The ABC’s of PCV13 and PPSV23, Making Sense of the New Pneumococcal Vaccination Recommendations

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Conflict of Interest

- Disclosure Statement
  - I am on the speaker bureau for Merck, Inc.
Objectives

- Describe the disease presentation of pneumococcal disease in adults
- Identify risk factors for developing invasive pneumococcal disease
- Compare and contrast the 2 commercially available vaccines used to prevent pneumococcal disease
- Review the recent update to the Advisory Committee on Immunization Practices (ACIP) recommendations for the use of PCV13 and PPSV23 in adults
Background

- Pneumococcal disease is caused by *Streptococcus pneumoniae*
  - Gram positive bacteria, polysaccharide capsule (important for virulence factor)
  - Which is a leading cause of acute bacterial infection
- Also known as pneumococcus, the organism was isolated by Pasteur in 1881 from the saliva of a patient with rabies
- This infection was confused with other types of pneumonia until the discovery of gram staining in 1884
Background

- During the first half of the 20\textsuperscript{th} century, the chemical structure and antigenicity of pneumococcal capsular polysaccharide, its virulence, and role in human disease was fully described
- More than 80 serotypes of pneumococci have been identified since 1940
  - Most \textit{S. pneumo}n\textit{oniae} serotypes cause serious disease
  - Only a few serotype produce a majority of pneumococcal infections
  - Currently 90 known serotypes
- Vaccine development for pneumococcal disease began in 1911
Background

- With the discovery of Penicillin in the 1940’s interest in vaccine development declined.
- In the late 1960’s vaccine development became a priority when many patient deaths still occurred despite the availability of antibiotic therapy.
- First pneumococcal vaccination was licensed in the US in 1977.
- 14-valent polysaccharide vaccine licensed in 1977.
Background

- First pneumococcal vaccination was licensed in the US in 1977
  - 23-valent polysaccharide vaccine licensed (PPSV23) in 1983
- First conjugated pneumococcal vaccination was licensed in 2000
  - 7-valent polysaccharide conjugate vaccine (PCV7) licensed in 2000
  - 13-valent polysaccharide conjugate vaccine (PCV13) licensed in 2010
Epidemiology
Epidemiology

- *Streptococcus pneumoniae* (pneumococcus) is still the leading cause of infectious serious illness in older adults
  - Including bacteremia, meningitis, and pneumonia
- The 10 most common serotypes cause approximately 62% of invasive disease worldwide
- The use of 7-valent pneumococcal conjugate vaccine (PCV7) since 2000 and PCV13 since 2010 in US children has reduced pneumococcal infections directly and indirectly among adults
Epidemiology

- As of 2013, incidence of invasive pneumococcal disease (IPD) has declined by approximately 50% compared to 2010 specifically those serotypes that are unique to PCV13
- In 2013, approximately 13,500 cases of invasive pneumococcal disease (IPD) were reported in individuals over the age of 65 years
- Between 20-25% of IPD and 10% of community acquired pneumonia cases in adults are caused by the serotypes contained within PCV13
Epidemiology

- Incidence of pneumococcal disease is highest in the first 2 years of life then declines, the incidence increases to its highest point again starting at age 65 years of age
- Up to 175,000 hospitalizations occur annually in the US from pneumococcal pneumonia
- Common bacterial complication from influenza or measles infection
Epidemiology

- Mortality rate of 5-7%, especially in elderly persons
- Pneumococcal disease occurs throughout the world
Disease Presentation
Disease Presentation

- *S. pneumoniae* is a human pathogen for this infection and serve as a reservoir typically in the nasopharynx of asymptomatic human carriers
  - No known animal or insect vector

- Transmission
  - Direct person to person contact
  - Autoinoculation via person carrying the bacteria in the upper respiratory tract
  - Respiratory droplets
Disease Presentation

- **Temporal pattern**
  - Occurs during and more frequently in the winter and early spring when respiratory diseases are more prevalent

- **Communicability**
  - Unknown but thought to be as long as organism is present in respiratory secretions

- **Major clinical syndromes associated with pneumococcal disease** include
  - Pneumonia, bacteremia, and meningitis
  - Considered to be invasive because infection is in normally aseptic environments
Disease Presentation

- Most often disease occurs when a predisposing condition exists.
- In adults, this often presents as pneumonia.
- Pneumococcal disease outbreaks are uncommon, if it occurs in crowded environments (jails, nursing homes).
- Persons with invasive disease often have underlying illnesses.
Disease Presentation

- Symptoms include:
  - Abrupt onset of fever and chills or rigors, repeated shaking chills is uncommon
  - Chest pain
  - Cough that is mucopurulent and productive
  - Rusty colored sputum, dyspnea (shortness of breath), tachypnea, hypoxia, tachycardia, malaise, and weakness
  - Less frequently – nausea, vomiting, and headache
Risk Factors
Risk Factors

- Conditions that increase the risk of invasive pneumococcal disease include
  - Alcoholism
  - Cerebrospinal fluid (CSF) leak
  - Chronic heart disease
  - Chronic pulmonary disease including asthma
  - Chronic liver disease
  - Chronic renal disease
Risk Factors

- Conditions that increase the risk of invasive pneumococcal disease include
  - Cigarette smoking
  - Cirrhosis
  - Cochlear implants
  - Decreased immune function (by drug or disease state)
    - Chronic renal failure or HIV infection
    - Hodgkin’s disease
    - Immunosuppressive chemotherapy (including high-dose corticosteroids)
    - Leukemia
    - Lymphoma
Risk Factors

- Conditions that increase the risk of invasive pneumococcal disease include
  - Decreased immune function (by drug or disease state)
    - Multiple myeloma
    - Nephrotic syndrome
  - Diabetes
  - Functional or anatomic asplenia including sickle cell
  - Those who live in special environments or social settings
    - American Indian or Alaska Natives age 50-64 years if recommended by the local health authorities
Commercially Available Vaccines
Prevnar®
Pneumococcal Vaccines

- **Prevnar 13®** by Wyeth a subsidiary of Pfizer
  - Approved by the FDA on February 24th, 2010
  - Replaced Prevnar 7®
  - December 30, 2011, PCV13 approved for adults ≥ 50 years for prevention of pneumonia and IPD
    - Vaccine approved under FDA’s accelerated approval pathway
  - June 20th, 2012 ACIP recommended routine use in adults ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leak, or cochlear implants

Image Reference
http://www.dealmed.com/Prevnar-13-Prefilled-Syringe-0-5-mL-.gif
Pneumococcal Vaccines

- **Prevnar 13®**
- **Indication**
  - For healthy children aged 6 weeks to 5 years (prior to 6th birthday) in prevention of invasive disease caused by *Streptococcus pneumonia* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F
  - For children 6 to 18 years and adults ≥ 19 years who are immunocompromised
- **Dose**
  - Four dose series of 0.5ml intramuscular (IM) injection (2, 4, 6, and 12-15 months)

Image Reference
http://www.dealmed.com/Prevnar-13-Prefilled-Syringe-0-5-mL-.gif
Pneumococcal Vaccine

- **Prevnar 13®**
  - Dose
    - A PCV series started with PCV7 should be completed with PCV13
    - A single PCV13 dose is recommended for all children aged 14 to 59 months who have received an age appropriate series of PCV7
    - A single supplemental dose of PCV13 is recommended for all children aged 60 to 71 months with underlying medical conditions
  - One dose in immunocompromised patients followed by PPSV23

Image Reference
http://www.dealmed.com/Prevnar-13-Prefilled-Syringe-0-5-mL-.gif
Pneumococcal Vaccine

- **Prevnar 13®**
  - Contraindications
    - Persons with a serious allergic reaction (anaphylaxis) to (PCV7) or any component of the vaccine or any diptheria toxoid-containing vaccine
  - Precaution
    - Moderate or severe acute illness
  - Adverse Effects
    - Redness, swelling and tenderness at the injection site, fever, decreased appetite, irritability, increased or decreased sleep

Image Reference
http://www.dealmed.com/Prevnar-13-Prefilled-Syringe-0-5-mL-.gif
Pneumovax23®
Pneumococcal Vaccine

- Pneumovax23® by Merck & Co., Inc.

- Indications
  - Active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F)
  - Approved for use in persons 50 years of age or older and persons aged ≥ 2 years who are at increased risk for pneumococcal disease

Image Reference
https://www.vaxserve.com/image.cfm?doc_id=12015&image_type=product_image
Pneumococcal Vaccine

- **Pneumovax23®**
  - Dosing - Younger than 65 years
    - Chronic cardiac or pulmonary disease (including asthma), chronic liver disease, alcoholism, diabetes, cigarette smoke
  - Those who live in a special environment or social settings (including American Indian/Alaska native age 50-64 years when recommended by local health authority)
Pneumococcal Vaccine

- Pneumovax23®
- Dosing - Indication 2\textsuperscript{nd} dose
  - Anatomic or functional asplenia, including sickle cell disease
  - Immunocompromising conditions, including HIV infection, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome
  - Receiving immunosuppressive chemotherapy (including high dose corticosteroids)
  - Receipt of organ or bone marrow transplant

Image Reference
https://www.vaxserve.com/image.cfm?doc_id=12015&image_type=product_image
Pneumococcal Vaccine

- Pneumovax23®
- Contraindications
  - Persons with a serious allergic reaction (anaphylaxis) to (PPSV23) or any component of the vaccine or any diptheria toxoid-containing vaccine
- Precaution
  - Moderate or severe acute illness
- Adverse Effects
  - Reported in >10% of subjects - Injection-site reactions, pain/soreness/tenderness, injection-site swelling/induration, headache, injection-site erythema, asthenia and fatigue, and myalgia
Efficacy and Immunogenicity
Herd immunity

- Routine use of PCV7 vaccine since 2000 and PCV13 since 2010 among children in the US
  - Has reduced pneumococcal infections directly and indirectly in children
  - Has reduced pneumococcal infections indirectly in adults
  - The indirect effects from PCV13 use among children if similar to those observed after PCV7 was introduced could represent a further reduction in disease burden in adult pneumococcal disease caused by PCV-13 types
Immunogenicity and Vaccine Efficacy

- In accordance with the accelerated approval process, a randomized placebo-controlled trial (CAPiTA trial) was conducted in the Netherlands
  - 85,000 adults ≥ 65 years during 2008-2013
  - Conducted to verify and further describe the benefits of PCV13 for the prevention of pneumococcal pneumonia
- PCV13
  - Trial results demonstrated
    - 45.6% efficacy of PCV13 against vaccine type pneumococcal pneumonia,
    - 45% efficacy against vaccine-type non-bacteremic pneumococcal pneumonia
    - 75% efficacy against vaccine type IPD among adults aged ≥ 65 years
Immunogenicity and Vaccine Efficacy

- **PCV13**
  - Two randomized, multicenter, immunogenicity studies conducted in the US and Europe in older adults showed PCV13 induced an immune response as good as or better than that induced by PPSV23

- **PPSV23**
  - More than 80% of healthy adults who receive this vaccine develop antibodies against the vaccine serotypes within 2-3 weeks of vaccination
  - Those who may not have as good of response include
    - Persons with chronic medical conditions or immunocompromised (by drug or disease state)
    - Children < 2 years of age
  - Overall efficacy 60-70% of invasive pneumococcal disease
ACIP Recommendations
Pneumococcal Vaccine Timing

Age 65 Years or Older – Everyone

- If PCV13 was given before age 65 years, no additional PCV13 is needed.

No history of pneumococcal vaccine

PCV 13
Prevnar 13®

6-12 month interval

PPSV 23
Pneumovax® 23

Received PPSV23 before age 65

1 year interval

PCV 13

6-12 month interval
(and at least 5 years after prior dose of PPSV23)

PPSV 23

Received PPSV23 at age 65 or older

1 year interval

PCV 13
Age 19-64 Years – Underlying Conditions

- Prior doses count towards doses recommended below and do not need to be repeated.
- If PPSV23 given previously – wait one year before giving PCV13
  - when dose indicated, wait at least five years before giving a second dose of PPSV23.

Smoker, Long-term facility resident, or Chronic conditions:
- heart disease (excluding hypertension)
- lung disease (including asthma)
- liver disease (including cirrhosis)
- diabetes
- alcoholism

Immunocompromised (including HIV infection), Chronic renal failure, Nephrotic syndrome, or Asplenia

PCV 13 → 8 week interval → PPSV 23 → 5 year interval → PPSV 23

CSF leaks or Cochlear implants

PCV 13 → 8 week interval → PPSV 23

• DO NOT administer PCV13 and PPSV23 at the same visit.
Recommendations

- Note: time limited utility of routine use of PCV13 use among adults ≥ 65 years
  - The recommendations for use among adults aged ≥ 65 years will be reevaluated by ACIP and revised if needed in 2018
  - ACIP recommends routine use of ≥ 19 to 64 years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leak, or cochlear implants remains unchanged
Adult Vaccination Schedules 2015
## 2015 Schedule Based on Indication

### Figure 2. Vaccines that might be indicated for adults based on medical and other indications

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Indication</th>
<th>Pregnancy</th>
<th>Immuno-compromising conditions (excluding human immunodeficiency virus [HIV])&lt;sup&gt;a,b&lt;/sup&gt;</th>
<th>HIV Infection CD4+ T lymphocyte count&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Men who have sex with men (MSM)</th>
<th>Kidney failure, end-stage renal disease, receipt of hemodialysis</th>
<th>Heart disease, chronic lung disease, chronic alcoholism</th>
<th>Asplenia (including elective splenectomy and persistent complement component deficiencies)&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Chronic liver disease</th>
<th>Diabetes</th>
<th>Healthcare personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1 dose ILV annually</td>
<td></td>
<td>1 dose ILV annually</td>
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<td></td>
<td></td>
<td></td>
<td>1 dose ILV or LAIV annually</td>
</tr>
<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap)&lt;sup&gt;3&lt;/sup&gt;</td>
<td>1 dose Tdap after pregnancy</td>
<td></td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs</td>
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<td>Varicella&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Contraindicated</td>
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<tr>
<td>Human papillomavirus (HPV) Female&lt;sup&gt;a&lt;/sup&gt;</td>
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<td></td>
<td>2 doses</td>
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<tr>
<td>Human papillomavirus (HPV) Male&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>3 doses through age 26 yrs</td>
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<tr>
<td>Zoster&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>3 doses through age 26 yrs</td>
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<tr>
<td>Measles, mumps, rubella (MMR)&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>1 dose</td>
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<tr>
<td>Pneumococcal 13-valent conjugate (PCV13)&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>1 or 2 doses</td>
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<tr>
<td>Pneumococcal polysaccharide (PPSV23)&lt;sup&gt;e&lt;/sup&gt;</td>
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<td></td>
<td>1 or 2 doses</td>
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<tr>
<td>Meningococcal&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>1 or more doses</td>
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<td>Hepatitis A&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>2 doses</td>
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<tr>
<td>Hepatitis B&lt;sup&gt;d&lt;/sup&gt;</td>
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<td>3 doses</td>
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<tr>
<td>Haemophilus influenzae type b (Hib)&lt;sup&gt;e&lt;/sup&gt;</td>
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<td></td>
<td>1 or 3 doses</td>
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</tr>
</tbody>
</table>

*Covered by the Vaccine Injury Compensation Program*

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster.

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications).

No recommendation.

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly recommended for adults ages 19 years and older, as of February 1, 2015. For all vaccines being recommended on the Adult Immunization Schedules a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine’s other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers’ package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/hcp/acip-recs/index.html). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.
### Recommended Adult Immunization Schedule—United States - 2015

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>AGE GROUP</th>
<th>19-21 years</th>
<th>22-26 years</th>
<th>27-49 years</th>
<th>50-59 years</th>
<th>60-64 years</th>
<th>≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
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<td>1 dose annually</td>
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<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap)</td>
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<td></td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs</td>
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<tr>
<td>Varicella</td>
<td></td>
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<td></td>
<td>2 doses</td>
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<td>2 doses</td>
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<td>Human papillomavirus (HPV) Female</td>
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<td>3 doses</td>
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<td>Human papillomavirus (HPV) Male</td>
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<td>3 doses</td>
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<td>Zoster</td>
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<td></td>
<td>1 dose</td>
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<tr>
<td>Measles, mumps, rubella (MMR)</td>
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<td>1 or 2 doses</td>
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<tr>
<td>Pneumococcal 13-valent conjugate (PCV13)</td>
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<td>1-time dose</td>
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<td>Pneumococcal polysaccharide (PPSV23)</td>
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<td>1 or 2 doses</td>
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<td>Meningococcal</td>
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<td>Hepatitis A</td>
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<td></td>
<td>2 doses</td>
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<td>Hepatitis B</td>
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<td>3 doses</td>
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<tr>
<td>Haemophilus influenza type b (Hib)</td>
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<td></td>
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<td></td>
<td>1 or 3 doses</td>
</tr>
</tbody>
</table>

*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster.

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication).

No recommendation

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Report any clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-395-6600.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines) or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the America College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

[www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)
Medicare/Medicaid Reimbursement

- The Centers for Medicare and Medicaid Services (CMS)
  - Largest insurer of our geriatric patient population (age ≥ 65 years)
  - Reimbursement is based on interval between vaccinations
  - Payment will be provided for both PCV13 and PPSV23
  - If billed 12 months apart with a minimum of 11 months required between PCV13 and PPSV23

Clinical Pearls

- Pneumococcal disease in adults still the leading cause of infectious serious illness in older adults
  - Invasive disease presentation includes bacterermia, meningitis, and pneumonia
- Risk factors for IPD including CSF leak, diabetes, alcoholism, cirrhosis, chronic heart, liver, renal, and pulmonary disease including asthma, cigarette smoking, cochlear implants, functional or anatomic asplenia, and immunosuppression (by drug or disease state)
- ACIP recommendations were changed in September 2014 and incorporated into the 2015 adult immunization schedule published in February 2015
Clinical Pearls

- Commercially available vaccines include PCV13 and PPSV23 which are both recommended for routine use in adults ≥ 65 years of age
- PCV13 has a limit of one dose in adulthood
- PPSV23 has a max of 3 doses in adulthood with the last dose being administered after the age of 65 years
- PCV13 should be administered first then followed by PPSV23 6 to 12 months later
  - If PPSV23 is administered first, PCV13 should be administered at least 1 year later
- CMS will reimburse for both vaccinations if separated by at least one year
- Prevention through vaccination is the key to for health adults
Special Thanks
References

- ACIP 2015 adult vaccination schedule by age and indication
- Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions – United States, 2012. MMWR 2012;61(40);816-819
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- Package Insert Prevnar13® last updated Jan 2015
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