

# **Pneumococcal Vaccination for Adults 65 Years and Older**

**VA NetConference**

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# Disclosure

- The presenter has no financial relationship to this program.

# Objectives

1. Describe the burden of pneumococcal disease among adults 65 years and older
2. Describe the potential impact of PCV13 on invasive pneumococcal disease and non-invasive pneumococcal pneumonia
3. Evaluate patients 65 years and older for pneumococcal vaccination in accordance with the ACIP recommendations
4. Identify two strategies to support implementation of PCV13 vaccination in IHS settings

# Burden of pneumococcal disease among adults $\geq 65$ years of age

- ❑ Adults  $\geq 65$  years at increased risk for pneumococcal disease and serious illness from the major clinical syndromes associated with it
- ❑ Case-fatality rate for pneumococcal bacteremia is  $\sim 15\%$  overall, but as high as  $60\%$  among adults  $\geq 65$  years
- ❑  $\sim 18,000$  fatal cases of pneumococcal disease among adults  $\geq 65$  years each year in the United States

# ACIP Recommendations through 2012: Pneumococcal Polysaccharide Vaccine (PPSV23)

- All adults 65 yrs and older
- Adults 19-64 years old with the following conditions

Risk group	Underlying medical condition or other indication
Immunocompetent persons	Chronic heart disease (excluding hypertension)* Chronic lung disease† Diabetes mellitus Cerebrospinal fluid leaks Cochlear implant Alcoholism Chronic liver disease, including cirrhosis Cigarette smoking
Persons with functional or anatomic asplenia <sup>§</sup>	Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, splenic dysfunction, or splenectomy
Immunocompromised persons <sup>§</sup>	Congenital or acquired immunodeficiencies <sup>¶</sup> HIV infection Chronic renal failure Nephrotic syndrome Leukemias Lymphomas Hodgkin disease Generalized malignancy Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids or radiation therapy Solid organ transplantation Multiple myeloma

\* Including congestive heart failure and cardiomyopathies.

† Including chronic obstructive pulmonary disease, emphysema, and asthma.

<sup>§</sup> A second dose of PPSV23 is recommended 5 years after the first dose for persons with functional or anatomic asplenia and for immunocompromised persons.

<sup>¶</sup> Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

# 13-valent Pneumococcal Conjugate Vaccine (PCV13) for Adults

- Licensed for use among adults  $\geq 50$  years old on 12/30/11
- FDA approved under the Accelerated Approval Pathway
- Based on non-inferior immunogenicity compared to PPSV23
- Indications
  - Prevention of pneumococcal disease (including pneumonia and invasive disease) in adults 50 years of age and older
  - Prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F
- Post-approval condition of licensure: Randomized controlled trial of PCV13 against pneumococcal pneumonia among adults  $\geq 65$  years old in the Netherlands (CAPiTA)

# ACIP Recommendations in 2012

- Deferred recommendation for adults  $\geq 65$  years old until more data available
  - Efficacy against pneumonia (CAPiTA)
  - Indirect (herd) effects of PCV13 use in children
- Recommended a dose of PCV13 in sequence with PPSV23 for adults with immunocompromising conditions (highest risk for pneumococcal disease)

## New Evidence Supporting PCV13 use among adults, CAPiTA results

Study/population	Endpoint	Vaccine Efficacy (95% CI)
CAPITA ~85,000 Adults 65+ Netherlands	PCV13-serotype IPD	75% (41%, 91%)
	PCV13-serotype non-bacteremic pneumonia	45% (14%, 65%)

# Summary of evidence supporting PCV13 use among adults $\geq 65$ years of age

- ❑ **Prevents IPD and non-bacteremic pneumonia<sup>1</sup>**
  - 75% reduction in vaccine type IPD
  - 45% reduction in vaccine type non-bacteremic pneumonia
  
- ❑ **Immune response non-inferior or improved (for some serotypes) for PCV13 (or PCV7) vs. PPSV23<sup>2,3</sup>**
  
- ❑ **Safety demonstrated in clinical trials**

<sup>1</sup>CAPITA, June 2014 ACIP

<sup>2</sup>Phase III trials, Pfizer, ACIP 2011, 2012

<sup>3</sup>DeRoux et al. CID 2008, Goldblatt et al 2009

# Summary of evidence supporting PCV13 use among adults $\geq 65$ years of age

- ❑ **Vaccine preventable disease burden remaining among adults  $\geq 65$  years**
  - Estimated 2,600 PCV13 type IPD cases in 2013<sup>1</sup>
  - Over 50,000 PCV13-type inpatient CAP<sup>2</sup>
  
- ❑ **In the short-term, PCV13 likely provides adequate coverage of disease causing serotypes**
  - 20-25% IPD due to PCV13 types<sup>1</sup>
  - ~10% of all CAP due to PCV13 types<sup>2</sup>

<sup>1</sup>Active Bacterial Core Surveillance, 2013

<sup>2</sup> Estimate based on studies using serotype-specific urine antigen test, Pfizer

**PCV13 now recommended in series  
with PPSV23 for all adults  $\geq 65$  years**

**Adults  $\geq 65$  years of age with  
no previous pneumococcal vaccine  
(PCV13 or PPSV23) or  
unknown vaccination history**

## **Recommendation**

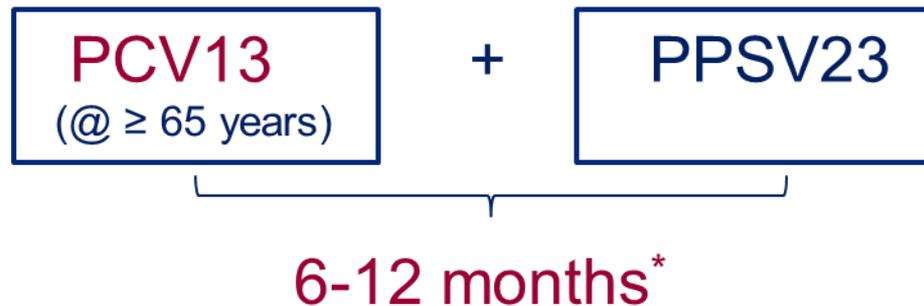
- ❑ Administer a dose of PCV13 first, followed by a dose of PPSV23
- ❑ The two vaccines should not be administered at the same visit

# **Adults $\geq 65$ years of age with no previous pneumococcal vaccine (PCV13 or PPSV23) or unknown vaccination history**

## **Guidance on intervals for sequential use**

- ❑ A dose of PPSV23 should be given 6 to 12 months following a dose of PCV13
- ❑ If PPSV23 cannot be given during this time window, a dose of PPSV23 should be given during the next visit
- ❑ Minimum interval = 8 weeks

**Adults  $\geq 65$  years of age with  
no previous pneumococcal vaccine  
(PCV13 or PPSV23) or  
unknown vaccination history**



\*Minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks

# PCV13-naïve adults $\geq 65$ years of age **previously vaccinated with PPSV23**

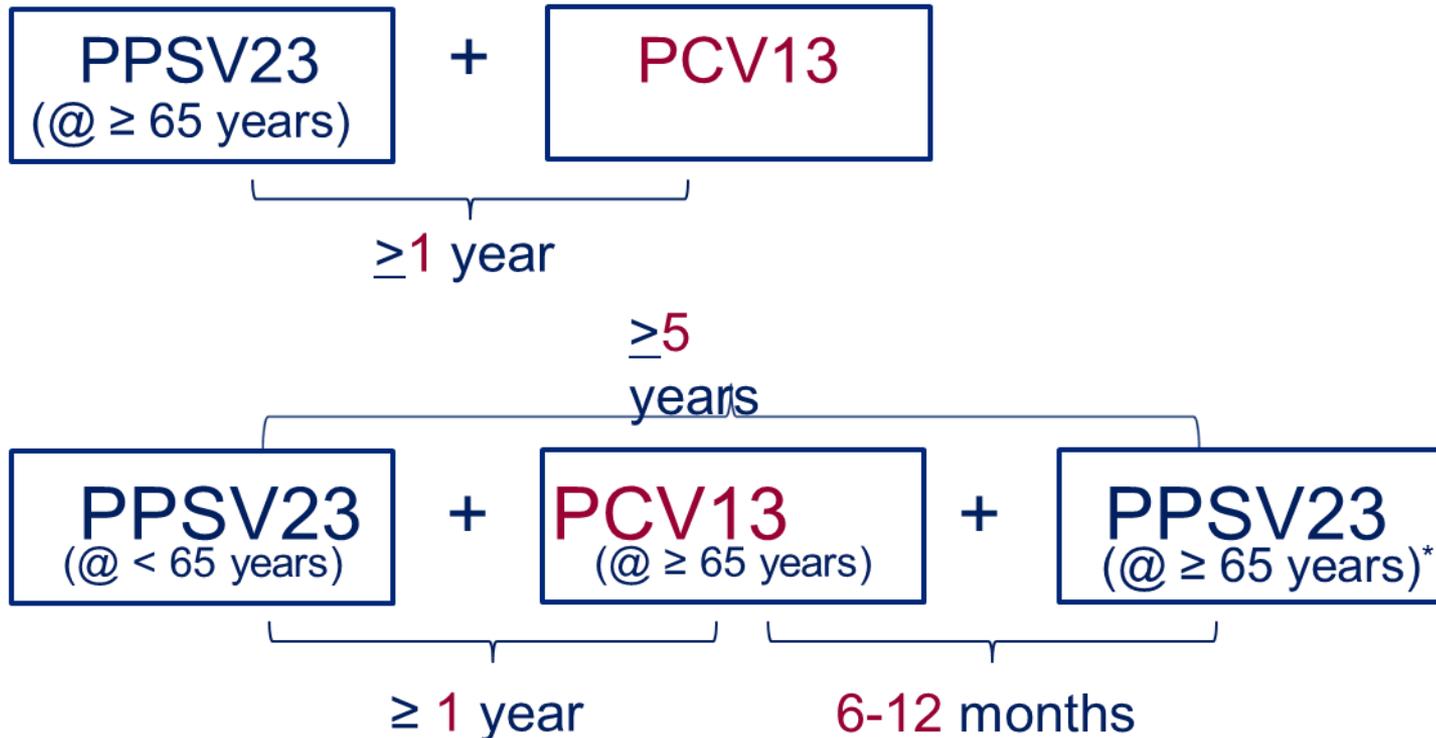
## Recommendation

- ❑ Administer a dose of PCV13

## Guidance on intervals for sequential use

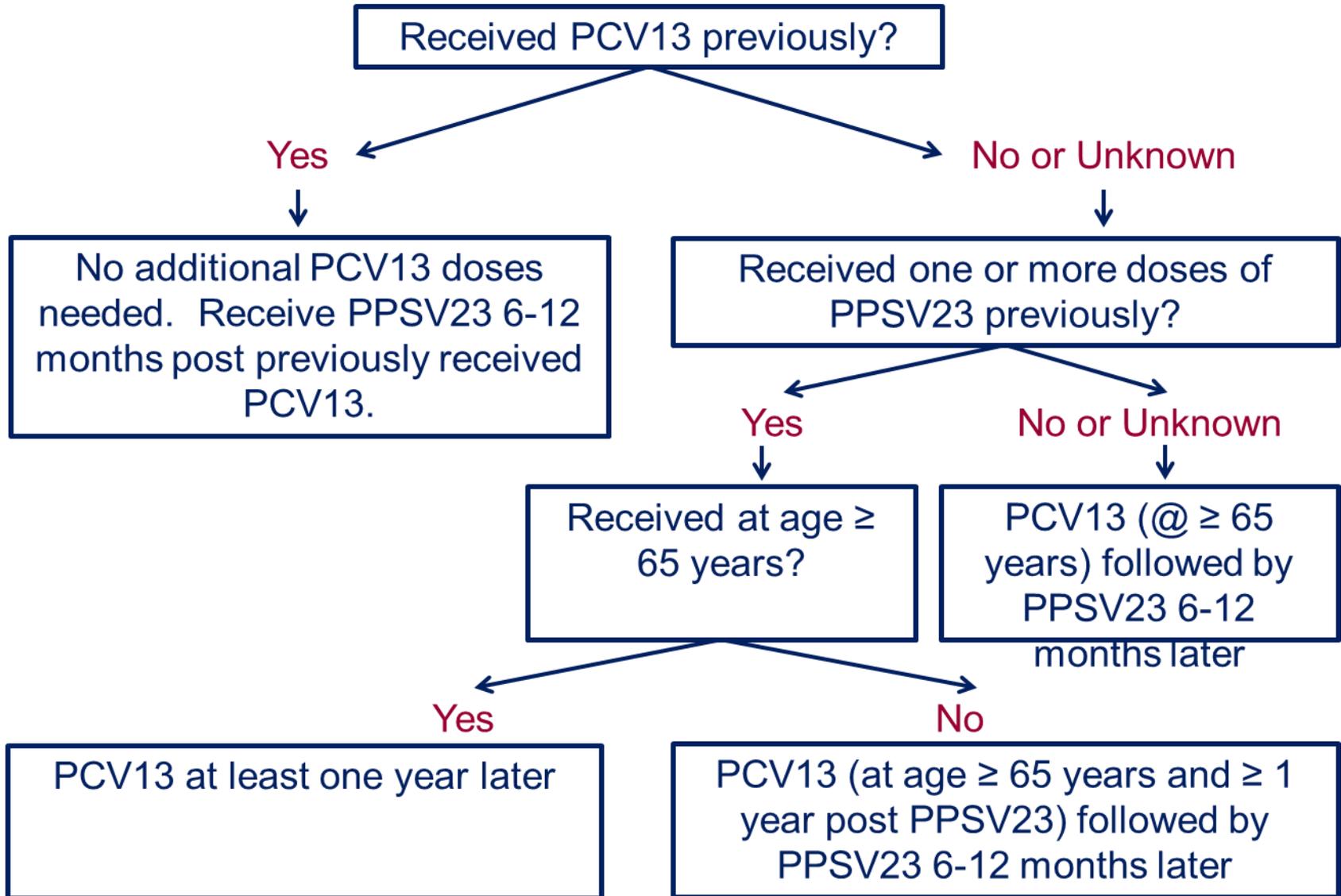
- ❑ Administer PCV13 at least 1 year after the receipt of the most recent PPSV23 dose
- ❑ For those for whom an additional dose of PPSV23 is indicated, administer it 6 to 12 months after PCV13 and at least 5 years after the most recent dose of PPSV23

# PCV13-naïve adults $\geq 65$ years of age **previously vaccinated with PPSV23**



\*Minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks.

# Categories of adults $\geq 65$ years old

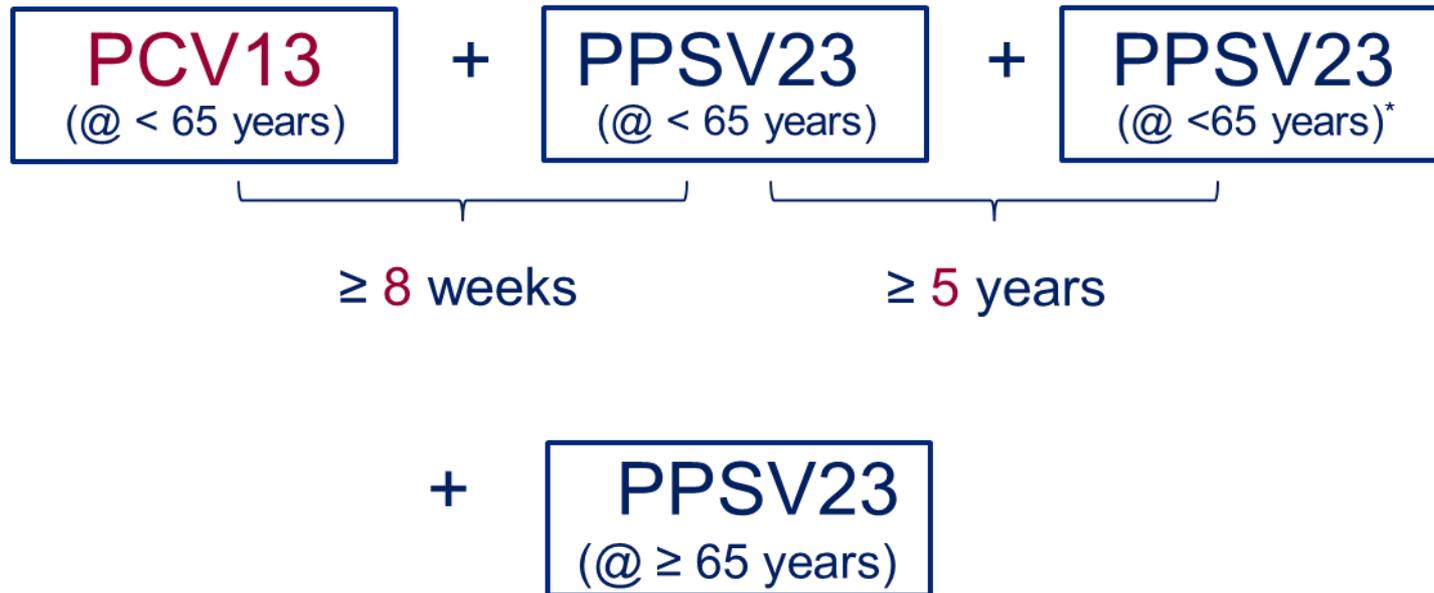


# Prevention of pneumococcal disease among adults $\geq 19$ years with **high risk conditions**

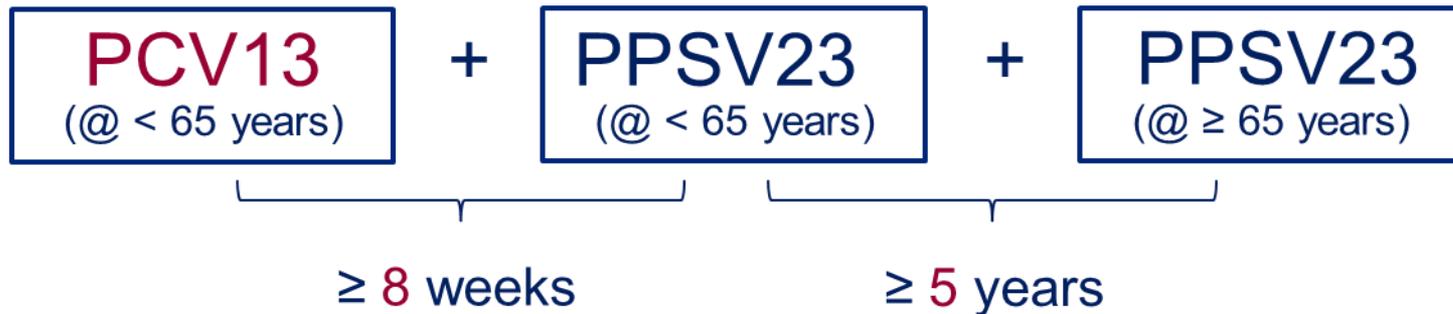
## Current guidelines

- ❑ “Use of PCV13 and PPSV23 for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP)” remain unchanged
- ❑ <http://www.medscape.com/viewarticle/772339>
- ❑ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm>

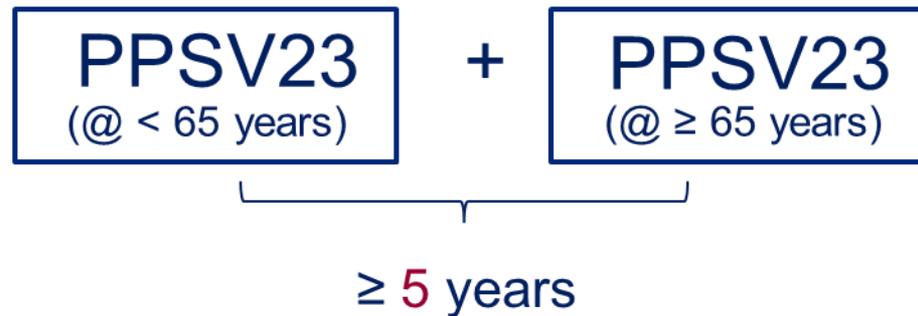
# Prevention of pneumococcal disease among adults $\geq 19$ years with **functional or anatomic asplenia or immunocompromising conditions**



# Prevention of pneumococcal disease among adults $\geq 19$ years with cochlear implants or CSF leaks



# Prevention of pneumococcal disease among adults $\geq 19$ years with **chronic medical conditions**



**PATIENT SCENARIOS FOR ADULTS  
≥65 YEARS OF AGE**

# Patient scenario #1

A 65 year old female patient with no underlying medical conditions and no previous pneumococcal vaccinations

❑ Administer vaccines as follows:

- ❑ 1 dose of PCV13 now
- ❑ 1 dose of PPSV23 6 to 12 months after administering PCV13

❑ Rationale:

- ❑ She is  $\geq 65$  years old and has no history of pneumococcal vaccination, so she is recommended both pneumococcal vaccines

## Patient scenario #2

A 67 year old male patient with no underlying medical conditions who received a dose of PPSV23 at age 65 years

- ❑ Administer vaccines as follows:

- ❑ 1 dose of PCV13 now

- ❑ Rationale:

- ❑ He is  $\geq 65$  years old
  - ❑ It has been  $\geq 1$  year since PPSV23
  - ❑ Only 1 dose of PPSV23 is recommended for adults  $\geq 65$  years

## Patient scenario #3

A 66 year old male patient with cochlear implants who received a dose of PPSV23 at age 55 years

- ❑ Administer vaccines as follows:
  - ❑ 1 dose of PCV13 now
  - ❑ 1 dose of PPSV23 6 to 12 months after administering PCV13
  
- ❑ Rationale:
  - ❑ He is  $\geq 65$  years old
  - ❑ At least 1 year has passed since he received PPSV23
  - ❑ It's been  $\geq 5$  years since his previous PPSV23 dose

## Patient scenario #4

A 66 year old female patient infection with HIV who received a dose of PPSV23 at ages 52, 57, and 65 years and a dose of PCV13 at 64 years

- ❑ Do not administer any vaccines
  
- ❑ Rationale:
  - ❑ Only 1 dose of PCV13 is recommended in an adult's lifetime
  - ❑ Only 1 dose of PPSV23 is recommended for adults  $\geq 65$  years

# Insurance coverage for pneumococcal vaccines

- ❑ Most private health insurance covers pneumococcal vaccines
- ❑ Medicare part B typically covered only the first dose of pneumococcal vaccines
- ❑ CMS recently updated coverage requirement for pneumococcal vaccines to align with the new ACIP recommendations and allow for the coverage of the two pneumococcal vaccines given in series
- ❑ Patients should check with their insurance providers, including those that supplement Medicare Part B, for coverage and cost details

# Summary

- ❑ Adults  $\geq 65$  years are at increased risk for pneumococcal disease and severe complications
- ❑ All adults  $\geq 65$  years should get PCV13
  - ❑ Only 1 dose of PCV13 is recommended in an adult's lifetime
- ❑ PPSV23 should be administered to adults  $\geq 65$  years old 6-12 months after PCV13
  - ❑ Only 1 dose of PPSV23 is recommended for adults  $\geq 65$  years
- ❑ Recommendations for PCV13 and PPSV23 use among adults  $< 65$  years with chronic medical conditions remain unchanged (ACIP 2010, ACIP 2012)

# Standards for Adult Immunization Practices

- ❑ Assess the immunization status of all your patients
- ❑ Strongly recommend vaccines that patients need
- ❑ Administer needed vaccines or refer patients to a vaccinating provider
- ❑ Document vaccines received by your patients



# CDC Resources

- ❑ Clinician: Adult immunization information/schedule
- ❑ Patient: Education materials on adult immunization
- ❑ Implementation of Standards
- ❑ Pneumococcal disease and vaccine resources



[www.cdc.gov/vaccines/adults](http://www.cdc.gov/vaccines/adults)

[www.cdc.gov/vaccines/AdultStandards](http://www.cdc.gov/vaccines/AdultStandards)

[www.cdc.gov/pneumococcal/clinicians](http://www.cdc.gov/pneumococcal/clinicians)

[www.cdc.gov/vaccines/vpd-vac/pneumo](http://www.cdc.gov/vaccines/vpd-vac/pneumo)

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.

# Implementing PCV13 in IHS, Tribal and Urban Indian Healthcare Facility Settings

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IHS Immunization Program Manager

# Pneumococcal Disease

## AI/AN population

- Higher rates of invasive pneumococcal disease in some AI/AN populations compared to whites
  - Alaska, Southwest
- Pneumonia & Influenza one of the top 10 leading causes of death for AI/AN
  - Mortality rates 1.9 times higher for AI/AN vs. White
    - Range of 1.7 to 4.86, depending on age group
- High burden of underlying chronic conditions

Source: Groom et al. Pneumonia and Influenza Mortality Among American Indian and Alaska Native People, 1990–2009, AJP 2014 Jun;104 Suppl 3:S460-9.

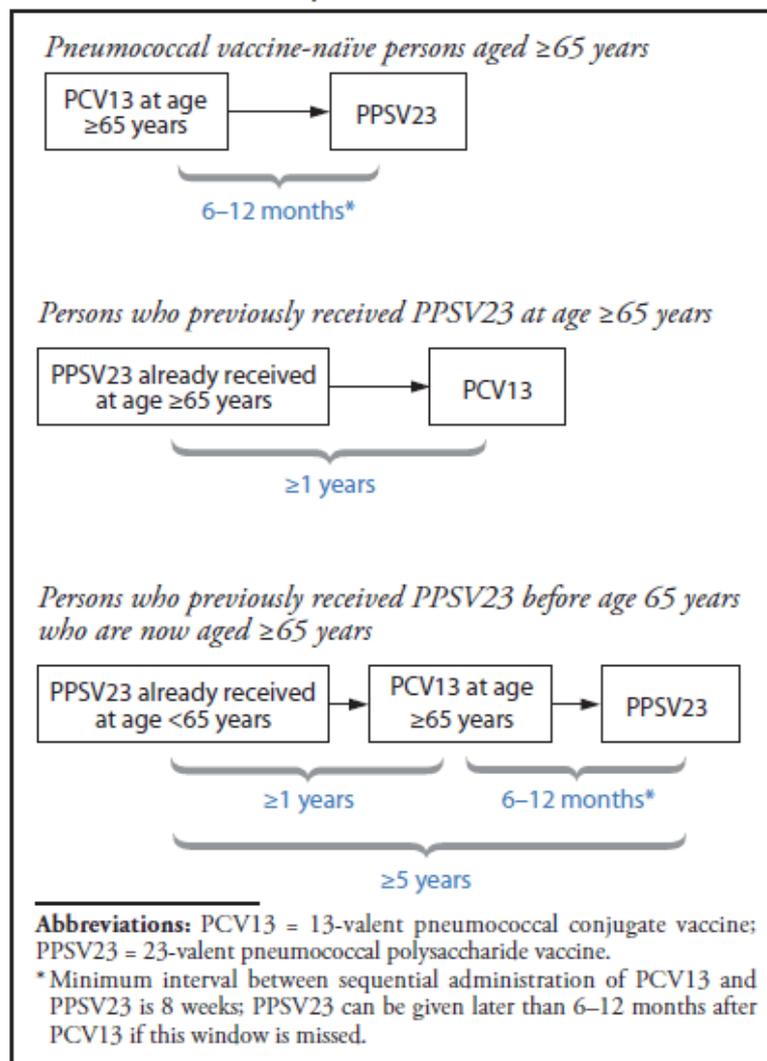
# Pneumococcal Recommendations

- For patients 65 years and older who have NEVER received a pneumococcal vaccine
  - Receive PCV13 first
  - Receive PPSV23 6 – 12 months later (recommended)
  - Minimum interval of 8 weeks between PCV13 and PPSV23
- For patient's previously vaccinated with PPSV23
  - Should receive dose of PCV13  $\geq 1$  year after PPSV23
  - If additional dose of PPSV23 needed, should be administered 6-12 months after PCV13, and 5 years after previous PPSV23 dose

ACIP Pneumococcal recommendations

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm>

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



**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.

# Clinical Decision Support In RPMS (Texas Children's Hospital Forecaster)

- TCH Forecaster Version 3.11.05 AND
- Immunization Package (BI) Path 10
  - PCV13 reminder for adults 65 years and older
  - Released May 19<sup>th</sup>, 2015
- Must update EHR Clinical Reminders for adult reminder to display

# TCH Forecast Logic for PCV13

- If no previous pneumococcal vaccine:
  - PCV13 at 65 years and older for all patients
  - PPSV23 forecast 6 months later
  - Valid if given at least 8 weeks later
- If previous PPSV23 given:
  - PCV13 forecast 1 year after PPSV23
  - If additional PPSV23 needed, will forecast 6 months after PCV13 and 5 years after previous PPSv23
- If previous PCV13 given:
  - PPSV23 forecast 6 months after PCV13
  - No additional PCV13 dose forecast

# Funding for PCV13

- Cost
  - NSSC Pricing
    - PCV13 – \$88.50
    - PPSV23 – \$24.08
- PCV13 is covered by Medicare Part B
  - Reimbursement for both PCV13 and PPSV23
  - <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9051.PDF>
- Pfizer RxPathways Vaccine Replacement Program
  - [http://pfizerrxpathways.com/sites/default/files/attachment/GroupCFo rm73114\\_Online.pdf](http://pfizerrxpathways.com/sites/default/files/attachment/GroupCFo rm73114_Online.pdf)
  - AI/AN patients whose only source of care is IHS are considered uninsured
  - Income requirements
  - Must seek approval before administering