

# immunizations **LINK. LOGIN. LEARN.** 411

hosted by the Missouri Department of Health and Senior Services' Bureau of Immunization Assessment and Assurance  
[www.health.mo.gov/immunizations](http://www.health.mo.gov/immunizations)

webinar series

**William Atkinson, MD, MPH\***

**Vaccine Update**

**A Summary of the Proceedings of the Advisory  
Committee on Immunization Practices (ACIP)**

**October 29-30, 2014**

**November 20, 2014**

**\*Representing the Immunization Action  
Coalition, Saint Paul, MN**



# Advisory Committee on Immunization Practices (ACIP)

- Composed of 15 experts in clinical medicine and public health who are not government employees
- Ex-officio (FDA, NIH, CMS, etc) and liaison (AAP, AAFP, ASTHO, Pharma, etc) members (non-voting)
- Provide guidance on the use of vaccines and other biologic products to the Department of Health and Human Resources, CDC, and the U.S. Public Health Service

# Advisory Committee on Immunization Practices (ACIP)

- A Work Group (WG) is created as necessary for each vaccine or issue
  - permanent WGs: General Recommendations, Influenza, Adult and Childhood Schedules
- WGs meet as needed via conference call to discuss issues and create provisional recommendations
- WG recommendations presented to full ACIP at regular meetings for discussion and vote

# Advisory Committee on Immunization Practices (ACIP)

- Recommendations are approved by a simple majority of voting ACIP members\*
- Recommendations approved by ACIP are not “official” until they are
  - approved by the CDC Director and the U.S. Secretary of Health and Human Services,  
AND
  - published in *Morbidity and Mortality Weekly Report (MMWR)*

\*ACIP members with real or potential financial conflicts of interest do not vote on issues related to the conflicted issue



ACIP Meeting  
Atlanta, Georgia  
February 26, 2014

**Special ACIP Webinar Meeting on  
Pneumococcal Conjugate Vaccine for  
Adults  
August 13, 2014**

# Pneumococcal Conjugate Vaccine (PCV13) and Adults

- FDA approved PCV13 for use among adults 50 years of age and older in December 2011
- Immunogenicity of PCV13 was found to be non-inferior to PPSV23
- ACIP recommended 1 dose of PCV13 for adults at high risk of invasive pneumococcal disease\* in October 2012

**\*immunocompromised, functional or anatomic asplenia, cochlear implant, CSF leak**

# CAPITA trial

- **C**ommunity-**A**cquired **P**neumonia  
**I**mmunization **T**rial in **A**dults
- Intended to determine if PCV13 was effective in reducing the risk of a first episode of CAP among persons 65 years and older
- Double-blind, placebo controlled
- ~85,000 persons 65 years or older in the Netherlands

Pfizer data presented to ACIP, June 25, 2014

# CAPITA trial

- 46% efficacy against vaccine-type CAP
- 75% efficacy against vaccine-type invasive pneumococcal disease
- More effective in persons younger than age 75
- 35% of recipients reported local AE (mostly pain)

Pfizer data presented to ACIP, June 25, 2014

# Pneumococcal Conjugate Vaccine (PCV13) and Adults

- On August 13, 2014 ACIP convened a special remote session to discuss PCV13 recommendations
- ACIP voted to recommend that
  - both PCV13 and PPSV23 should be routinely administered in series to all adults age 65 years and older
  - recommendations for routine PCV13 use among adults age 65 and older years will be reevaluated in 2018 and revised as needed

## Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged $\geq 65$ Years: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Sara Tomczyk, MSc<sup>1,2</sup>, Nancy M. Bennett, MD<sup>3,4</sup>, Charles Stoecker, PhD<sup>5</sup>, Ryan Gierke, MPH<sup>2</sup>, Matthew R. Moore, MD<sup>2</sup>, Cynthia G. Whitney, MD<sup>2</sup>, Stephen Hadler, MD<sup>2</sup>, Tamara Pilishvili, MPH<sup>2</sup> (Author affiliations at end of text)

On August 13, 2014, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of 13-valent pneumococcal conjugate vaccine (PCV13 [Pneumovax 13, Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer Inc.]) among adults aged  $\geq 65$  years. PCV13 should be administered in series with the 23-valent pneumococcal polysaccharide vaccine (PPSV23 [Pneumovax23, Merck & Co., Inc.]), the vaccine currently recommended for adults aged  $\geq 65$  years. PCV13 was approved by the Food and Drug Administration (FDA) in late 2011 for use among adults aged  $\geq 50$  years. In June 2014, the results of a randomized placebo-controlled trial evaluating efficacy of PCV13 for preventing community-acquired pneumonia among approximately

85,000 adults aged  $\geq 65$  years with no prior pneumococcal vaccination history (CAPiTA trial) became available and were presented to ACIP (1). The evidence supporting PCV13 vaccination of adults was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework and determined to be type 2 (moderate level of evidence); the recommendation was categorized as a Category A recommendation (2). This report outlines the new recommendations for PCV13 use, provides guidance for use of PCV13 and PPSV23 among adults aged  $\geq 65$  years, and summarizes the evidence considered by ACIP to make this recommendation.

### Epidemiology of Pneumococcal Disease Among Adults Aged $\geq 65$ Years

*Streptococcus pneumoniae* (pneumococcus) remains a lead-

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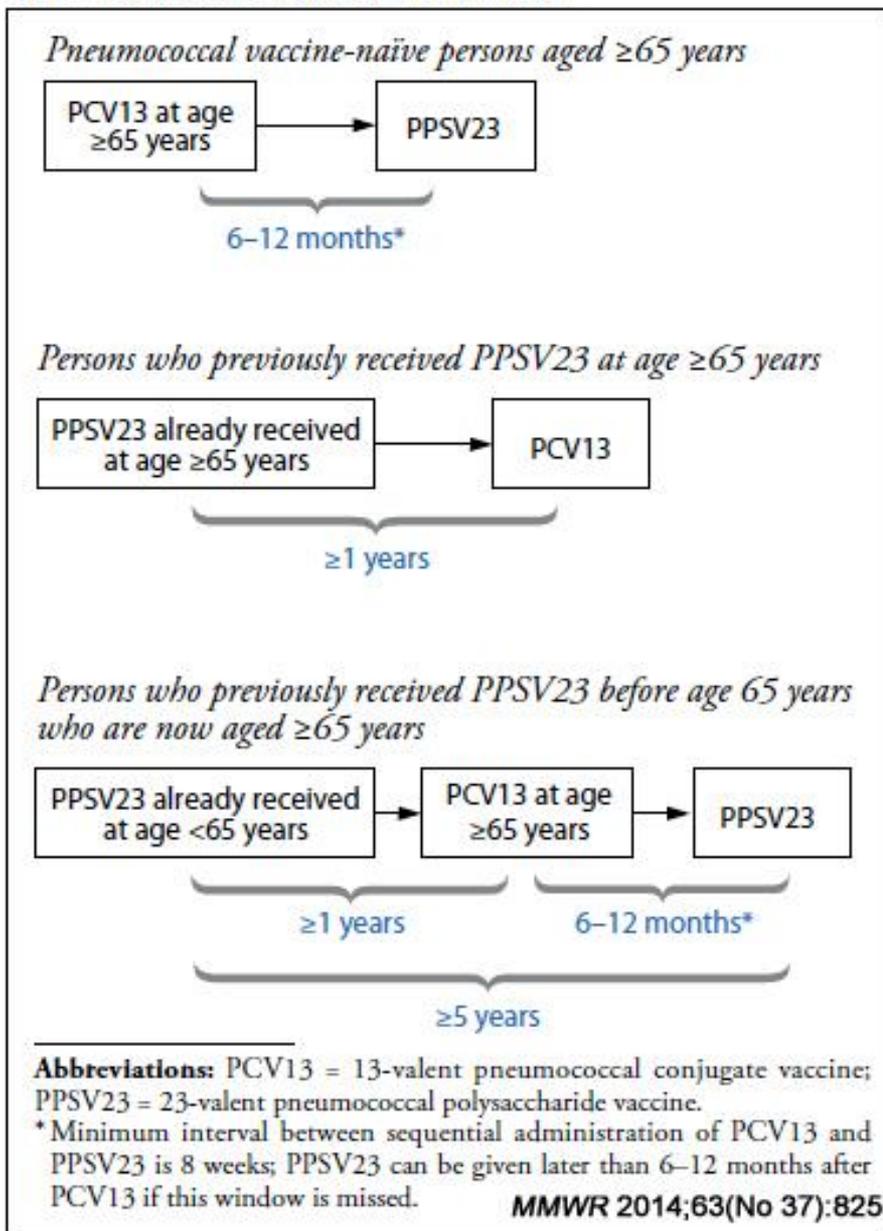
webinar series

*Recommendations for routine use of vaccines in*

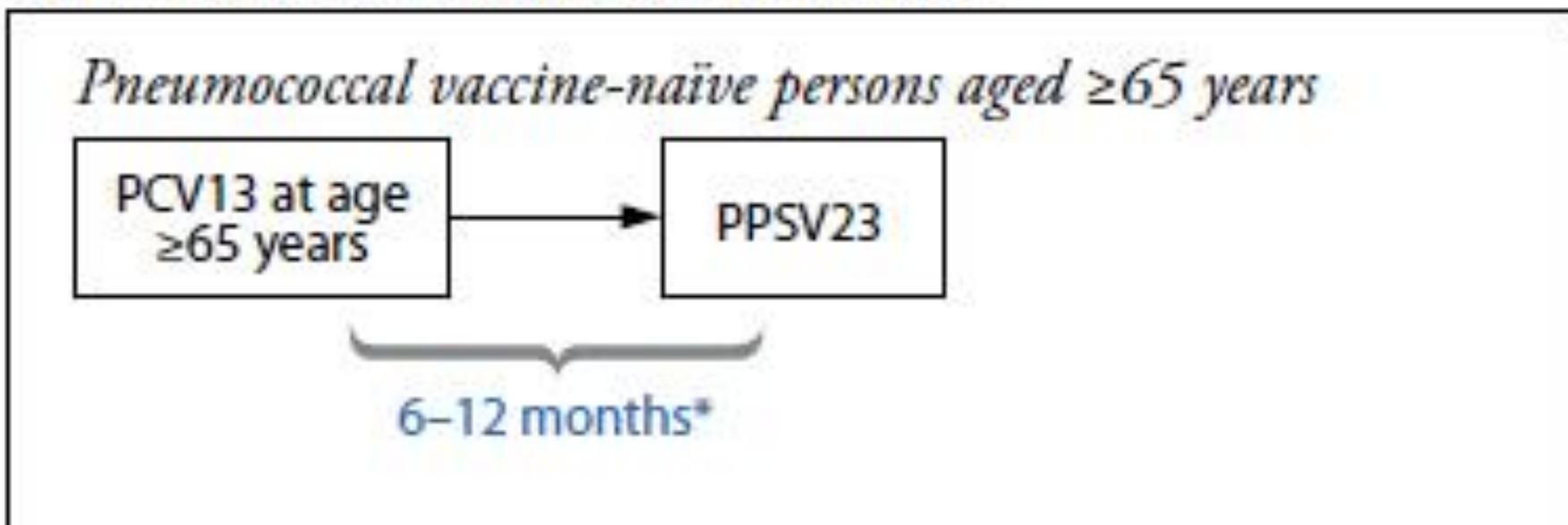
# Pneumococcal Vaccines for Persons Age 65 Years and Older

- One lifetime dose of PCV13 for adults
- PCV13 and PPSV23 should NOT be administered at the same visit
- Administer PCV13 before PPSV23, whenever possible
- PCV13 should be administered to those who have already received PPSV23

**BOX. Sequential administration and recommended intervals for PCV13 and PPSV23 for adults aged  $\geq 65$  years — Advisory Committee on Immunization Practices, United States**

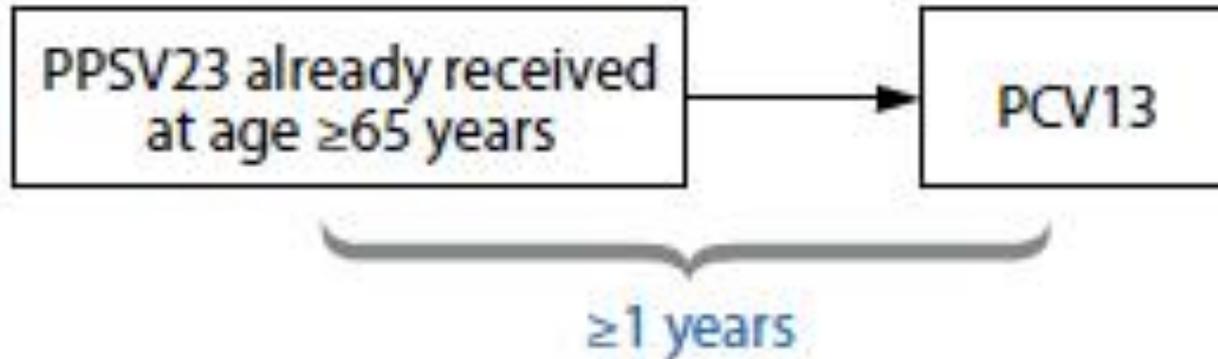


## BOX. Sequential administration and recommended intervals for PCV13 and PPSV23 for adults aged $\geq 65$ years — Advisory Committee on Immunization Practices, United States



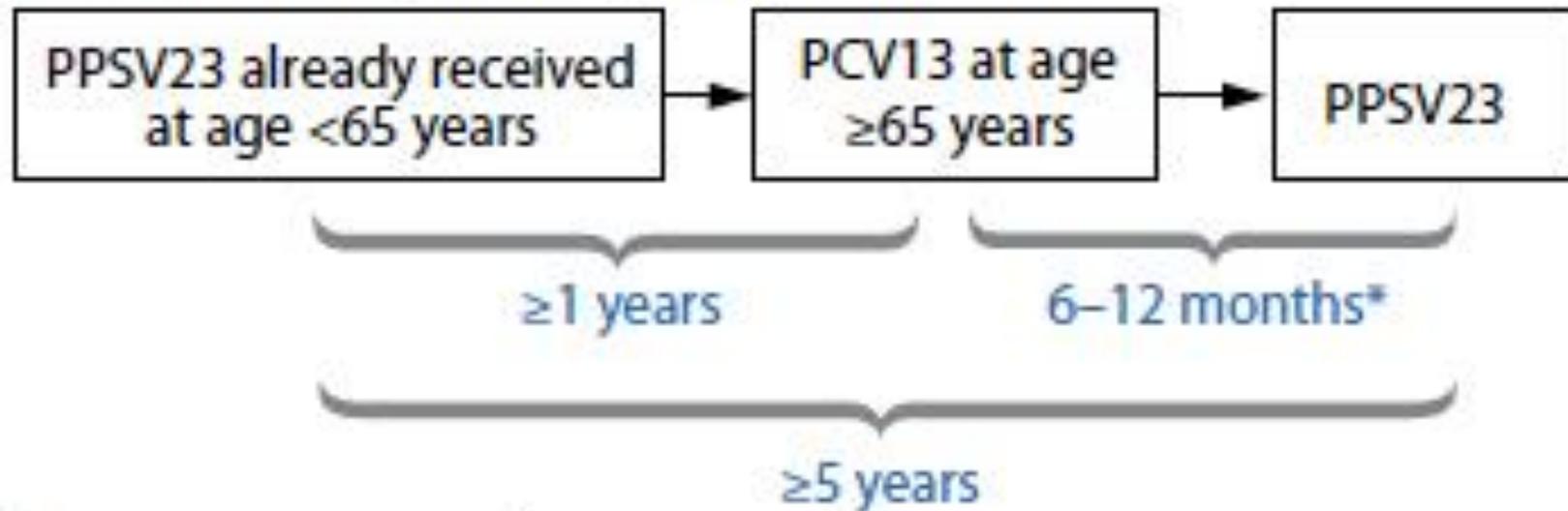
**\*for persons at high risk of IPD the interval between PCV13 and PPSV23 is 8 weeks**

*Persons who previously received PPSV23 at age  $\geq 65$  years*



**\*if more than 1 year has elapsed since PPSV23 give PCV13 at the next visit**

*Persons who previously received PPSV23 before age 65 years who are now aged  $\geq 65$  years*



**Abbreviations:** PCV13 = 13-valent pneumococcal conjugate vaccine; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

\* Minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks; PPSV23 can be given later than 6–12 months after PCV13 if this window is missed.

**MMWR 2014;63(No 37):825**

# Recommendations for PCV13 and PPSV23 in Pneumococcal Vaccine-Naïve Adults

- For high-risk adults (asplenia, immunocompromised, etc)
  - single dose of PCV13
  - dose of PPSV23 at least **8 weeks** later
- For persons 65 years or older who are not at high risk
  - single dose of PCV13
  - dose of PPSV23 **6 to 12 months** later
- Minimum interval for all groups is 8 weeks

# PPSV23 at 65 Years or Age

- Recommendations for PPSV23 have not changed
- All adults are eligible for a dose of PPSV23 at 65 years of age regardless of previous pneumococcal vaccination
- Maximum of 3 lifetime doses of PPSV23
- Adults vaccinated with PPSV23 at/after age 65 require no further doses of PPSV23

**MMWR 2012;61(No. 40):816-9**

# Pneumococcal Vaccines for Persons Age 65 Years and Older

- Currently Medicare will reimburse for only 1 dose of pneumococcal vaccine
- Will reimburse for either PCV13 OR PPSV23 but not both
- Persons who have already been reimbursed for PPSV23 may be denied payment for PCV13
- CMS is working to change this rule

# ACIP Meeting, Atlanta, Georgia

- Day 1 – October 29, 2014
- Agency updates
  - CMS - working on pneumococcal vaccine reimbursement
  - FDA - Menactra approved for revaccination dose (age 15-55 years)
  - NIH
    - 2 Ebola candidate vaccines, 1 in Phase 1 trial
    - “universal” influenza and HCV vaccines in clinical trials

# ACIP Meeting, Atlanta, Georgia

- Day 1 – October 29, 2014
  - Influenza
  - Pertussis
  - General Recommendations (timing, spacing, contraindications and precautions, vaccine administration) VOTE
  - Child/Adolescent schedules VOTE
  - Adult schedule VOTE
  - Hepatitis A

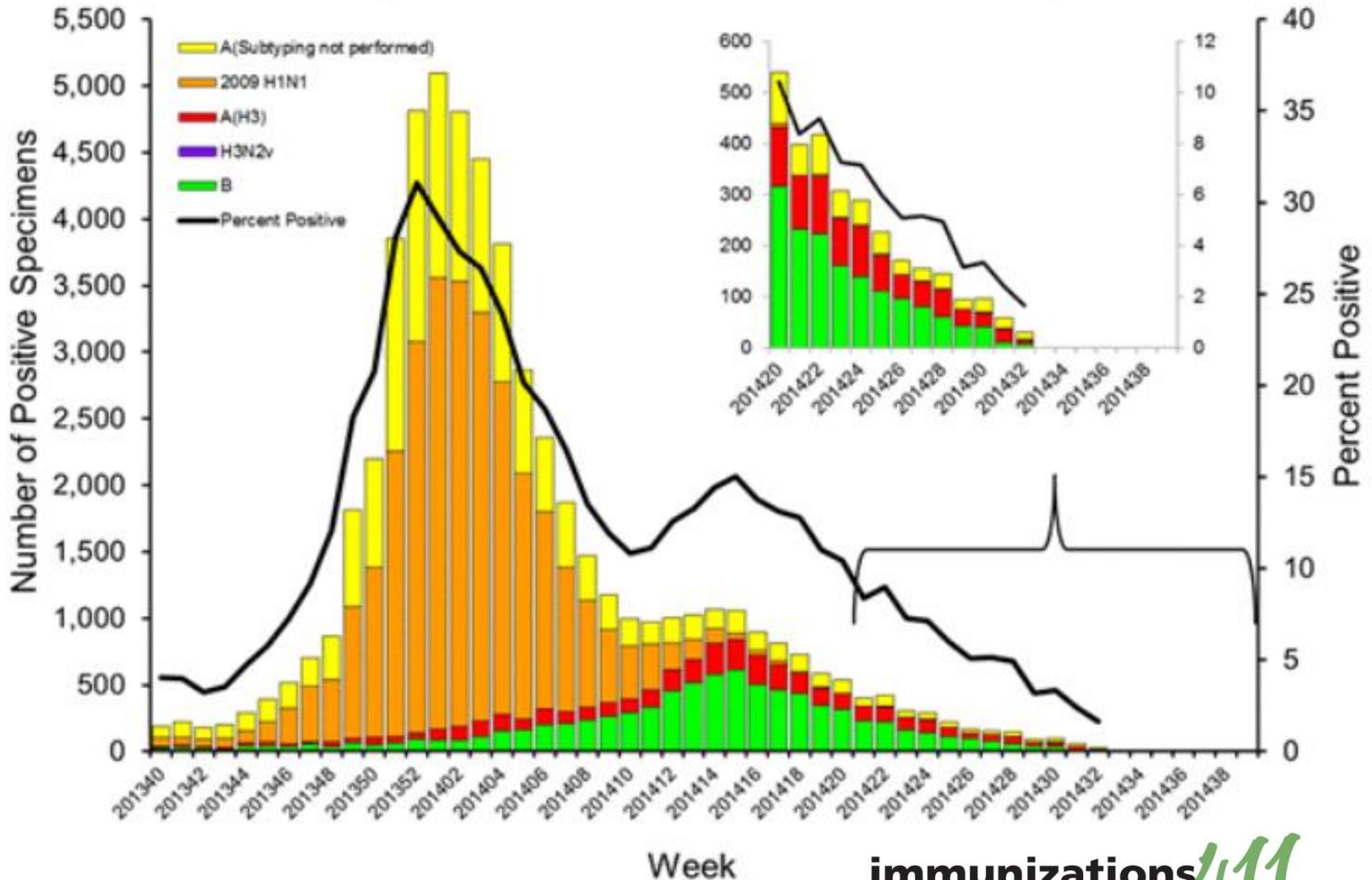
# ACIP Meeting, Atlanta, Georgia

- Day 2 – October 30, 2014
  - Meningococcal serogroup B
  - Typhoid vaccine VOTE
  - Vaccine safety - VAERS
  - Human papillomavirus vaccines

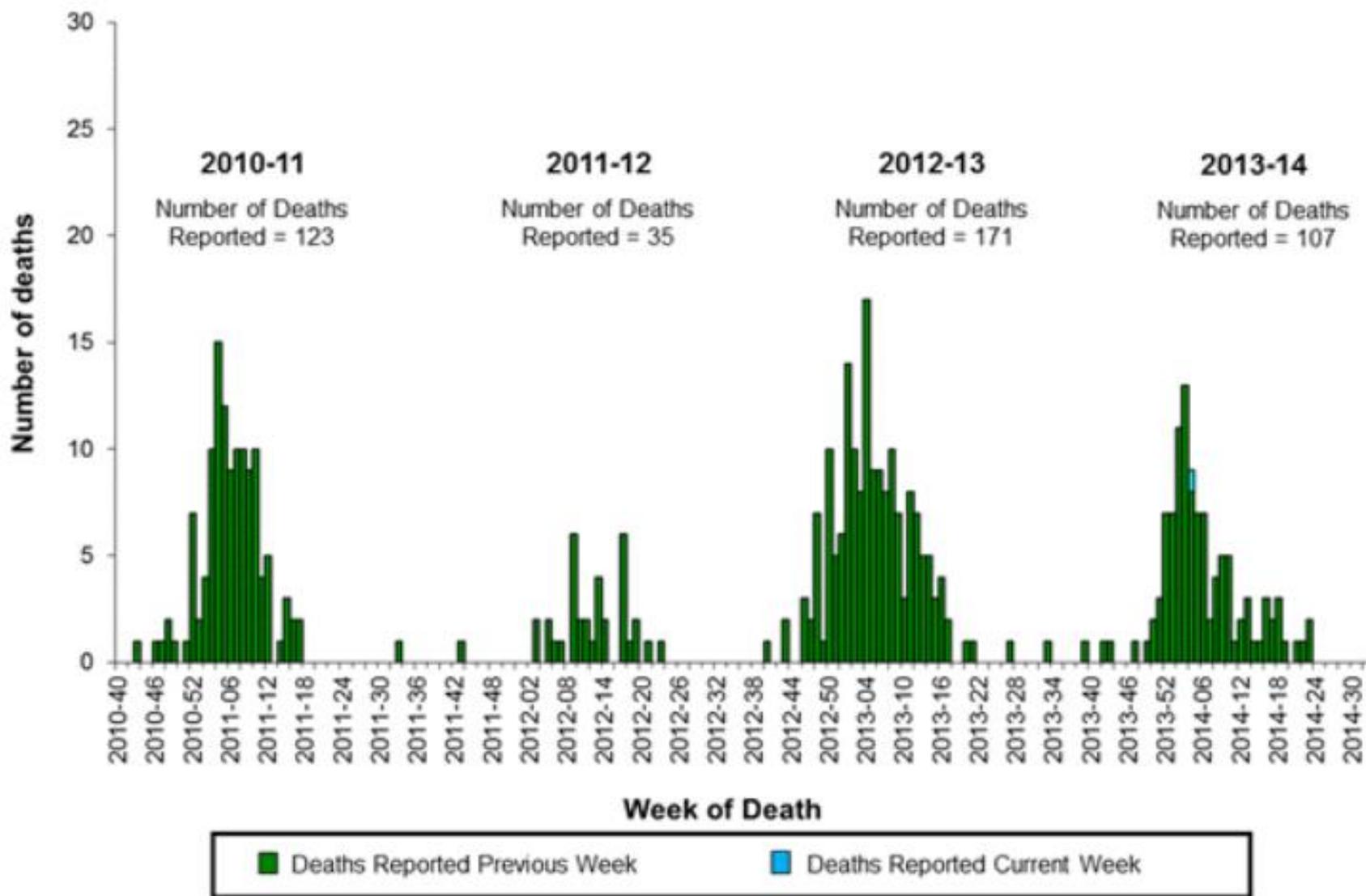
# Influenza Vaccine

- No vote taken
- Topics
  - Surveillance update (too early to tell)
  - Effectiveness of LAIV and IIV
  - Administration of Afluria with the PharmaJet Needle-Free system
  - H5N1 vaccine

# Influenza Positive Tests Reported to CDC by U.S. WHO/NREVSS Collaborating Laboratories, National Summary, 2013-14



# Number of Influenza-Associated Pediatric Deaths by Week of Death: 2010-11 season to present



# Influenza Vaccine Effectiveness

- Studies conducted by CDC and MedImmune both found good efficacy against influenza B but little or no efficacy against influenza A H1N1 during the 2013-2014 season
- MedImmune found efficacy lower for lots shipped in late summer – possible temperature effect on vaccine
- No change in ACIP recommendation for LAIV

# LAIV Preference, 2014-2015

- When immediately available, LAIV should be used for healthy children aged 2 through 8 years who have no contraindications or precautions
- If LAIV is not immediately available, IIV should be used
- Vaccination should not be delayed to procure LAIV

# FDA Approves Use of AFLURIA® Influenza Vaccine with PharmaJet's Needle-Free Injector

*Jet injector device delivers single dose of injectable flu vaccine without a needle*

KING OF PRUSSIA, Penn. / GOLDEN, Colo. – August 19, 2014 – PharmaJet® Inc., the developer of a needle-free injection technology to administer medications and vaccines to patients, and bioCSL Inc., the maker of AFLURIA® (Influenza Vaccine) today announced the U.S. Food and Drug Administration (FDA) has approved the [PharmaJet Stratis® 0.5mL Needle-Free Jet Injector](#) for delivery of AFLURIA in individuals aged 18 to 64 years. This is the first needle-free delivery system approved by the FDA for the administration of an inactivated influenza vaccine.

“Healthcare providers now have the option of delivering AFLURIA without a needle,” said Ron Lowy, PharmaJet CEO and co-chairman. “The PharmaJet injection technology is an especially important innovation for the millions of individuals who suffer from fear of needles and who consequently forego their annual flu vaccination. We believe this is a significant step forward in the effort to improve public health through broader immunization coverage, as well as improved safety of caregivers.”

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**Approved only for persons 18 through 64 years of age**

# Afluria Administered by PharmaJet Device

- Randomized trial of PharmaJet vs. standard IM injection
- Immunogenicity and safety
  - no difference in titer or seroprotection rates
  - more local reactions with PharmaJet
  - no difference in systemic AEs

## Components

### Reusable hardware:

- Injector
- Reset Station

### Disposables:

- Syringe
- Filling/Vial Adapter

### Simple, Robust Design Injector Unique features:

- Durable
- Double safety feature
- Tested for 20,000 cycles



# Pertussis Vaccine and Healthcare Personnel

# Tdap Vaccines

- Both vaccines approved by FDA for only 1 dose
- Tdap vaccine is effective but protection begins to wane within 3 years (75% to 35% in 3 years)
- Both companies are studying Tdap revaccination
- A second dose of Tdap is safe and immunogenic

# Pertussis Vaccine and HCPs

- Pertussis transmission occurs in healthcare settings
- HCP are at risk of pertussis exposure
- Current Tdap coverage among HCP is 31% (2012)
- No current evidence that additional doses of Tdap would help reduce exposures or transmission in healthcare setting

# Pertussis Vaccine and HCPs

- At this time the pertussis Work Group does not propose a change to the current Tdap recommendation for HCP
- Focus on current Tdap program
  - improve adult Tdap coverage, including HCP
  - vaccinate pregnant women to protect infants

## General Recommendations on Immunization

### Recommendations of the Advisory Committee on Immunization Practices (ACIP)



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/conted.html>



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention

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webinar series

# General Recommendations on Immunization

- Major sections
  - Timing and spacing (intervals, ages, etc)
  - Contraindications and precautions
  - Vaccine administration
  - Storage and handling
  - Altered immunocompetence
  - Special situations (pregnancy, breastfeeding, allergy, vaccination outside the U.S.
  - Vaccination records and IISs
  - Vaccination programs

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**Approved at October  
2014 meeting**

# General Recommendations on Immunization

- Scheduled to vote on the entire document at the February 2015 meeting
- Estimated publication in 2016 (?)

# Immunization Schedules

- Published in *MMWR* each February
- Schedules must be approved by ACIP at each October meeting
- Minor wording changes in footnotes of child/adolescent schedule
- Inclusion of new PCV13 recommendations for adults

# Hepatitis A

- Coverage among children is suboptimal (54%)
- Most reported cases among persons 20 years and older
- Outbreaks (mostly foodborne) continue to occur
- ACIP recommendations (2006) to be revised
  - may include catch-up for older children

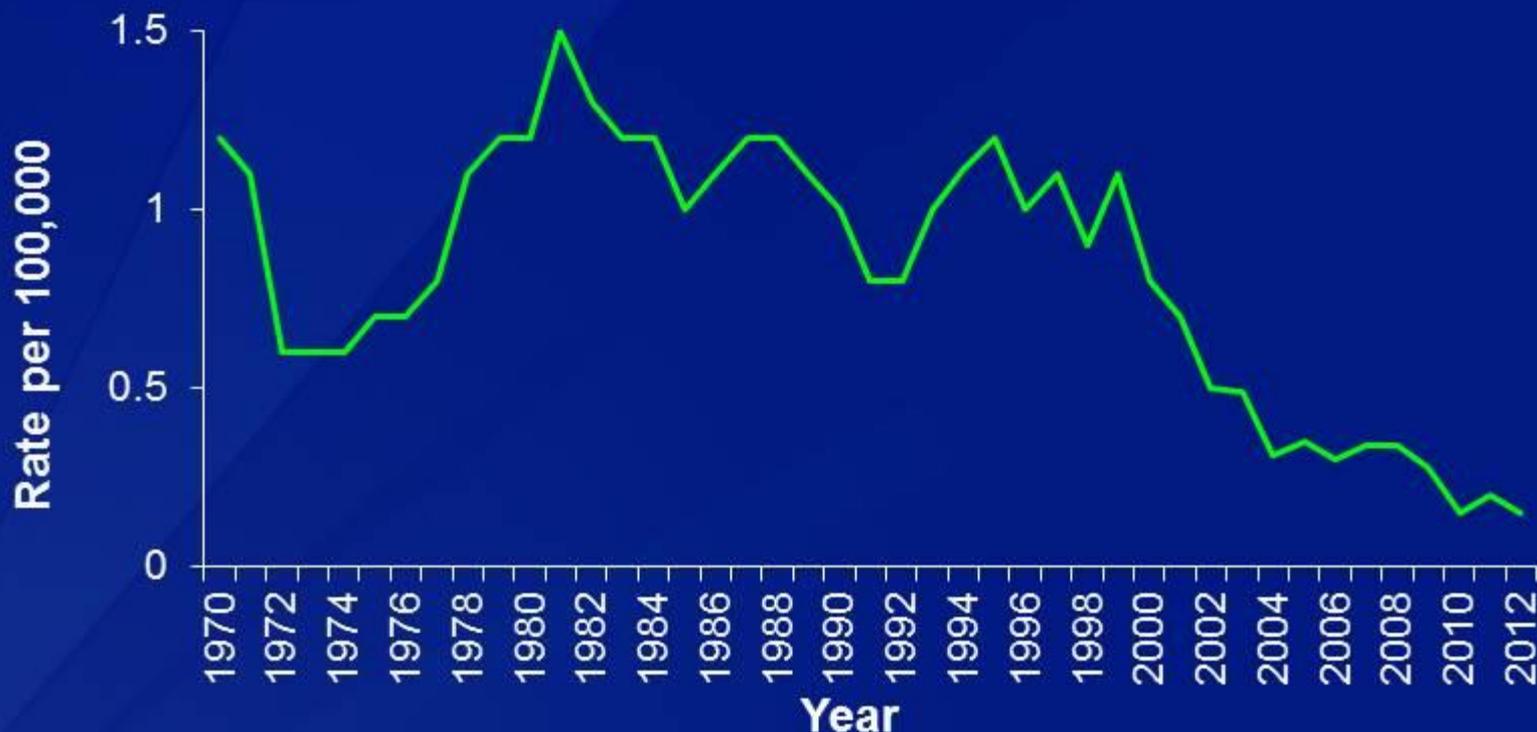
# ACIP Meeting, Atlanta, Georgia

- Day 2 – October 30, 2014
  - Meningococcal serogroup B
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# Meningococcal Vaccines

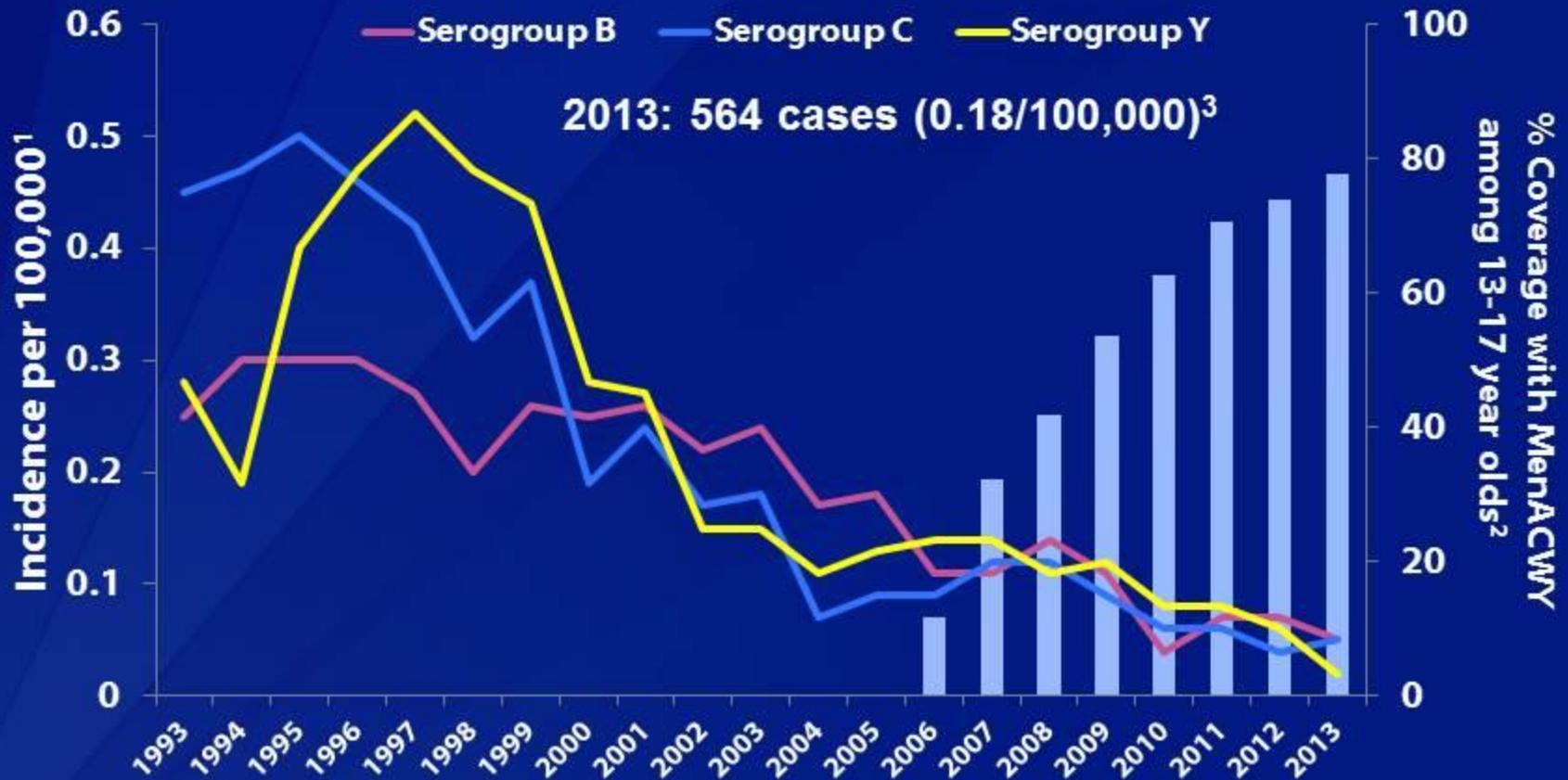
- Information only
- Topics
  - epidemiology of meningococcal serogroup B disease in the United States
  - considerations for recommendations for use of men B vaccines

# Meningococcal Disease Incidence, United States, 1970-2012



1970-1996 NNDSS data, 1997-2012 ABCs data estimated to U.S. population

# Meningococcal Incidence in All Ages by Serogroup and Adolescent MenACWY Vaccine Coverage, 1993-2013

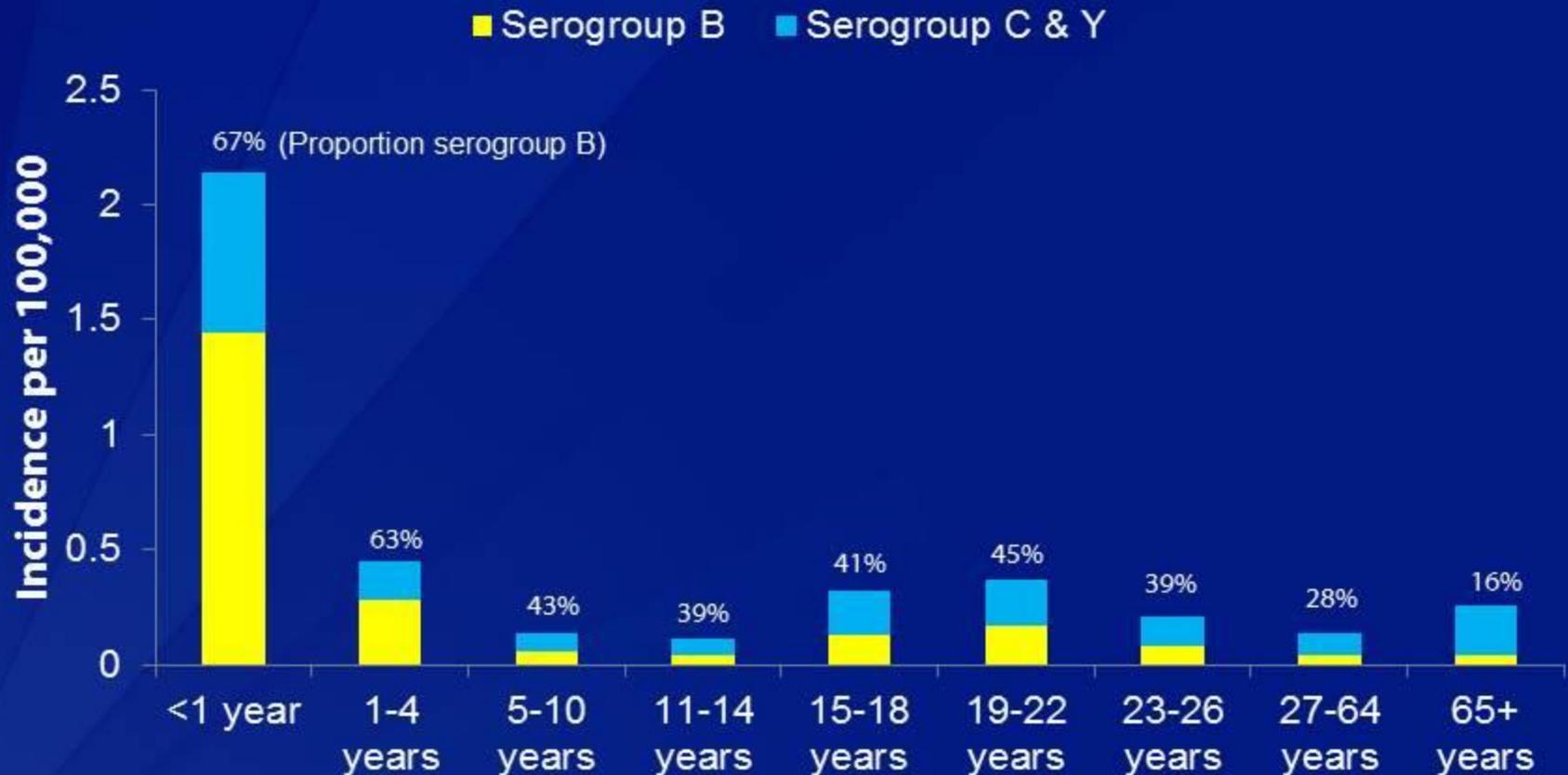


<sup>1</sup>Source: ABCs cases from 1993-2013 estimated to the U.S. population with 18% correction for underreporting

<sup>2</sup>National Immunization Survey – Teen; 2006-2013

<sup>3</sup>NNDSS 2013 final case count

# Meningococcal Incidence by Serogroup\* and Age-Group, 2005-2012



\*NNDSS data with additional serogroup data from ABCs and state health departments  
Unknown serogroup (23%) and other serogroups (8%) excluded

# Groups at Increased Risk for Meningococcal B Disease

- High-risk medical conditions:
  - persistent complement component deficiencies
  - functional or anatomic asplenia
- Certain microbiologists
- Populations at risk during an outbreak

# Outbreaks of Meningococcal Disease

- Meningococcal outbreaks are rare, historically causing ~2-3% of US cases
- Five serogroup B meningococcal disease clusters/outbreaks on college campuses
  - Princeton: 1400 fold increased risk; 5,800 recommended vaccine
  - UCSB: 200 fold increased risk; 20,000 recommended vaccine

# Meningococcus Serogroup B (MenB)

- MenB capsular polysaccharide is poorly immunogenic and structurally similar to certain proteins in human tissue
  - concern (unproven) about auto-immunity created by using MenB capsular polysaccharide in a vaccine
- Vaccine research has focused on surface proteins
- However, MenB strains are highly diverse with more than 8,000 genetically different B strains identified

# Meningococcal Serogroup B Vaccines

- rLP2086 bivalent vaccine (Trumenba, Pfizer)
  - 2 fHbp (factor H-binding protein) subvariants (B/v1 and A/v2-3)
- 4CMenB (Bexsero, Novartis)
  - Single subvariant of FHbp (B/v1)
  - NadA (Neisserial adhesin A)
  - NhbA (Neisserial heparin binding antigen)
  - Outer membrane vesicles of the New Zealand epidemic strain (OMV - NZ)

# rLP2086 Bivalent Vaccine (Trumenba, Pfizer)

- Licensed by FDA on October 29, 2014
- Licensure based on serologic response to vaccination
- Approved for 10 through 25 years of age
- 3 dose series (0, 2, 6 months)
- Intramuscular

# ACIP Recommendations for Meningococcal B Vaccine

- ACIP has not yet made recommendations for use of meningococcal B vaccine
- Recommendations will probably include persons with
  - persistent complement component deficiencies
  - anatomic or functional asplenia
  - risk in a serogroup B meningococcal disease outbreak
  - certain microbiologists
- A recommendation to vaccinate the general population is unlikely



December 9, 1994 / Vol. 43 / No. RR-14

# MNWR

*Recommendations  
and  
Reports*

MORBIDITY AND MORTALITY WEEKLY REPORT

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## Typhoid Immunization

**Recommendations of the Advisory  
Committee on Immunization Practices (ACIP)**

# Typhoid Vaccine ACIP Recommendations

- New statement approved on October 30, 2014
- No changes in current recommendations for use
- Publication in 2015

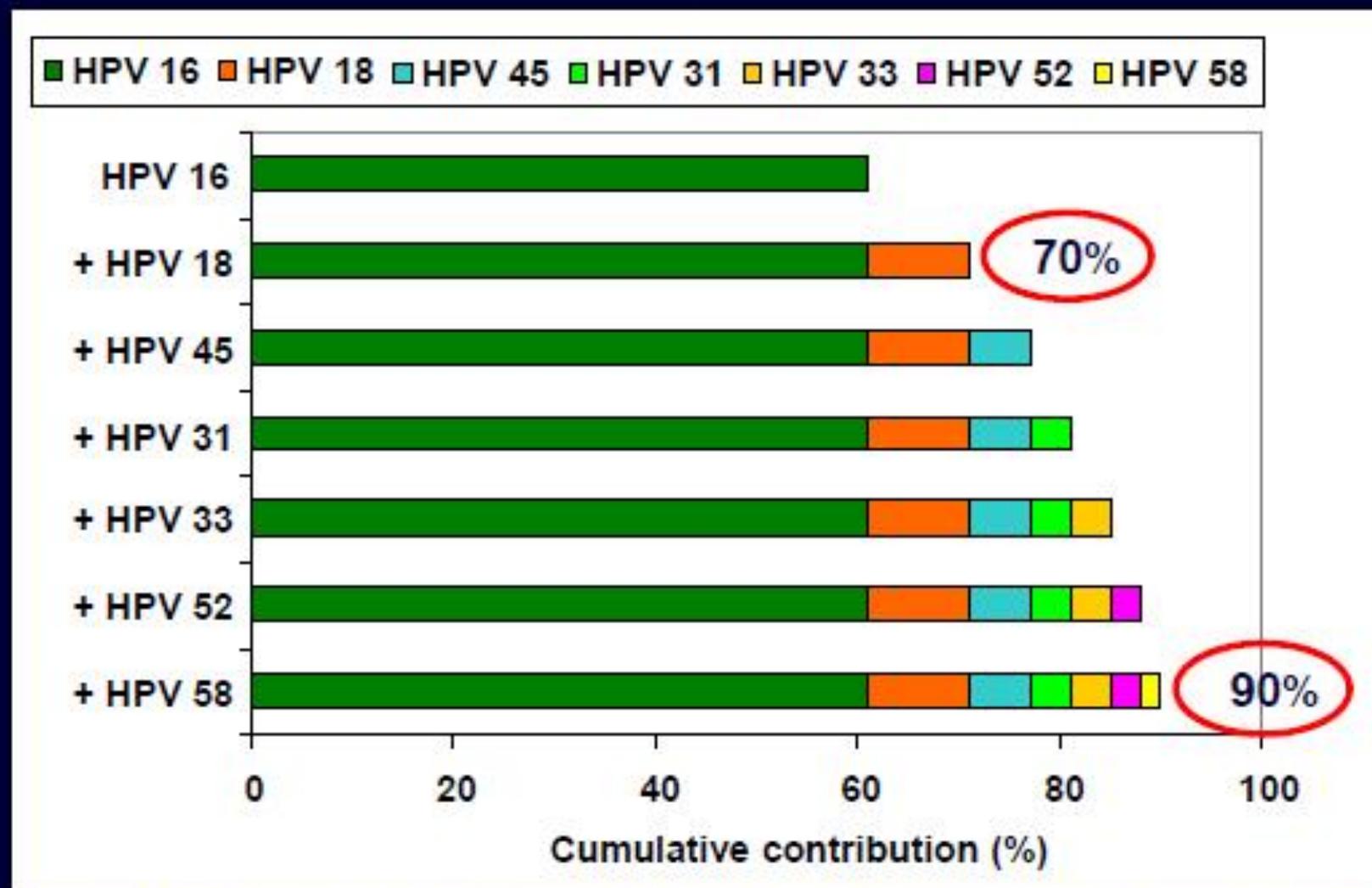
# Human Papillomavirus Vaccine

- Information only
- Topics
  - 9-valent vaccine clinical trial data
  - cost effectiveness and evidence consideration for 9-valent vaccine
  - considerations for recommendations for 9-valent vaccine

# 9-Valent HPV Vaccine

- Expected to be licensed by FDA before the end of 2014
- Application is for females 9 through 26 years and males 9 through 15 years
- Both HPV4 and HPV9 will be available for up to 24 months after licensure

# Relative Contribution of HPV Types in 9vHPV Vaccine to Cervical Cancers Worldwide



Among HPV-positive cervical cancers; based on de Sanjose et al. *Lancet Oncol.* 11:1048-56 (2010); Serrano et al. *Infect Agent Cancer* 7:38 (2012)

# HPV9 ACIP Recommendations

- Will likely be the same as the current recommendations for HPV4 (female 9 through 26, male 9 through 21, permissive through 26)
- Guidance on “mixed” schedules and revaccination?
- Vote at February 2015 meeting

# ACIP Meeting Slides, Video and Minutes

- Slides and video usually available about 6 weeks after the meeting
- Minutes available about 2 months after the meeting
- ACIP website
  - [www2a.cdc.gov/vaccines/acip/](http://www2a.cdc.gov/vaccines/acip/)

# Next ACIP Meeting

- February 25-26, 2015
- CDC Headquarters, Atlanta, Georgia
- You may attend in person or view via internet
- Register by October 13, 2014 (to attend in person)
- [www2a.cdc.gov/vaccines/acip/](http://www2a.cdc.gov/vaccines/acip/)

# Thank You

# Questions?

