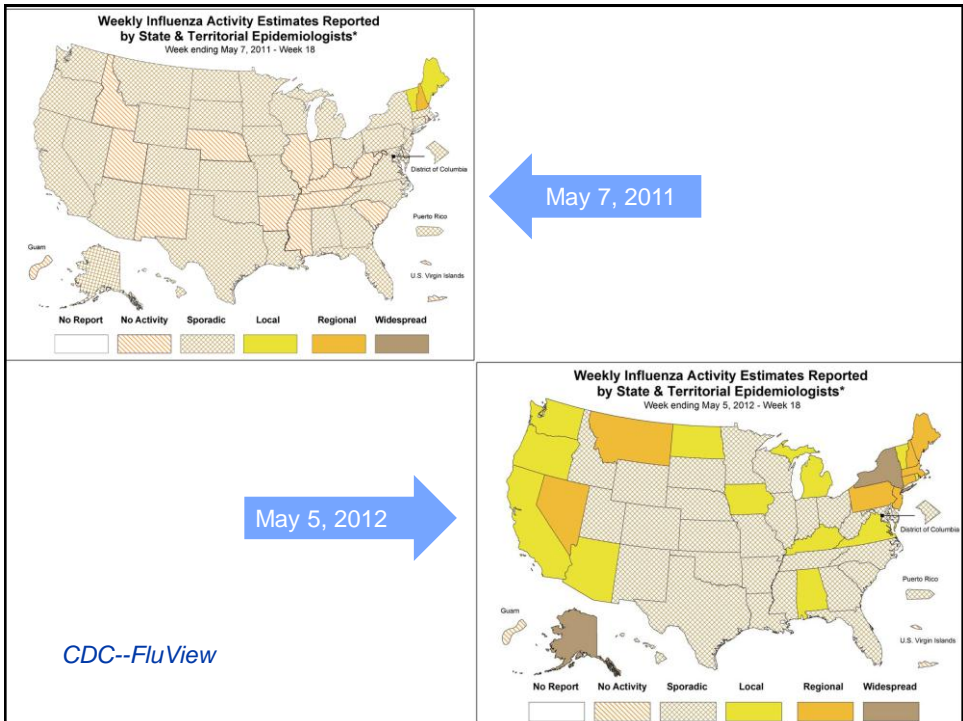
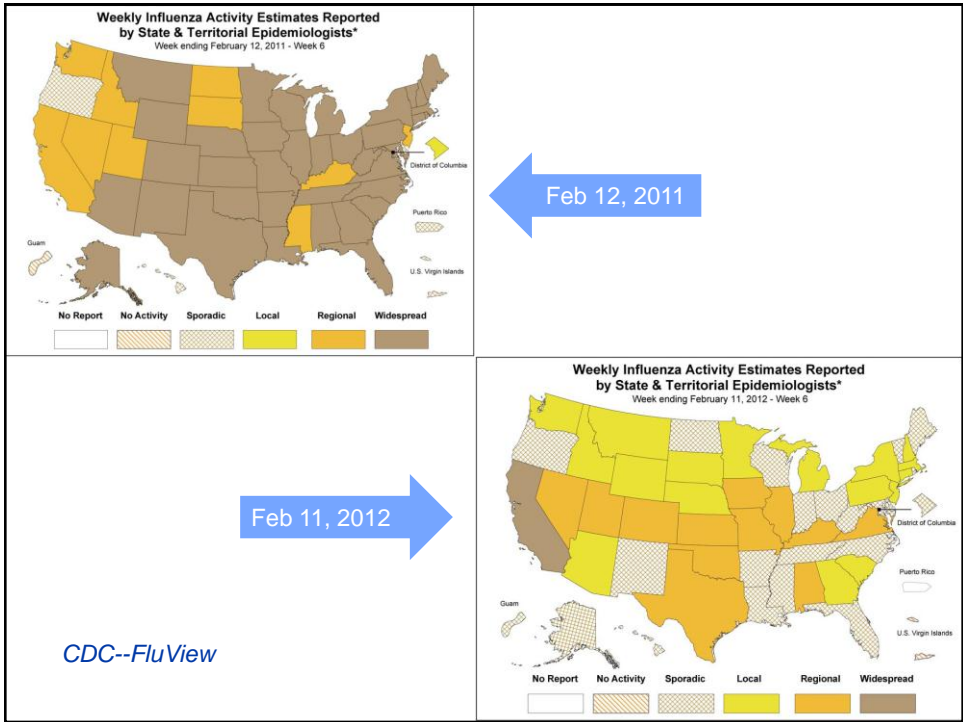
- **No new vaccine approvals at this time for products to be available in 2012-2013**
 - ACIP to discuss new products as they become approved/available

Influenza Activity and Surveillance

Lisa Grohskopf, MD, MPH

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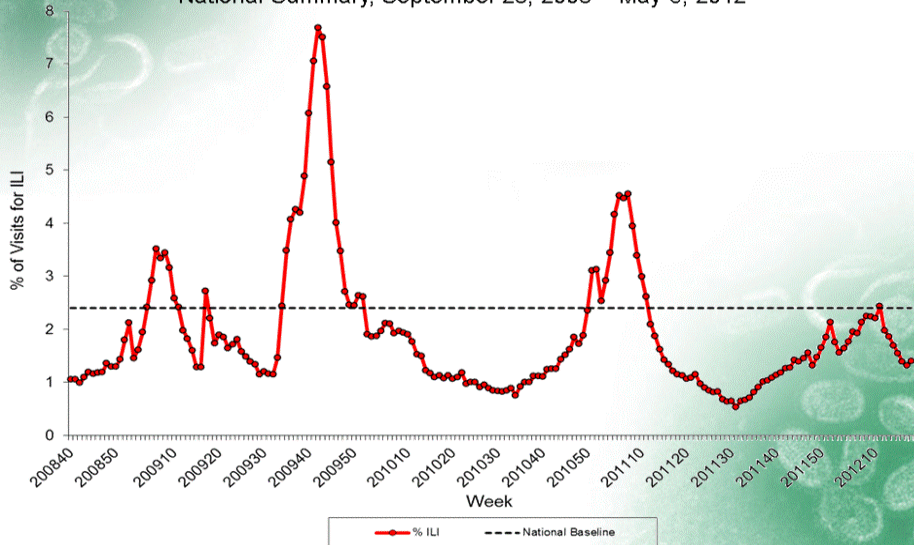


FLUVIEW

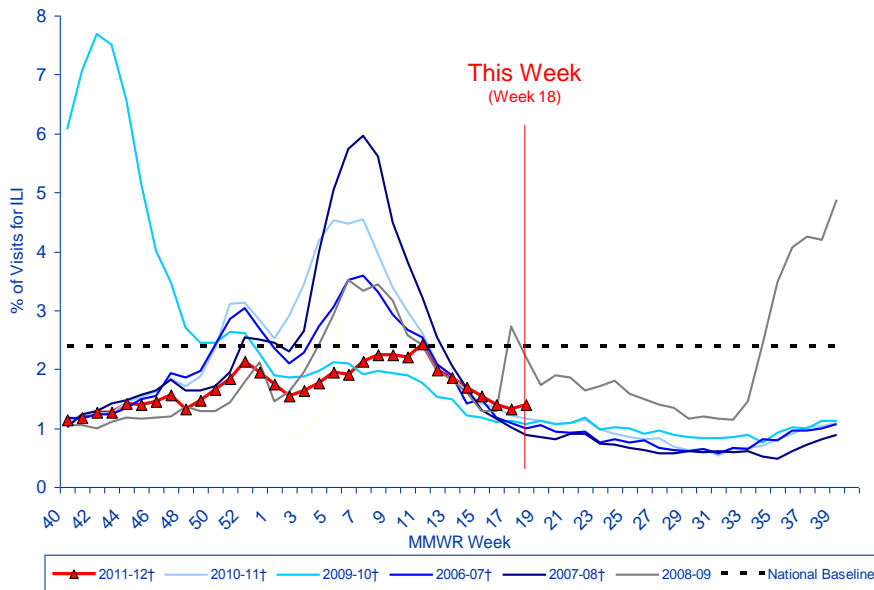


A Weekly Influenza Surveillance Report Prepared by the Influenza Division

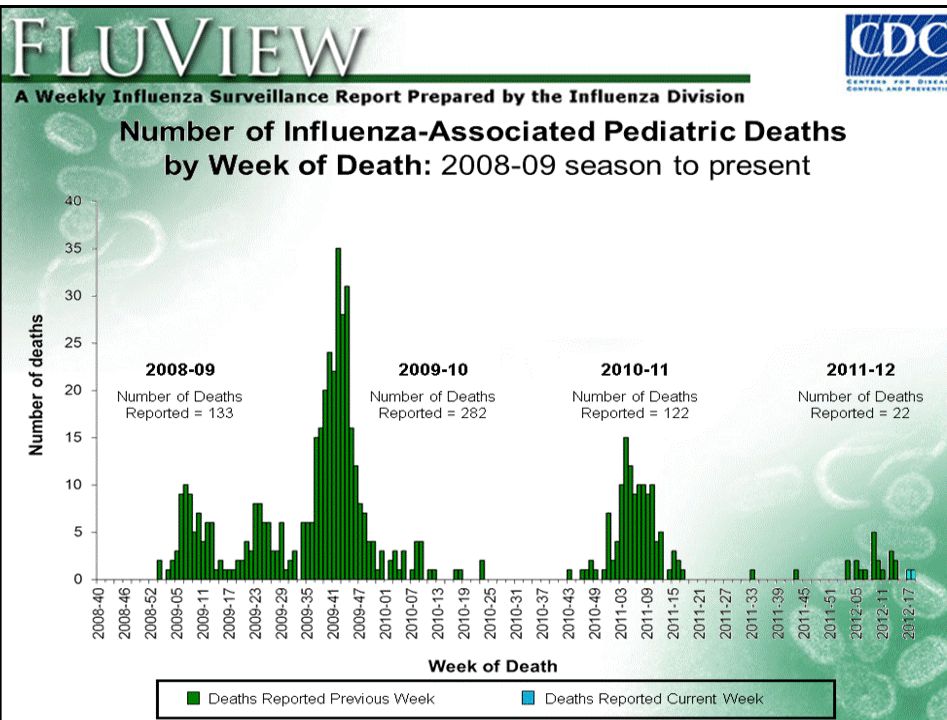
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, September 28, 2008 – May 5, 2012



Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2011-12 and Previous Five Seasons



† There was no week 53 during these seasons, so the week 53 data point is an average of week 52 and week 1.



Characteristics of Recent Influenza Viruses Tested at CDC

Of 1,438 viruses collected by U.S. laboratories and antigenically characterized at CDC since October 1, 2011:

- 369 (26%) Influenza A (H1N1)
 - 363 (98%) A/California/7/2009-like
- 817 (57%) Influenza A (H3N2)
 - 648 (79%) A/Perth/16/2009-like
- 252 (17%) Influenza B
 - 117 (46%) Victoria lineage; 198 (99%) B/Brisbane/60/2008-like
 - 135 (54%) Yamagata lineage
 - Few B viruses available for testing in US
 - Worldwide most similar to the 2011-2012 vaccine strain

Source: CDC FluView, Week 18 (May 5, 2012)

Human Infections with Variant Influenza A Viruses, United States

- 36 human cases of variant influenza A virus infection identified from Dec 2005 – April 2012
 - Previously ~ 1 case every 1-2 years
 - Better diagnostics
 - Greater awareness
- All triple reassortant swine-origin viruses
- 13 H1N1, 21 H3N2, and 2 H1N2 infections



Reports of Influenza A(H3N2)v, 2011-2012

(N=13)

- Occurred between 7/2011 - 4/2012
- 5 states: IN (2), PA (3) ME (2), IA (3), WV (2) UT (1)
- Swine origin H3N2 with matrix (M) gene from A(H1N1)pdm 2009
- Median age 3 years (range 11 months - 58 years);
 - 12 were children <18 years
 - 11 were <10 years
- Mild to moderate influenza-like illness
- Estimated incubation period 2-4 days (range 1-7 days)
- Exposures:
 - 5 with direct exposure to swine
 - 2 with indirect exposure
 - 6 with no history of swine exposure (potential human-to-human transmission)

MMWR 2011;60(47):1615-1617
MMWR 2011;60(51):1641-1644

Reports of Influenza A(H3N2)v, 2011-2012

(N=13)

- Hemagglutinin genes related to H3N2 viruses circulated in 1990s
- Analyses of serum samples from 2010-2011 TIV study and NHANES:
 - Little or no cross-reactive antibody among children <10 years; 2010-2011 TIV had no impact on antibody levels
 - Cross-reactive antibodies detected in 20-30% of those ≥10 years; among adults, TIV provided a modest boost to cross-reactive antibodies
- An (H3N2)v reassortant vaccine strain based on A/Minnesota/11/2010 has been developed for use in production of an H3N2v vaccine, if needed

MMWR 2011;61(14):237-241

Thank You!

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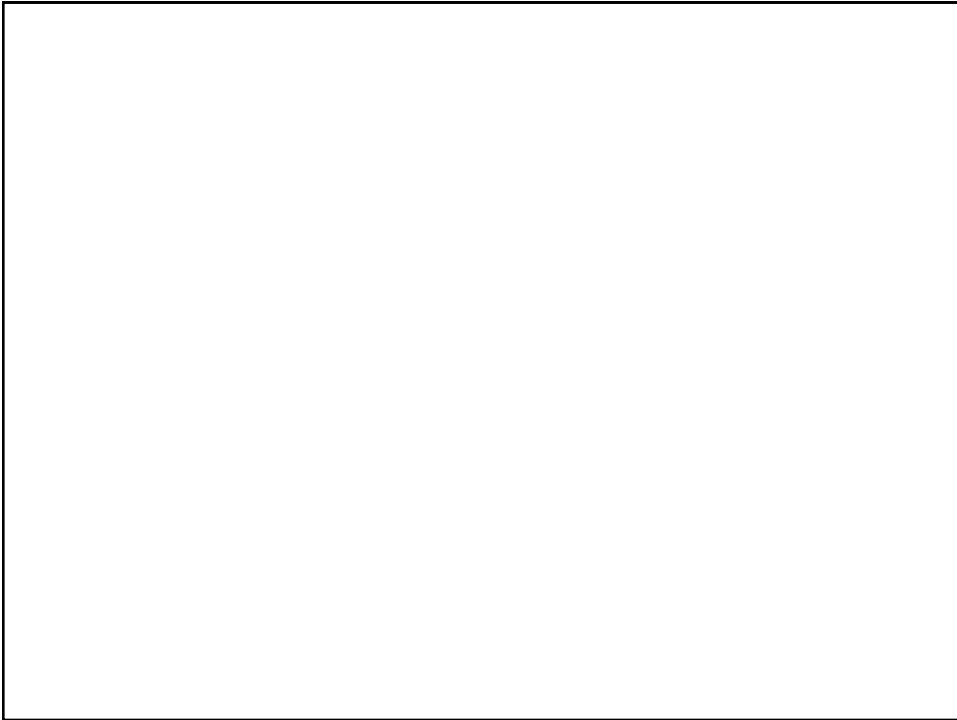
Joe Bresee

ACIP Influenza Workgroup

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Groups at Higher Risk for Influenza Complications

- Persons <2 or ≥65 years of age;
- Persons with the following conditions:
 - chronic pulmonary (including asthma),
 - cardiovascular (except hypertension),
 - renal, hepatic, hematological (including sickle cell) disease,
 - neurological, neuromuscular, or metabolic disorders (including diabetes mellitus);
- Immunosuppression, including that caused by medications or by HIV infection;
- Women who are pregnant or post-partum (2 weeks)
- Persons younger than 19 years of age who are receiving long-term aspirin therapy;
- American Indians and Alaskan Natives;
- Persons who are morbidly obese (body-mass index ≥40);
- Residents of nursing homes and other chronic-care facilities.

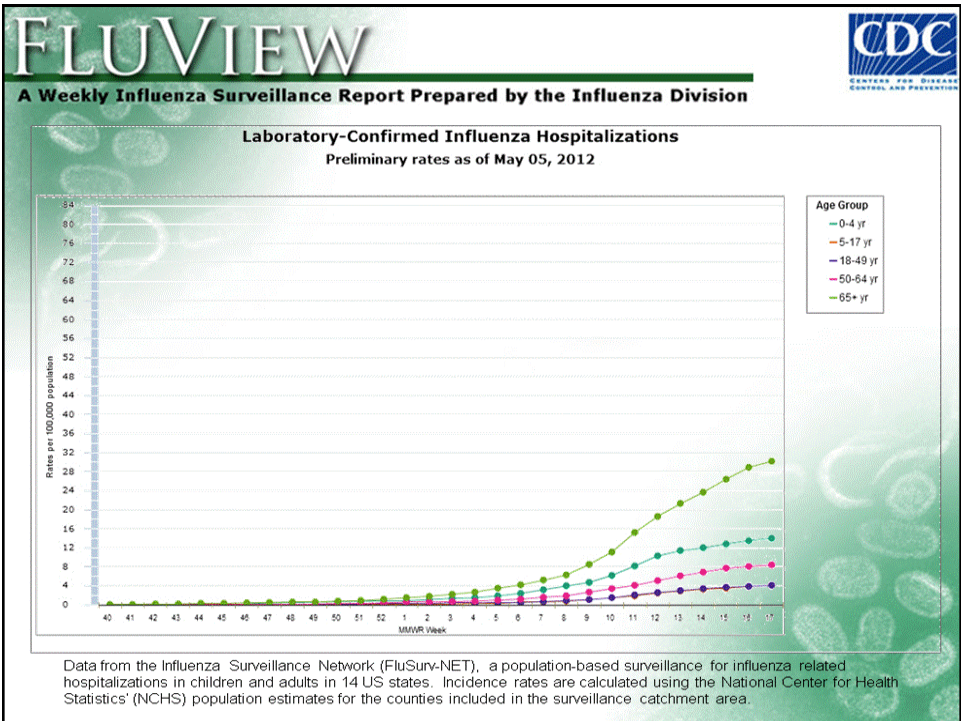
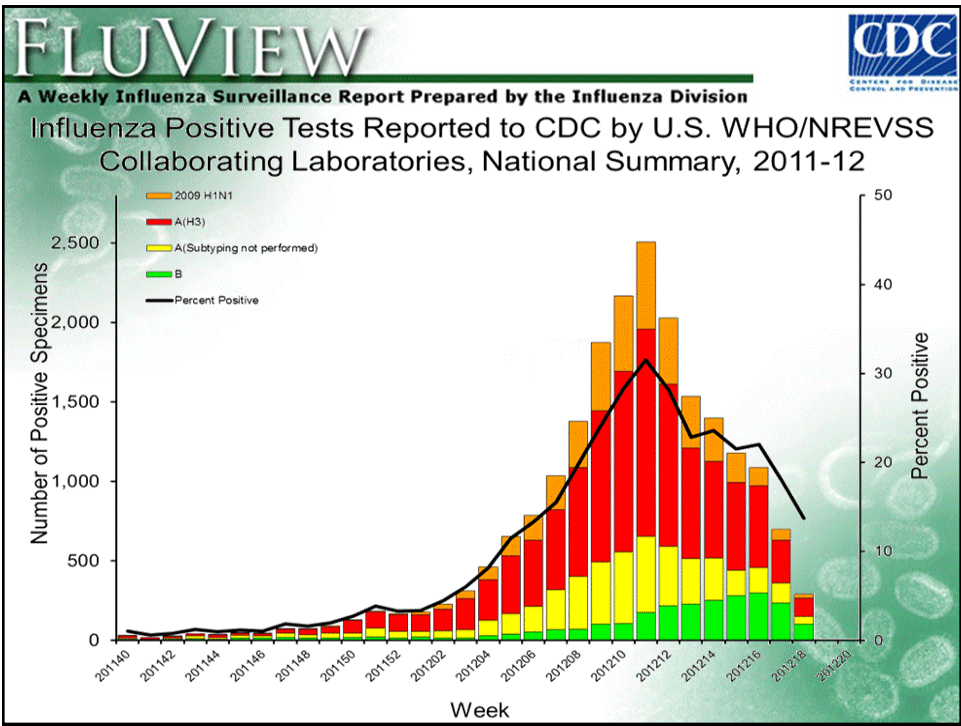
Vaccine Strain Selection for 2012-2013

- **WHO Consultation and Information Meeting on the Composition of Influenza Virus Vaccines for the Northern Hemisphere, 2012-2013**
 - February 20-22, 2012.

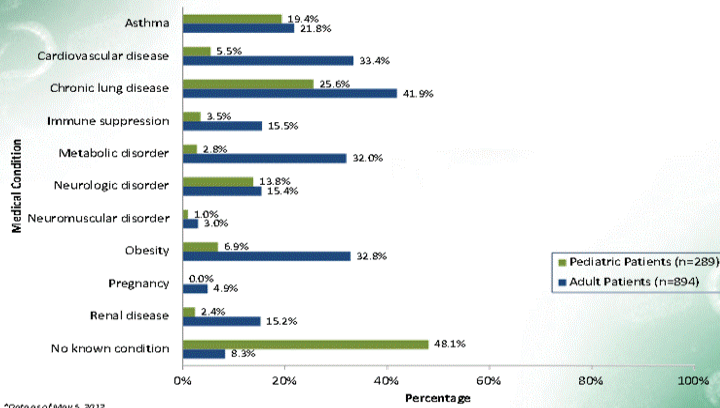
- **FDA Vaccine and Related Biologic Products Advisory Committee (VRBPAC)**
 - February 28-29, 2012.

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Selected underlying medical conditions¹ among laboratory-confirmed influenza-associated hospitalizations, FluSurv-NET, 2011-2012²



¹Data as of May 5, 2012

²Asthma includes a diagnosis of asthma or reactive airway disease; Cardiovascular diseases include conditions such as coronary heart disease, cardiac valve disorders, congestive heart failure, pulmonary hypertension, and aortic stenosis; Chronic lung diseases include conditions such as asthma, bronchiolitis obliterans, chronic aspiration pneumonia, and interstitial lung disease; Immune suppression includes conditions such as immunoglobulin deficiency, leukemia, lymphoma, HIV/AIDS, and individuals taking immunosuppressive medications; Metabolic disorders include conditions such as diabetes mellitus, thyroid dysfunction, adrenal insufficiency, and liver disease; Neurologic diseases include conditions such as seizure disorders, cerebral palsy, and cognitive dysfunction; Neuromuscular diseases include conditions such as multiple sclerosis and muscular dystrophy; Obesity was assigned if indicated in patient's medical chart or if body mass index (BMI) > 30 kg/m²; Renal diseases include conditions such as acute or chronic renal failure, nephrotic syndrome, glomerulonephritis, and impaired creatinine clearance.

³Only includes cases for which data collection has been completed through the medical chart review stage.

Neuraminidase Inhibitor Resistance Testing at CDC: U.S. Samples Collected Since October 1, 2011

	Oseltamivir		Zanamivir	
	Virus Samples tested (n)	Resistant Viruses, Number (%)	Virus Samples tested (n)	Resistant Viruses, Number (%)
Influenza A (H3N2)	1,196	0 (0.0)	1,196	0 (0.0)
Influenza B	271	0 (0.0)	271	0 (0.0)
2009 H1N1	1,129	16 (1.4)	478	0 (0.0)

- Rare sporadic cases of oseltamivir-resistant 2009 H1N1 and A(H3N2) virus infections have been detected worldwide.
- Due to high levels of resistance to adamantanes (amantadine and rimantadine) among Influenza A viruses, adamantane use is *not* recommended.

Source: CDC FluView, Week 18 (May 5, 2012)