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Evaluation of 13-Valent Pneumococcal Conjugate Vaccine (PCV13) Policy for Adults ≥65 Years Old, United States

Almea Matanock, MD, MS

48th National Immunization Conference
Session: Pneumococcal carriage, disease, and vaccine policy
May 17th, 2018
Outline

- Evidence that led to the 2014 Advisory Committee on Immunization Practices (ACIP) pneumococcal vaccine recommendations for adults ≥65 years old
- ACIP decision making process applied to the adult ≥65 years old pneumococcal vaccine recommendations
- Evidence presented to date evaluating the 2014 recommendation
Pneumococcal Conjugate Vaccine Recommendations

PCV13 for individuals with immunocompromising conditions

PCV13 for children

PCV13 for children

Evaluation of PCV13 in adults ≥65 years old

PCV13 in series with PPSV23 for adults ≥65 years old

Indirect effects for adults ≥65 years old

Direct and indirect effects for adults ≥65 years old

PCV7 for children


Presently
Impact of Pediatric PCV13 on Pneumococcal Disease

- Invasive pneumococcal disease (IPD) caused by PCV13 serotypes has declined since introduction of PCV13 in the routine pediatric immunization schedule
  - Children <5 years old: PCV13-type IPD incidence declined from 13 cases/100,000 in 2010 to ~2 cases/100,000 in 2012–2016
  - Adults ≥65 years old: PCV13-type IPD incidence declined from 14 cases/100,000 in 2010 to ~5 cases/100,000 in 2014–2016
- Impact on non-invasive pneumococcal disease has been less clear in the post-PCV13 era
Non-Invasive Pneumococcal Disease

- Non-bacteremic pneumococcal pneumonia (NBPP) incidence estimated to be ~90 times more common than IPD incidence among ≥65 years olds
  - Pneumonia etiology difficult to establish given available diagnostic tests
  - No clinically available test to measure serotype-specific burden of pneumococcal pneumonia

- In 2014, it was estimated that PCV13 use among adults ≥65 years old could prevent 4,961 NBPP hospitalizations and 226 IPD episodes annually
  - Anticipated that most benefits would be observed during the first few years after the PCV13 recommendation for adults due to continued indirect PCV13 effects
# ACIP 2014 PCV13 Recommendation for Adults ≥65 Years Old

<table>
<thead>
<tr>
<th>Key Factors for ACIP decision</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence type/quality for benefits and harms</td>
<td>Evidence to support that PCV13 prevents IPD and NBPP</td>
</tr>
</tbody>
</table>
| Balance of benefits versus harms | Expected benefits outweigh harms  
Short-term: No uncertainty about the balance  
Long-term: Indirect (herd) effects of infant vaccination expected to further reduce burden of vaccine-preventable pneumococcal disease in adults |
| Values | General consensus reached on which outcomes are critical to prevent |
| Cost-effectiveness | Short-term: The net benefits are worth the costs  
Long-term: Uncertainty due to continued indirect effects |
ACIP 2014 PCV13 Recommendation for Adults ≥65 Years Old

- Adults ≥65 years old who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive PCV13 first followed by PPSV23
- Adults ≥65 years old who have not previously received PCV13 and who have previously received ≥1 dose(s) PPSV23 should receive a dose of PCV13
- The recommendation for routine PCV13 use among adults ≥65 years old should be re-evaluated in 2018 and revised as needed

- Vote: 13 favored, 2 opposed, 0 abstentions
  - Concerns among those opposed:
    - Recommendation may not be warranted given anticipated continued indirect effects
    - Assumption that 10% of NBPP, especially for outpatient pneumonia, was due to vaccine-type *S. pneumonia*, was too generous
In 2014 when the ACIP decision was made...

- Short-term, PCV13 recommendation for older adults was warranted
  - While indirect effects had decreased vaccine-type IPD, there was still a significant burden of pneumonia, especially among older adults
  - PCV13 use among adults had the potential to reduce disease during seasonal peaks (respiratory disease season)

- Long-term public health benefits were expected to be limited because of anticipated continued indirect effects from pediatric PCV13 program

- Therefore, the recommendation was made with a commitment to re-evaluate this policy in 2018 and revise as needed
ACIP Evidence to Recommendation (EtR)

To provide a forum for discussion of best practices for the evidence-based recommendation process, including development and use of evidence tables and an evidence to recommendation framework to ensure consistency and enhance transparency in the development of ACIP recommendations, with the goal of developing a uniform approach to evaluation and use of the evidence base for ACIP recommendations.
ACIP EtR Framework

- Statement of problem
  - Public health priority
  - Burden of disease

- Benefits and harms
  - Balance of desirable and undesirable effects
  - Certainty in evidence

- Values and preferences of target population

- Acceptability to stakeholders

- Resource use
  - Health economic analyses

- Feasibility
  - Implementation considerations
Grading of Recommendations Assessment, Development and Evaluation (GRADE)

- Formulating a question
  - Population, Intervention, Comparison, Outcomes (PICO)
  - PICO question in 2014: “Should PCV13 be administered routinely to all adults aged ≥65 years?”

- Choosing and ranking outcomes
  - Focus on studies that directly answer the question
  - Surrogate outcomes, such as immunogenicity and nasopharyngeal carriage, considered only when clinical outcomes have not been studied

- Evidence retrieval

- Type or quality of evidence
Evidence Presented to ACIP since 2014

- Studies monitoring nasopharyngeal carriage before and after PCV13 introduction to identifying serotypes circulating in the community
  - PCV13-serotype carriage among children has declined from 8 in 100 children in 2011 and <1 in 100 in 2017, but total *S. pneumoniae* carriage has remained the same (~30%)
  - Pneumococcal carriage among adults ≥65 years old very low, 1.8% total and 0.2% carrying PCV13-type in 2015–2016

- Estimates of PCV13 uptake among adults
  - ≥65 years old: coverage increased to ~40% through 2017
  - 19–64 years old with PCV13 indications: coverage is lower, but likely varies by indication
Evidence Presented to ACIP since 2014

- PCV13-type IPD declined among all age groups
- Overall and PCV13-type IPD incidence in adults ≥65 years old plateaued in 2014–2016
- Combined direct and indirect effects since 2014
  - Mathematical model to estimate contribution of direct vs indirect PCV13 effects on observed trends in IPD among adults ≥65 years old
  - Model estimated that ~580 IPD cases were prevented (95% CI: 123, 1,077) since 2014 among adults ≥65 years old in the U.S., with benefits decreasing over time
### Evidence Presented to ACIP since 2014

**Vaccine effectiveness (VE) against PCV13-type IPD among adults ≥65 years old**

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPiTA (Netherlands)</td>
<td>Randomized placebo-controlled trial among community-dwelling adults</td>
<td>75% (41–91)</td>
</tr>
<tr>
<td>CDC Case-Control Study</td>
<td>IPD cases identified through ABCs matched with population-based controls</td>
<td>65% (19–85)</td>
</tr>
<tr>
<td>CDC/CMS Vaccine Effectiveness Evaluation</td>
<td>Medicare part B beneficiaries: IPD cases matched with controls</td>
<td>47% (4–71)</td>
</tr>
</tbody>
</table>

### VE against PCV13-type pneumococcal pneumonia among adults ≥65 years old

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPiTA</td>
<td>Randomized placebo-controlled trial among community-dwelling adults</td>
<td>45% (14–65)</td>
</tr>
<tr>
<td>Louisville Pneumonia Study</td>
<td>Test-negative design nested within pneumonia surveillance (non-PCV13-type pneumonia cases used as controls)</td>
<td>73% (13–92)</td>
</tr>
</tbody>
</table>
Upcoming ACIP Meetings

- Policy question under consideration:
  - Should PCV13 be administered routinely to all adults aged ≥65 years in a setting of sustained PCV13 indirect effects?

- Upcoming data to be shared with ACIP:
  - PCV13 impact on all-cause pneumonia, NBPP, and PCV13-type NBPP
  - Potential public health impact and cost-effectiveness of changing the PCV13 policy for adults ≥65 years old recommendation
Lessons

- PCV13 has been very effective in reducing IPD
  - Strong indirect effects through PCV13 use among children
  - Post-licensure studies demonstrated PCV13 effectiveness in adults against IPD
  - Overall impact on IPD since 2014 limited—separating direct from indirect effects for adults ≥65 years old is challenging

- PCV13 impact on pneumonia is critical to evaluate since NBPP contributes to largest pneumococcal disease burden among older adults

- EtR framework and GRADE process provide a systematic and transparent method for re-evaluating adults PCV13 policy and supporting ACIP decisions
Pneumococcal vaccine timing for adults with certain medical conditions

Indicated to receive 1 dose of PPSV23 at 19 through 64 years

PCV13

PPSV23

PCV13

PPSV23

Indicated to receive 1 dose of PCV13 at ≥ 19 years

PCV13

PPSV23

Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

Two pneumococcal vaccines are recommended for adults:
- 13-valent pneumococcal conjugate vaccine (PCV13, Prevnar13®)
- 23-valent pneumococcal polysaccharide vaccine (PPSV23, Pneumovax®23)

PCV13 and PPSV23 should not be administered during the same office visit.

When both are indicated, PCV13 should be given before PPSV23, whenever possible.

If either vaccine is inadvertently given earlier than the recommended window, do not repeat the dose.

For those who have already received 1 or more doses of PPSV23, or those with unclear documentation of the type or pneumococcal vaccine received:
- Administer 1 dose of PCV13 at least 1 year after the most recent pneumococcal vaccine dose.
- Administer a second dose of PPSV23 at least 8 weeks after PCV13 and at least 5 years after the previous dose of PPSV23 (note: a second dose is not indicated for those with CSF leaks or cochlear implants).
- Administer a final dose of PPSV23 at 65 years or older. This dose should be given at least 5 years after the most recent dose of PPSV23.
- For those who have already received 1 dose of PCV13, do not administer an additional dose at 65 years or older.

Pneumococcal vaccine timing for adults 65 years or older

For those who have not received any pneumococcal vaccines, or those with unknown vaccination history

PCV13

PPSV23

For those who have previously received 1 dose of PPSV23 at ≥ 65 years and no doses of PCV13

PCV13

PPSV23

PCV13

PPSV23

Pediatric Pneumococcal Carriage

Stepy Thomas, MSPH
Monica M. Farley, MD
Shabnam Jain, MD
The introduction of the 13-valent pneumococcal conjugate vaccine (PCV13) in 2010 decreased pediatric invasive pneumococcal disease (IPD) caused by vaccine serotypes. Despite this decline, the rate of S. pneumoniae carriage in children has remained the same in Georgia. Trends in nasopharyngeal (NP) carriage of S. pneumoniae were analyzed to describe characteristics of carriers and carriage serotypes.
Methods

- NP swabs collected from children 6-59 months of age during ED visits for any reason from
  - Pre-PCV13: January - August 2009
  - Post-PCV13: July 2010 - December 2017
- Pediatric flock swabs stored in STGG transport media at -80°C and processed in the Georgia EIP Lab
  - Serotype by Quellung and antimicrobial susceptibility testing by BMD—at CDC
- Survey and immunization records reviewed
- Comparison to invasive pneumococcal disease (IPD)
Results

• Pre-PCV13
  – 451 children enrolled
  – 139/451 (31%) colonized with *S. pneumoniae*
  – 22% PCV13 serotypes (most 19A)

• Post-PCV13
  – 5,081 children enrolled
  – 1,538/ 5,081 (30.3%) colonized with *S. pneumoniae*
  – Serotype trends on following slides
Demographic and Risk Factors Associated with Pneumococcal Carriage in Post-PCV13

- Mean age for carriers is 25 months; non-carriers is 28 months
- Carriage higher among children with respiratory infection (p<0.001), otitis media (p=0.03), child in daycare (p<0.001), child with siblings in household (p=0.03), and black race (p=0.04)
- Overall carriage similar whether up-to-date for PCV13 vaccine (30.1%) or not (29.4%)
- Up-to-date for PCV13 had lower PCV13 ST carriage rate (1.8 vs. 5.7 per 100 study population, p<0.001).
- By late 2012, most children (>90%) were up-to-date for PCV13 vaccine
Rate of PCV13 Carriage and percent up to date with PCV13 vaccination over 6 month study periods, July 2010-December 2017

PCV13 Carriage Rate
Percent up to date
Differences in Rates of Pneumococcal Carriage Serotypes January-August 2009 vs. July 2010-December 2017

Rate Difference

PCV13

NON-PCV13
PCV13 Serotype Carriage After the Introduction of PCV13 by year

Carriage Rate (per 100 study population)

- PCV13ST
- 19A
- 3
- 19F
- 6A
- 6C+

- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017

+ vaccine-related serotype
Pediatric IPD and Carriage, 2016-2017

IPD Serotype Distribution, n=36
- **Other**: 33%
- **15A**: 11%
- **15B/C**: 11%
- **23A/B**: 6%
- **021**: 3%
- **19A**: 8%
- **19F**: 11%
- **23F**: 3%
- **003**: 6%

Carriage Serotype Distribution, n=354
- **Other**: 19%
- **23A/B**: 11%
- **35B**: 15%
- **35F**: 1%
- **034**: 1%
- **17F**: 2%
- **09N**: 7%
- **021**: 8%
- **07C**: 3%
- **09L**: 1%
- **15A**: 5%
- **15B/C**: 19%
- **12F**: 1%
- **10A**: 3%
- **19F**: 3%
- **16F**: 2%
- **33F**: 6%

Others (n)
- **35F**: 7
- **16F**: 6
- **33F**: 6
- **034**: 5
- **17F**: 4
- **10A**: 3
- **22F**: 3
- **031**: 3
- **09N**: 3
- **038**: 2
- **034**: 1
- **09L**: 1
- **28A**: 1
Conclusions

• Overall, pneumococcal NP carriage was stable at ~30%
• Significant reductions in carriage of serotype 19A and to lesser extent 6C noted after introduction of PCV13
• Low level carriage of 19F, 003, 19A, and 6C carriage persists
• No single non-vaccine serotype has emerged as a dominant carriage serotype
• IPD generally mirrors NP carriage with some exceptions (11A, 7C, 6C, NT carriage with no IPD)
Changing epidemiology of Invasive Pneumococcal Disease (IPD) following six years of 13-valent pneumococcal conjugate vaccine (PCV13) use in the United States

Ryan Gierke, MPH

48th National Immunization Conference

May 17th, 2018
Spectrum of Pneumococcal Disease

Otitis media

Colonization precedes disease

Pneumonia

Meningitis

Bacteremia

Invasive Pneumococcal Disease (IPD)
Pneumococcal Disease

• Leading cause of pneumonia, meningitis, and bacteremia worldwide

• Estimated 22,000 deaths and greater than 400,000 hospitalizations annually in the United States

• Groups at increased risk for IPD include:
  • Children <5, adults ≥65, and persons with chronic and immunocompromising medical conditions

• Over 90 serotypes of *S. pneumoniae*
  • Serotypes vary in their ability to cause IPD

1 Huang et al, 2011
Pneumococcal Vaccines

**Conjugate Vaccines:**
- 7-valent (PCV7) – available since 2000
  - Covered 7 serotypes that caused 80% of IPD (4, 6B, 9V, 14, 18C, 19F, 23F)
- 13-valent (PCV13) – replaced PCV7 in 2010
  - Covers PCV7 serotypes, plus 6 additional types (1, 3, 5, 6A, 7F, 19A)
  - Immunogenic among all ages
  - Prevents colonization and reduces transmission to unvaccinated individuals

**Polysaccharide Vaccine:**
- 23-valent (PPSV23) – available since 1983
  - Covers 23 serotypes (including 12 serotypes covered by PCV13)
  - Not immunogenic in children < 2 years old
  - No effect on colonization
Current Pneumococcal Vaccination Recommendations

• PCV13 recommended for
  • Children at 2, 4, 6 months, and 12-15 months
  • Adults aged 65 and older
  • Persons 6-64 years with immunocompromising conditions

• PPSV23 recommended for
  • Adults aged 65 and older
  • Persons aged 2-64 years with select chronic medical conditions

- PCV7-type IPD decreased rapidly in both children (direct effects) and adults (indirect effects) after vaccine introduction
- IPD due to non-vaccine types increased (serotype replacement)
- Increases in non-vaccine types of small magnitude compared to overall disease reductions
Objectives

• Evaluate changes in incidence rates of IPD pre- and post-PCV13 introduction

• Monitor changes:
  • Serotype distribution— replacement?
  • Disease severity
    • Syndromes (meningitis, pneumonia)
    • Case fatality ratio
Active Bacterial Core surveillance (ABCs)

- Case definition: pneumococcus isolated from normally sterile site and resident of 10 site surveillance area
- Chart review for clinical information
- Isolates serotyped at reference laboratories

Total population under *S. pneumoniae* surveillance = 32 million
Methods

• Active Bacterial Core surveillance (ABCs) data

• Annual incidence rate (cases per 100,000) of IPD among select age groups for 2007-2017

  • Percent change and 95% confidence interval pre- vs. post-PCV13
Results
Incidence rates of IPD among children < 5 years, by serotype group, July 2007 – June 2017

[Graph showing trends in incidence rates of IPD among children < 5 years, with a vertical line indicating the PCV13 introduction for children.]
Incidence rates of IPD among adults ≥65 years, by serotype group, July 2007 – June 2017

Cases per 100,000
Changes in IPD incidence comparing July 2007- June 2009 (pre-PCV13) to July 2016 – June 2017 (post-PCV13)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Serotype group</th>
<th>% change (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5</td>
<td>PCV13</td>
<td>-87 (-90.8, -81.8)*</td>
</tr>
<tr>
<td></td>
<td>Non-PCV13</td>
<td>-19.1 (-35.5, 1.5)</td>
</tr>
<tr>
<td></td>
<td>All IPD</td>
<td>-62.2 (-68.3, -55)*</td>
</tr>
<tr>
<td>&gt;65</td>
<td>PCV13</td>
<td>-65.6 (-69.9, -60.8)*</td>
</tr>
<tr>
<td></td>
<td>PPSV23 only</td>
<td>-7.1 (-19.5, 7.1)</td>
</tr>
<tr>
<td></td>
<td>Non-vaccine type</td>
<td>0.6 (-12.6, 15.9)</td>
</tr>
<tr>
<td></td>
<td>All IPD</td>
<td>-34.7 (-39.6, -29.5)*</td>
</tr>
</tbody>
</table>

* statistically significant decrease
Changes in the distribution of IPD syndromes (proportion of all IPD)

**Children <5 years**

Pre- vs post-PCV13:
- Meningitis increased from 9% to 13% (p=0.09)
- Pneumonia decreased from 35% to 26% (p=0.02)

* Meningitis and pneumonia are not mutually exclusive categories

**Adults ≥65 years**

Pre- vs post-PCV13:
- Meningitis unchanged at 4% (p=0.6)
- Pneumonia decreased from 77% to 72% (p=0.01)
Changes in pneumococcal meningitis rates

Children <5 years

Adults ≥ 65 years
Changes in disease severity pre- vs post-PCV13

• Case fatality ratio:
  • children <5 increased from 1% to 5% (p<0.01)
  • adults unchanged at 15% (p=0.7)

• Immunocompromised:
  • children <5 increased from 5% to 12% (p=0.02)
  • Adults ≥65 decrease from 34% to 31% (p=0.07)
Conclusion

• Incidence rates of invasive pneumococcal disease in children and adults have decreased significantly since the introduction of the 13-valent pneumococcal conjugate vaccine
  • Sustained decreases in IPD caused by PCV13 serotypes
  • Overall and PCV13 type incidence plateaued in 2014-2017

• Serotype replacement?
  • Non-vaccine serotypes have not increased significantly

• Disease Severity
  • Increased proportions of IPD meningitis cases and deaths among children likely a result of greater reductions in disease among immunocompetent persons
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  – Centers for Disease Control and Prevention
For more information, contact CDC
1-800-CDC-INFO (232-4636)

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.
Extra Slides
IPD rates among children < 5 years old, July 2007 – June 2016; most common non-PCV13 serotypes in 2015-2017

Cases per 100,000
PCV13-type IPD rates among children < 5 years old by serotype, July 2007 – June 2017
IPD rates among adults ≥65 years old, July 2007 – June 2017, by PCV13+6A serotypes
## IPD syndrome distribution July 2007- June 2017

<table>
<thead>
<tr>
<th>Syndrome</th>
<th>Children &lt;5 years</th>
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<tbody>
<tr>
<td></td>
<td>07-08 n(%)</td>
<td>08-09 n(%)</td>
<td>09-10 n(%)</td>
<td>10-11 n(%)</td>
<td>11-12 n(%)</td>
<td>12-13 n(%)</td>
<td>13-14 n(%)</td>
<td>14-15 n(%)</td>
<td>15-16 n(%)</td>
</tr>
<tr>
<td>Meningitis*</td>
<td>8.9</td>
<td>7.3</td>
<td>6.8</td>
<td>10.1</td>
<td>9.7</td>
<td>8.2</td>
<td>10.4</td>
<td>13.4</td>
<td>12.2</td>
</tr>
<tr>
<td>Pneumonia*</td>
<td>34.7</td>
<td>38.0</td>
<td>36.4</td>
<td>35.9</td>
<td>28.6</td>
<td>25.6</td>
<td>31.8</td>
<td>27.3</td>
<td>29.1</td>
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<tr>
<td>Bacteremia</td>
<td>44.4</td>
<td>42.8</td>
<td>40.9</td>
<td>40.8</td>
<td>48.5</td>
<td>53.1</td>
<td>43.9</td>
<td>44.0</td>
<td>44.2</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Syndrome</th>
<th>Adults &gt;65 years</th>
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<tbody>
<tr>
<td></td>
<td>07-08 (%)</td>
<td>08-09 (%)</td>
<td>09-10 (%)</td>
<td>10-11 (%)</td>
<td>11-12 (%)</td>
<td>12-13 (%)</td>
<td>13-14 (%)</td>
<td>14-15 (%)</td>
<td>15-16 (%)</td>
</tr>
<tr>
<td>Meningitis*</td>
<td>3.6</td>
<td>3.6</td>
<td>3.1</td>
<td>4.3</td>
<td>3.8</td>
<td>4.6</td>
<td>4.3</td>
<td>3.8</td>
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</tr>
<tr>
<td>Pneumonia*</td>
<td>77.7</td>
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<td>76.3</td>
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<td>76.1</td>
<td>74.0</td>
<td>76.3</td>
<td>73.8</td>
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<tr>
<td>Bacteremia</td>
<td>15.4</td>
<td>18.2</td>
<td>16.5</td>
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<td>14.5</td>
<td>15.3</td>
<td>14.9</td>
<td>15.3</td>
</tr>
</tbody>
</table>

*Meningitis and Pneumonia are not mutually exclusive*
Changes in hospitalized IPD rates

**Children <5 years**

- PCV13 introduction for children

<table>
<thead>
<tr>
<th>Year</th>
<th>Cases per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-08</td>
<td></td>
</tr>
<tr>
<td>08-09</td>
<td></td>
</tr>
<tr>
<td>09-10</td>
<td></td>
</tr>
<tr>
<td>10-11</td>
<td></td>
</tr>
<tr>
<td>11-12</td>
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<tr>
<td>12-13</td>
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</tr>
<tr>
<td>13-14</td>
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<td>14-15</td>
<td></td>
</tr>
<tr>
<td>15-16</td>
<td></td>
</tr>
<tr>
<td>16-17</td>
<td></td>
</tr>
</tbody>
</table>

**Adults ≥65 years**

- PCV13 introduction for adults

<table>
<thead>
<tr>
<th>Year</th>
<th>Cases per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-08</td>
<td></td>
</tr>
<tr>
<td>08-09</td>
<td></td>
</tr>
<tr>
<td>09-10</td>
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<td>10-11</td>
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<td>11-12</td>
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<td>12-13</td>
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<tr>
<td>13-14</td>
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<td>14-15</td>
<td></td>
</tr>
<tr>
<td>15-16</td>
<td></td>
</tr>
<tr>
<td>16-17</td>
<td></td>
</tr>
</tbody>
</table>
## Changes in IPD deaths

### Children <5 years

<table>
<thead>
<tr>
<th></th>
<th>07-08</th>
<th>08-09</th>
<th>09-10</th>
<th>10-11</th>
<th>11-12</th>
<th>12-13</th>
<th>13-14</th>
<th>14-15</th>
<th>15-16</th>
<th>16-17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Survived</strong></td>
<td>n</td>
<td>479</td>
<td>447</td>
<td>525</td>
<td>280</td>
<td>222</td>
<td>199</td>
<td>172</td>
<td>203</td>
<td>166</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>99.6</td>
<td>98.9</td>
<td>98.7</td>
<td>98.3</td>
<td>97.8</td>
<td>96.6</td>
<td>99.4</td>
<td>97.1</td>
<td>97.7</td>
</tr>
<tr>
<td><strong>Died</strong></td>
<td>n</td>
<td>2</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>5</td>
<td>7</td>
<td>1</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>0.4</td>
<td>1.1</td>
<td>1.3</td>
<td>1.8</td>
<td>2.2</td>
<td>3.4</td>
<td>0.6</td>
<td>2.9</td>
<td>2.4</td>
</tr>
</tbody>
</table>

**P-value** 0.001

### Adults >65 years

<table>
<thead>
<tr>
<th></th>
<th>07-08</th>
<th>08-09</th>
<th>09-10</th>
<th>10-11</th>
<th>11-12</th>
<th>12-13</th>
<th>13-14</th>
<th>14-15</th>
<th>15-16</th>
<th>16-17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Survived</strong></td>
<td>n</td>
<td>1096</td>
<td>1116</td>
<td>1097</td>
<td>1086</td>
<td>969</td>
<td>1076</td>
<td>892</td>
<td>949</td>
<td>942</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>85.03</td>
<td>83.91</td>
<td>84.51</td>
<td>83.15</td>
<td>84.55</td>
<td>85.06</td>
<td>84.79</td>
<td>84.43</td>
<td>84.79</td>
</tr>
<tr>
<td><strong>Died</strong></td>
<td>n</td>
<td>193</td>
<td>214</td>
<td>201</td>
<td>220</td>
<td>177</td>
<td>189</td>
<td>160</td>
<td>175</td>
<td>169</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>14.97</td>
<td>16.09</td>
<td>15.49</td>
<td>16.85</td>
<td>15.45</td>
<td>14.94</td>
<td>15.21</td>
<td>15.57</td>
<td>15.21</td>
</tr>
</tbody>
</table>

**P-value** 0.70
## Changes in Immunocompromised Cases

### Children <5 years

<table>
<thead>
<tr>
<th></th>
<th>07-08</th>
<th>08-09</th>
<th>09-10</th>
<th>10-11</th>
<th>11-12</th>
<th>12-13</th>
<th>13-14</th>
<th>14-15</th>
<th>15-16</th>
<th>16-17</th>
<th>07-09 vs 16-17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompetent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>P-value 0.02</td>
</tr>
<tr>
<td>n</td>
<td>459</td>
<td>422</td>
<td>506</td>
<td>257</td>
<td>201</td>
<td>183</td>
<td>153</td>
<td>183</td>
<td>156</td>
<td>150</td>
<td>150</td>
</tr>
<tr>
<td>%</td>
<td>95.2</td>
<td>93.2</td>
<td>94.9</td>
<td>89.6</td>
<td>88.6</td>
<td>88.4</td>
<td>88.4</td>
<td>87.6</td>
<td>90.2</td>
<td>88.2</td>
<td></td>
</tr>
<tr>
<td>Immunocompromised</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>23</td>
<td>31</td>
<td>27</td>
<td>30</td>
<td>26</td>
<td>24</td>
<td>20</td>
<td>26</td>
<td>17</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>4.77</td>
<td>6.84</td>
<td>5.07</td>
<td>10.45</td>
<td>11.45</td>
<td>11.59</td>
<td>11.56</td>
<td>12.44</td>
<td>9.83</td>
<td>11.76</td>
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</tbody>
</table>

### Adults ≥65 years

<table>
<thead>
<tr>
<th></th>
<th>07-08</th>
<th>08-09</th>
<th>09-10</th>
<th>10-11</th>
<th>11-12</th>
<th>12-13</th>
<th>13-14</th>
<th>14-15</th>
<th>15-16</th>
<th>16-17</th>
<th>07-09 vs 16-17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompetent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>P-value 0.07</td>
</tr>
<tr>
<td>n</td>
<td>850</td>
<td>873</td>
<td>843</td>
<td>879</td>
<td>748</td>
<td>829</td>
<td>708</td>
<td>758</td>
<td>741</td>
<td>873</td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>65.9</td>
<td>65.6</td>
<td>65.0</td>
<td>67.3</td>
<td>65.3</td>
<td>65.5</td>
<td>67.3</td>
<td>67.4</td>
<td>66.5</td>
<td>69.1</td>
<td></td>
</tr>
<tr>
<td>Immunocompromised</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>n</td>
<td>440</td>
<td>457</td>
<td>455</td>
<td>427</td>
<td>398</td>
<td>436</td>
<td>344</td>
<td>366</td>
<td>373</td>
<td>390</td>
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</tr>
<tr>
<td>%</td>
<td>34.1</td>
<td>34.4</td>
<td>35.1</td>
<td>32.7</td>
<td>34.7</td>
<td>34.5</td>
<td>32.7</td>
<td>32.6</td>
<td>33.5</td>
<td>30.9</td>
<td></td>
</tr>
</tbody>
</table>
Background: PCV13 Introduction in Adults in the U.S.

- **Dec 2011**: PCV13 licensed for adults > 50 years
- **Jun 2012**: Recs for PCV13 among high risk adults ≥ 19 years
- **Aug 2014**: Recs for PCV13 for all adults ≥ 65 years
- **Sept 2014**: MMWR with adult PCV13 and PPSV23 Recs published
- **Jan 2015 (01/29/2015)**: CMS updates coverage of pneumo vaccines to align with ACIP recs**

** allows for PCV13 reimbursement if first vaccine given or 1 year after PPSV23 administration

---

**Abbreviations:**
- **FDA**: Food and Drug Administration
- **ACIP**: Advisory Committee on Immunization Practices

---

**Notes:**
- CMS updates coverage of pneumo vaccines to align with ACIP recs**
- PCV13 licensed for adults ≥ 50 years
- Recs for PCV13 among high risk adults ≥ 19 years
- Recs for PCV13 for all adults ≥ 65 years
- MMWR with adult PCV13 and PPSV23 Recs published
- CMS updates coverage of pneumo vaccines to align with ACIP recs**
Timeline for pneumococcal conjugate vaccines in the U.S.

ACIP

Feb 2000  Recs for PCV7
Oct 2000  Recs for PCV13
Feb 2010  Recs for PCV13 among high risk adults >19 years
Dec 2011  Recs for PCV13 for adults >65 years
Jun 2012
Aug 2014

FDA

PCV7 licensed for infants and young children
PCV13 licensed (replaced PCV7)
PCV13 licensed for adults >50 years

FDA= Food and Drug Administration
ACIP=Advisory Committee on Immunization Practices
## Polysaccharide & Conjugate Vaccines: A Comparison

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Polysaccharide</th>
<th>Conjugate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td>Purified polysaccharide</td>
<td>Purified polysaccharide covalently bound to carrier protein</td>
</tr>
<tr>
<td>Immunogenic?</td>
<td>Only among &gt;2 year-olds</td>
<td>All ages</td>
</tr>
<tr>
<td>Number of serotypes</td>
<td>4→14→23</td>
<td>7→10→13</td>
</tr>
<tr>
<td>Effect against bacteremia</td>
<td>Substantial</td>
<td>Substantial</td>
</tr>
<tr>
<td>Effect against carriage</td>
<td>None</td>
<td>Substantial</td>
</tr>
<tr>
<td>Effect against non-bacteremic pneumonia</td>
<td>No consensus</td>
<td>Moderate</td>
</tr>
<tr>
<td>Schedule</td>
<td>&lt;3 doses after age 2 years</td>
<td>4 doses &lt;age 2 years; possibly 1 after</td>
</tr>
<tr>
<td>Cost</td>
<td>US$ 55</td>
<td>US$ 124</td>
</tr>
</tbody>
</table>
TABLE. Medical conditions or other indications for administration of 13-valent pneumococcal conjugate vaccine (PCV13), and indications for 23-valent pneumococcal polysaccharide vaccine (PPSV23) administration and revaccination for adults aged ≥19 years,* by risk group — Advisory Committee on Immunization Practices, United States, 2012

<table>
<thead>
<tr>
<th>Risk group</th>
<th>Underlying medical condition</th>
<th>PCV13 Recommended</th>
<th>PPSV23 Recommended</th>
<th>Revaccination 5 yrs after first dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompetent persons</td>
<td>Chronic heart disease†</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic lung disease⁵</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes mellitus</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cerebrospinal fluid leak</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cochlear implant</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alcoholism</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic liver disease, cirrhosis</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cigarette smoking</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Persons with functional or anatomic asplenia</td>
<td>Sickle cell disease/other hemoglobinopathy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Congenital or acquired asplenia</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>Congenital or acquired immunodeficiency⁴</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Human immunodeficiency virus infection</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td>Chronic renal failure</td>
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</tr>
<tr>
<td></td>
<td>Nephrotic syndrome</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Leukemia</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lymphoma</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hodgkin disease</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generalized malignancy</td>
<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td></td>
<td>Iatrogenic immunosuppression**</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td></td>
<td>Solid organ transplant</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Multiple myeloma</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

* All adults aged ≥65 years should receive a dose of PPSV23, regardless of previous history of vaccination with pneumococcal vaccine.

† Including congestive heart failure and cardiomyopathies, excluding hypertension.

⁵ Including chronic obstructive pulmonary disease, emphysema, and asthma.

⁴ Including 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.
TABLE. Summary of recommended intervals, by risk and age groups, for persons with indications to receive PCV13 and PPSV23 sequence — Advisory Committee on Immunization Practices, United States, September 2015

<table>
<thead>
<tr>
<th>Risk group/Underlying medical condition</th>
<th>24–71 months</th>
<th>6–18 years</th>
<th>19–64 years</th>
<th>≥65 years</th>
<th>24–71 months</th>
<th>6–18 years</th>
<th>19–64 years</th>
<th>≥65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>No underlying chronic conditions</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>≥1 year</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>≥1 year</td>
</tr>
<tr>
<td>Immunocompetent persons</td>
<td>≥8 weeks</td>
<td>NA</td>
<td>NA</td>
<td>≥1 year</td>
<td>≥8 weeks</td>
<td>NA</td>
<td>NA</td>
<td>≥1 year</td>
</tr>
<tr>
<td>Chronic heart disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic lung disease</td>
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<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcoholism*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic liver disease, cirrhosis*</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Cigarette smoking*</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunocompetent persons</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥1 year</td>
<td>≥1 year</td>
</tr>
<tr>
<td>Cerebrospinal fluid leak</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cochlear implant</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persons with functional or anatomic asplenia</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥1 year</td>
<td>≥1 year</td>
</tr>
<tr>
<td>Sickle cell disease/other hemoglobinopathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congenital or acquired asplenia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
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<td>Congenital or acquired immunodeficiency</td>
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<td>Human immunodeficiency virus infection</td>
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<td>Chronic renal failure</td>
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<td>Nephrotic syndrome</td>
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<td>Leukemia</td>
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<td>Lymphoma</td>
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<td>Hodgkin disease</td>
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<td>Generalized malignancy</td>
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<td>Latrogenic immunosuppression</td>
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<td>Solid organ transplant</td>
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<td>Multiple myeloma*</td>
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Abbreviation: NA = not applicable, sequential use of PCV13 and PPSV23 is not recommended for these age and risk groups.
* Underlying medical conditions that are not included in the recommendations for children aged <6 years.
### Current and Proposed Intervals Between PCV13 → PPSV23

<table>
<thead>
<tr>
<th>Age groups</th>
<th>Underlying conditions</th>
<th>Interval Recommendations</th>
</tr>
</thead>
</table>
| 24–71 mo   | • Immunocompetent with underlying chronic conditions  
             • Functional or anatomic asplenia  
             • Immunocompromised                | Current: ≥8 weeks  
                            Proposed: No change                  |
| 6–18 years | • High-risk immunocompetent (CSF leak, cochlear implants)  
             • Functional or anatomic asplenia  
             • Immunocompromised                | Current: ≥8 weeks  
                            Proposed: No change                  |
| ≥19 years  | • High-risk immunocompetent (CSF leak, cochlear implants)  
             • Functional or anatomic asplenia  
             • Immunocompromised                | Current: ≥8 weeks  
                            Proposed: No change                  |
| ≥65 years  | NA                                                                                   | Current: 6–12 months (minimum 8 weeks)  
                            Proposed: ≥1 year                    |
## Currently Recommended Intervals Between PPSV23 $\rightarrow$ PCV13

<table>
<thead>
<tr>
<th>Age groups</th>
<th>Underlying Conditions</th>
<th>Current interval recommendations</th>
</tr>
</thead>
</table>
| 24–71 mo   | • Immunocompetent with underlying chronic conditions  
             • Functional or anatomic asplenia  
             • Immunocompromised              | ≥8 weeks                        |
| 6–18 years | • High-risk immunocompetent (CSF leak, cochlear implants)  
             • Functional or anatomic asplenia  
             • Immunocompromised              | ≥8 weeks                        |
| ≥19 years  | • High-risk immunocompetent (CSF leak, cochlear implants)  
             • Functional or anatomic asplenia  
             • Immunocompromised              | ≥1 year                         |
| ≥65 years  | NA                    | ≥1 year                         |

September 19, 2014 / 63(37);822-825; October 12, 2012, Vol 61, #40; June 28, 2013 / 62(25);521-524; December 10, 2010 / 59(RR11);1-18
Why has serotype 19A increased?

- Cause of invasive disease (Robinson et al, JAMA 2001)
- Common in carriage (Brueggemann et al, JID 2003)
- Associated with antibiotic resistance (Pai et al, JID 2005)
- New clones emerging in the absence of vaccination (Dagan et al. ICAAC 2007, Choi et al. EID 2008)
- Evidence of capsular switching (Brueggemann et al, PLoS Pathogen In press)
- PCV7 not effective against type 19A IPD (Whitney et al. Lancet 2006)

Key point: Multiple factors are contributing to observed increases in serotype 19A disease