Pneumococcal Vaccines for Adults

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Disclosures

- Tina Objio is a federal government employee with no financial interest in or conflict with the manufacturer of any product named in this presentation.
- The speaker will discuss the off-label use of vaccines.
- The speaker will not discuss a vaccine not currently licensed by the FDA.
Pneumococcal Vaccines for Adults

- History
- Epidemiology
- Risk factors
- Vaccines
- Tools
- Recommendations
- Case studies
**S. pneumoniae** first isolated by Pasteur in 1881

Confused with other causes of pneumonia until discovery of Gram stain in 1884

More than 80 serotypes described by 1940

First U.S. vaccine licensed in 1977

[History](https://www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html)

Image from: [https://en.wikipedia.org/wiki/Louis_Pasteur](https://en.wikipedia.org/wiki/Louis_Pasteur)
*Streptococcus pneumoniae*

- Gram-positive bacteria
- 92 known serotypes
- Polysaccharide capsule important virulence factor
- Type-specific antibody is protective
- Limited cross-reactivity

https://www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html
Pneumococcal Disease

- Second most common cause of vaccine-preventable death in the U.S.

- Major clinical syndromes
  - Pneumonia
  - Bacteremia
  - Meningitis

https://www.cdc.gov/pneumococcal/about/facts.html
https://www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html
Invasive Pneumococcal Disease Incidence by Age Group–2013*

Risk Factors for Invasive Pneumococcal Disease

- Functional or anatomic asplenia, including sickle-cell disease
- Altered immunocompetence
- Underlying medical conditions, including chronic renal disease, nephrotic syndrome, and CSF leak
- Cigarette smoking (adults 19 years and older)
- Cochlear implant
Incidence of IPD in Adults Aged 18-64 Years with Selected Underlying Conditions, United States, 2009

Unpublished data, Active Bacterial Core surveillance, 2009
Pneumococcal Disease Epidemiology

- **Reservoir**: Human carriers

- **Transmission**: Respiratory and autoinoculation

- **Temporal pattern**: Winter and early spring

- **Communicability**: Unknown; probably as long as organism in respiratory secretions
Pneumococcal Vaccines

- **1977**  14-valent polysaccharide vaccine licensed
- **1983**  23-valent polysaccharide vaccine licensed (PPSV23)
- **2000**  7-valent polysaccharide conjugate vaccine licensed (PCV7)
- **2010**  13-valent polysaccharide conjugate vaccine licensed (PCV13)
PCV7 Introduction Among U.S. Children and its Impact on Invasive Pneumococcal Disease

- PCV7 introduced into routine schedule 2000

Rates of IPD Among Children <5 yrs old

![Graph showing the decrease in cases per 100,000 from 1998 to 2009 after PCV7 introduction. The graph indicates a significant reduction in rates, with a notable drop in 2000.]

Moore, IDSA, 2009 and CDC, unpublished data
Trends in Invasive Pneumococcal Disease Among Adults 19–64 Years of Age, 1998–2015

Active Bacterial Core surveillance data, 1998–2015, unpublished

*PPSV23 serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F

*PCV13 serotype: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F

http://www.cdc.gov/abcs/reports-findings/survreports/spneu-types.html
Trends in Invasive Pneumococcal Disease Among Adults 65 Years of Age and Older, 1998–2015

http://www.cdc.gov/abcs/reports-findings/survreports/spneu-types.html

*PPSV23 serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F

*PCV13 serotype: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F

Active Bacterial Core surveillance data, 1998–2015, unpublished
Pneumococcal Conjugate Vaccine (PCV13) in Adults

- In 2013, 20%-25% of invasive pneumococcal disease cases among adults 65 years old and older were attributable to PCV13 serotypes

- 10 percent of community-acquired pneumonia in adults due to PCV13 serotypes
## Pneumococcal Vaccines

<table>
<thead>
<tr>
<th></th>
<th>23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)</th>
<th>13-Valent Pneumococcal Conjugate Vaccine (PCV13)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td>Purified polysaccharide</td>
<td>Purified polysaccharide covalently bound to carrier protein</td>
</tr>
<tr>
<td><strong>Ages</strong></td>
<td>2 years and older</td>
<td>6 weeks and older*</td>
</tr>
<tr>
<td><strong>Number of serotypes</strong></td>
<td>23</td>
<td>13</td>
</tr>
</tbody>
</table>

*ACIP off-label recommendation

**MMWR** 2012; 61(40):816-19
Pneumococcal Polysaccharide Vaccine (PPSV23)
Immunogenicity/Effectiveness

- Most estimates range between 60%-70% effective against invasive disease among immunocompetent older persons and adults with underlying illnesses

- Effectiveness among immunocompromised or very old persons not demonstrated
PCV13

- PCV13 is approved by the Food and Drug Administration for:
  - Children 6 weeks through 17 years of age
  - Adults 18 years of age and older

- ACIP recommended use of PCV13 for immunocompromised persons 6 years and older (2012, 2013)

- ACIP recommended use of PCV13 for all adults 65 years or older in 2014
PCV13 for Adults

- Licensed for use among adults >50 years old on 12/30/11

- Based on noninferior immunogenicity compared to PPSV23

- Postlicensure condition of approval:
  - Randomized, controlled trial of PCV13 against pneumococcal pneumonia among adults >65 years old in the Netherlands
New Evidence Supporting PCV13 Use Among Adults, CAPiTA Results

<table>
<thead>
<tr>
<th>Study/Population</th>
<th>Endpoint</th>
<th>Vaccine Efficacy (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPiTA</td>
<td>PCV13-serotype IPD</td>
<td>75% (41%, 91%)</td>
</tr>
<tr>
<td>~85,000 Adults 65+</td>
<td></td>
<td></td>
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<tr>
<td>Netherlands</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PCV13-serotype nonbacteremic pneumonia</td>
<td>45% (14%, 65%)</td>
</tr>
</tbody>
</table>

CAPiTA, ACIP, June 2014
ACIP Adult Pneumococcal Vaccination Recommendations

- **PPSV23 recommendations**
  - PPSV23 is recommended for persons 19 through 64 years of age at increased risk
  - PPSV23 is routinely recommended for persons 65 years of age and older

- **PCV13 recommendations**
  - PCV13 is recommended for persons 6 years and older at increased risk (2012, 2013)
  - PCV13 is routinely recommended for adults 65 years or older (2014)
Administering PCV13 and PPSV23 Vaccines

General Rules

- Administer PCV13 before PPSV23 whenever possible
- PCV13 and PPSV23 should not be administered during the same clinic visit
  - Either vaccine may be administered simultaneously with influenza vaccine
- Prior doses count and do not need to be repeated
Pneumococcal Vaccination Schedule

- **PCV13 schedule:**
  - Administer 1 dose to eligible adults who have no history of PCV13 vaccination
  - If PCV13 was administered before age 65, no additional doses are indicated at 65 years of age and older

- **PPSV23 schedule:**
  - No more than 2 doses of PPSV23 are recommended before age 65 and 1 dose after
  - Separate doses of PPSV23 by at least 5 years
Immunization Action Coalition
Pneumococcal Recommendations

data from CDC:

www.immunize.org
http://eziz.org/assets/docs/IMM-1152.pdf
## Table 1. Medical conditions or other indications for administration of PCV13 and PPSV23 for adults

<table>
<thead>
<tr>
<th>Medical indication</th>
<th>Underlying medical condition</th>
<th>PCV13 for &gt; 19 years</th>
<th>PPSV23* for 19 through 64 years</th>
<th>PCV13 at ≥ 65 years</th>
<th>PPSV23 at ≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None of the below</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>High Risk</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Immunocompetent persons</td>
<td>Alcoholism</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Chronic heart disease‡</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Chronic liver disease</td>
<td></td>
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<tr>
<td></td>
<td>Chronic lung disease§</td>
<td></td>
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<tr>
<td></td>
<td>Cigarette smoking</td>
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<td></td>
<td>Diabetes mellitus</td>
<td></td>
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<tr>
<td></td>
<td>Cochlear implants</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>≥ 8 weeks after PCV13</td>
</tr>
<tr>
<td></td>
<td>CSF leaks</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Persons with functional or anatomic asplenia</td>
<td>Congenital or acquired asplenia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>≥ 8 weeks after PCV13</td>
</tr>
<tr>
<td></td>
<td>Sickle cell disease/other hemoglobinopathies</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>≥ 8 weeks after PCV13</td>
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<tr>
<td><strong>Higher Risk</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>Chronic renal failure</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Congenital or acquired immunodeficiencies§</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>≥ 8 weeks after PCV13</td>
</tr>
<tr>
<td></td>
<td>Generalized malignancy</td>
<td></td>
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<td></td>
<td>HIV infection</td>
<td></td>
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<td></td>
<td>Hodgkin disease</td>
<td></td>
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<tr>
<td></td>
<td>Iatrogenic immunosuppression$</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>≥ 8 weeks after PCV13</td>
</tr>
<tr>
<td></td>
<td>Leukemia</td>
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<td></td>
<td>Lymphoma</td>
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<tr>
<td></td>
<td>Multiple myeloma</td>
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<tr>
<td></td>
<td>Nephrotic syndrome</td>
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<tr>
<td></td>
<td>Solid organ transplant</td>
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</tbody>
</table>

*This PPSV23 column only refers to adults 19 through 64 years of age. All adults 65 years of age or older should receive one dose of PPSV23 5 or more years after any prior dose of PPSV23, regardless of previous history of vaccination with pneumococcal vaccine. No additional doses of PPSV23 should be administered following the dose administered at 65 years of age or older.*

‡Including congestive heart failure and cardiomyopathies

§Including chronic obstructive pulmonary disease, emphysema, and asthma

$Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)

$Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

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Pneumococcal Vaccination and Adults

- PCV13 and PPSV23 adult vaccination recommendations are divided between 2 age groups. Persons who are:
  - 19 through 64 years of age
  - 65 years of age and older

- Immunization recommendations for persons 19 through 64 years of age are based on risk, including those at:
  - High risk
  - Higher risk
  - Highest risk
High Risk for IPD

- Administer 1 dose of PPSV23 to adults 19 through 64 years of age at high risk for IPD
  - PCV13 is NOT indicated

- This includes persons with:
  - Pulmonary disease (including asthma)
  - Cardiac disease (excluding hypertension)
  - Liver disease (including cirrhosis)
  - Diabetes
  - Alcoholism
  - Smokers
  - Residents of a long-term care facility
Higher Risk for IPD

- Administer PCV13 and PPSV23 to adults 19 through 64 years of age at higher risk for IPD, including those with:
  - CSF leak
  - Cochlear implant

- Administer PCV13 followed by PPSV23 vaccine
### Highest Risk for IPD

- Adults 19 through 64 years of age at highest risk for IPD, including those who:
  - Are immunocompromised (including HIV infection)
  - Have chronic renal failure or nephrotic syndrome
  - Are asplenic

- Administer PCV13 and 2 doses of PPSV23

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**Diagram:**
- PCV13 (8 weeks)
- PPSV23 (5 years)

*MMWR 2015;64(34):944-47*
Persons Age 65 Years and Older

- No history of pneumococcal vaccine
- Immunization history of PPSV23 at age 65 or older

*8 weeks if at higher or highest risk

*MMWR 2015;64(34):944-47*
Persons Age 65 Years and Older

- Received PPSV23 before age 65 years

- Separate doses of PPSV23 by at least 5 years

*8 weeks if at higher or highest risk

MMWR 2015;64(34):944-47
Pneumococcal Vaccines
Contraindications and Precautions

- Severe allergic reaction to vaccine component or following prior dose of vaccine

- Moderate or severe acute illness
**Vaccine Administration**

**Pneumococcal Vaccines**

- **Route:** IM injection PCV13 and PPSV23
  - Needle gauge: 22 – 25 gauge
  - Needle length:* 1 – 1.5 inch depending on the patient’s age and/or weight

- **IM injection site:** *
  - Deltoid muscle is preferred; vastus lateralis muscle may be used

- **Note:** PPSV23 may also be administered by Subcut injection in the upper outer triceps area
  - Needle gauge/length: 23 – 25 gauge; 5/8th inch needle

- **Vaccine administration error:**
  - Schedule error: more than 1 PPSV23 revaccination dose to at-risk persons 19 – 64 years of age

*Professional judgment should be used to determine the proper needle length and site. Influencing factors include injection technique, local reaction, number of vaccines to be administered, patient age, size, and muscle mass.
## Pneumococcal Vaccines

### Adverse Reactions

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>PPSV23</th>
<th>PCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local reactions</td>
<td>30%-50%</td>
<td>5%-49%</td>
</tr>
<tr>
<td>Fever, myalgia</td>
<td>&lt;1%</td>
<td>24-35%</td>
</tr>
<tr>
<td>Febrile seizures</td>
<td>---</td>
<td>Rare: 1-14/100,000; with IIV 4-45/100,000</td>
</tr>
<tr>
<td>Severe adverse reactions</td>
<td>rare</td>
<td>8% (local)</td>
</tr>
</tbody>
</table>
Vaccine Storage and Handling

- Store PCV13 and PPSV23 vaccines in a refrigerator between 2°C - 8°C (36°F - 46°F)
- Store:
  - In the original packaging with the lids closed
  - In a clearly labeled bin and/or area of the storage unit – not next to each other
- Do not freeze the vaccine

PCV13 (Prevnar 13)
- **Ages:** All children 6 weeks through 5 years
- **Increased risk children:** 6 years through 18 years
- **Increased risk adults:** 19 years and older
- **Adults 65 years and older who have never received PCV13**
- **Route:** Intramuscular (IM) injection

PPSV23 (Pneumovax 23)
- **Ages:** Healthy adults 65 years and older
- **Increased risk persons:** 2 years through 64 years
- **Route:** Intramuscular (IM) injection OR Subcutaneous (subcut) injection
- **No more than two doses of PPSV23 recommended before 65th birthday and one dose after 65.**

Labels available at www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf
Case Studies
What do you think?

- Rita just turned 65 years old. Today, she is being seen by her primary health care provider. Rita was diagnosed with diabetes when she was 63 years old and received PPSV23 at the time of her diagnosis. She has never received PCV13.

- Should she receive any pneumococcal vaccines today? If so, which one(s)?
  - A. None
  - B. Yes, PCV13
  - C. Yes, PPSV23
  - D. Both B and C
What do you think?

- Margaret is a 70-year-old patient with immunosuppression due to cancer treatment that began two months ago. Her immunization history includes PCV13 and PPSV23, both administered after 65 years of age, but before the onset of her immunosuppressing condition. Should PPSV23 be administered today?

A. Yes
B. No
What do you think?

- Enrique is a 54-year-old man who lost his spleen as a result of an automobile accident when he was 50 years old. He is otherwise healthy and prior to his accident had never had any pneumococcal vaccines. What pneumococcal vaccines should he have received after losing his spleen, if any?

  • A. None
  • B. PCV13
  • C. PPSV23
  • D. Both B and C
What do you think?

- Enrique is now 55 years old and is being seen for a routine visit. It has been at least 5 years since his first pneumococcal vaccines (given at age 50 years, following loss of his spleen). What vaccine(s) should he receive now, if any?

  • A. None
  • B. PCV13
  • C. PPSV23
  • D. Both B and C
What do you think?

- Should Enrique ever receive additional doses of pneumococcal vaccines?
  
  • A. No, he should not receive additional doses.
  • B. Yes, he should receive PPSV23 and PCV13 when he turns 65.
  • C. Yes, he should receive only PPSV23 when he turns 65.
  • D. Yes, he should receive only PCV13 when he turns 65.
What do you think?

Mari is a 20-year-old college student who just received a cochlear implant. She received PCV7 in childhood and has no other pneumococcal vaccination history. Should her health care provider recommend and administer any pneumococcal vaccines and, if so, which one(s)?

- A. None
- B. PCV13
- C. PPSV23
- D. Both B and C
What do you think?

- Mari receives PCV13 and PPSV23 vaccine per her health care provider’s recommendation. What should the provider tell Mari about the need for any future dose(s) of pneumococcal vaccine(s)?

  • A. The next dose of PPSV23 is due in 5 years.
  • B. The next dose of PCV13 is due in 5 years.
  • C. No further pneumococcal vaccines would be indicated at any future time.
  • D. A dose of PPSV23 would be recommended on or after Mari turns 65 years old.
Mari is now 30 years old and has been diagnosed with Hodgkin disease. What, if any, additional pneumococcal vaccines should she receive at this time?

- A. None
- B. PCV13
- C. PPSV23
- D. Both B and C
A few additional points

- Treatment planning
- Timing interval errors
- Hematopoietic cell transplant (HCT) therapy
- Check for updates:
  - https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- Off-label use (ACIP):

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Notes</th>
</tr>
</thead>
</table>

Additional Pneumococcal Vaccine Training Resources

- **Vaccine Training:**
  - [https://www.cdc.gov/vaccines/ed/index.html](https://www.cdc.gov/vaccines/ed/index.html)

- **You Call the Shots:**
  - [https://www.cdc.gov/vaccines/ed/youcalltheshots.html](https://www.cdc.gov/vaccines/ed/youcalltheshots.html)

- **Pink Book Courses:**
Questions?

Email us for vaccine specific questions at:

NIPINFO@CDC.gov