PNEUMOCOCCAL VACCINATION GUIDANCE

General Pneumococcal Vaccination Questions

1. Why get vaccinated for pneumococcal disease?
   The most effective way to treat pneumococcal disease is to prevent it through immunization.

   Pneumococcal disease is a common, yet potentially serious infection caused by Streptococcus pneumoniae bacteria. Streptococcus pneumoniae is the leading cause of serious community-acquired illness worldwide. In addition to being the most common cause of community acquired pneumonia, it also causes invasive pneumococcal disease (IPD) which includes bacteremia and meningitis.

   Older adults are at increased risk from pneumococcal disease. In the United States, the rate of IPD among adults = 65 is 3-fold greater than the population average. More alarmingly, the rate of death among adults = 65 is 4.5-fold greater than the population average. Outbreaks of pneumococcal disease do occur in nursing homes and are likely under-reported.

   In addition to the potential for severe illness associated with pneumococcal disease, there is a growing concern about the prevalence of antibiotic resistant Streptococcus pneumonia. Currently it is estimated that almost one third of Streptococcus pneumoniae strains are resistant to one or more antibiotics. The prevalence of resistance varies however by region and even higher rates have been reported.

   For these reasons, efforts at preventing pneumococcal disease are a national health priority, particularly in older adults and in nursing home settings.

   Since the introduction of the first pneumococcal conjugate vaccine (PCV7) among children in 2000, the overall incidence of IPD caused by the strains included in PCV7 decreased 94%. Among adults = 65, the proportion of IPD caused by strains included in PCV7 decreased from 56% to 9%. This marked reduction in IPD is especially notable in that only children received PCV7. That all age groups, especially older adults, saw a reduction in disease burden is a
strong testament to the use of this vaccine. The well-designed Dutch study, *Community-Acquired Pneumonia Immunization Trial in Adults* (CAPITA) demonstrated the efficacy of an expanded pneumococcal conjugate vaccine (PCV13) among adults. In a country that had not previously adopted pneumococcal polysaccharide vaccine (PPSV23), the rate of IPD and the rate of pneumococcal pneumonia decreased by 85% and 45% respectively, among those who received PCV13 compared to unvaccinated controls. This study also highlights the safety of PCV13 in that no vaccine-related serious adverse events were reported.

2. **What are the different types of pneumococcal vaccines that are available?**

Currently two pneumococcal vaccines are recommended for adults. These include the pneumococcal polysaccharide vaccine (PPSV23) and the pneumococcal conjugate vaccine (PCV13). PPSV23, which was developed in 1983 and has long been recommended by the Advisory Committee on Immunization Practices (ACIP) for prevention of pneumococcal disease in adults, provides protection against 23 different serotypes of pneumococcus. PCV13 was first recommended for use adults with selected medical conditions beginning in 2012. The ACIP expanded its recommendation in 2014 to include all adults 65 years of age and older. PCV13 covers 13 serotypes. Diminished immunogenicity of PPSV23 in older adults prompted a search for alternative vaccine options and hence the development of PCV13. PCV13 was evaluated against placebo in the *Community Acquired Pneumonia Immunization Trial in Adults* (CAPITA), a large multicenter trial enrolling > 85,000 subjects over the age of 65. Both pneumococcal pneumonia and invasive pneumococcal disease were significantly reduced (45% and 85% respectively). Since PPSV23 covers strains not found in PCV13, both vaccines have been recommended.
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Vaccine Type</th>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCV 13</td>
<td>Pneumococcal conjugate</td>
<td>Prevnar 13</td>
<td>Wyeth Pharmaceuticals (Pfizer)</td>
<td>First recommended for adults with immunocompromised conditions in 2012. In 2014, recommended for all adults = 65 yrs.</td>
</tr>
<tr>
<td>PCV 7</td>
<td>Pneumococcal conjugate</td>
<td>Prevnar</td>
<td>Wyeth Pharmaceuticals (Pfizer)</td>
<td>Licensed for children. Not used in older adults.</td>
</tr>
</tbody>
</table>

3. As a nursing facility, are we required to assess our residents for pneumococcal vaccination status?
YES – Nursing facility licensure regulations require facilities to assess the pneumococcal vaccination status of each resident, provide education regarding pneumococcal vaccination, and administer the vaccine when indicated, unless refused by the resident or responsible party. Facilities must document the resident was assessed, educated, offered the vaccine, or declined due to refusal or contraindication. These requirements are found under F334 (Section §483.25(n) of the State Operations Manual).
4. As a nursing facility, are we required to administer pneumococcal vaccines to unvaccinated or incompletely vaccinated residents at our facility?

YES – Nursing facility licensure regulations require facilities to assess the pneumococcal vaccination status of each resident, provide education regarding pneumococcal vaccination, and administer the vaccine when indicated, unless refused by the resident or responsible party. Facilities must document the resident was assessed, educated, offered the vaccine, or declined due to refusal or contraindication. These requirements are found under F334 (Section §483.25(n) of the State Operations Manual). If a resident is determined to be unvaccinated for pneumococcal disease, is a candidate for pneumococcal vaccination, and does not refuse vaccination or have a contraindication, the facility should administer an appropriate pneumococcal vaccine consistent with current ACIP and CDC guidance.

5. As a nursing facility, are we required to administer the new pneumococcal vaccine (PCV13)?

YES – Nursing facility licensure regulations require facilities to assess the pneumococcal vaccination status of each resident, provide education regarding pneumococcal vaccination, and administer the vaccine when indicated, unless refused by the resident or responsible party. Facilities must document the resident was assessed, educated, offered the vaccine, or declined due to refusal or contraindication. These requirements are found under F334 (Section §483.25(n) of the State Operations Manual). The choice of which pneumococcal vaccine to give should be determined in accordance with current ACIP and CDC guidance. If a resident has not received PCV13 and is a candidate for this vaccine, it should be administered, unless refused or contraindicated.

6. Which adults should receive a pneumococcal vaccine?

All adults = 65 years of age should receive both pneumococcal vaccinations. Adults younger than 65 who have conditions or risk factors predisposing them to serious pneumococcal disease should also be vaccinated. A list of these conditions can be found in Figure 1.

7. Pneumococcal conjugate vaccine (PCV13) is recommended in adults with chronic renal failure. What constitutes chronic renal failure?

The term chronic renal failure has been replaced with chronic kidney disease. Chronic kidney disease (CKD) is present when a person’s glomerular filtration rate (GFR) is < 60 mL/min/1.73 m2 for 3 or more months (i.e., National Kidney Foundation CKD Stages 3a, 3b, 4, or 5) or whenever there is kidney damage (e.g. nephrotic syndrome) present for 3 or more months. Thus, all persons with Stages 3 – 5 CKD are candidates for PCV13.
8. Can nursing facilities administer pneumococcal vaccines through the use of a standing orders policy (SOP) (i.e., without requiring an individual physician order for each resident)?


Questions About Common Clinical Situations

1. We have a resident in our facility over the age of 65 who reports she/he never had the pneumococcal vaccine. Which pneumococcal vaccine should she/he receive at this time?

   **PCV13** – Individuals over the age of 65 should receive both pneumococcal vaccines. It is recommended that PCV13 be administered first. PPSV23 should then be administered 12 months or more following PCV13. Immunogenicity studies demonstrate better antibody response when PCV13 is given as the first vaccine, thus the recommendation to give PCV13 first (see Figure 2).

2. We have a resident in our facility over the age of 65 who is uncertain if she/he ever had a pneumococcal vaccine. Should this resident be offered a pneumococcal vaccine and if so, which vaccine should be recommended first?

   Yes, starting with PCV13 – Individuals with an uncertain vaccine history should be considered unvaccinated. Often it is difficult to obtain vaccination histories, even in an age with increasing use of electronic health records. Individuals may receive vaccines in a variety of settings, making it difficult to remember if, where, or when a vaccine was administered. Providers are encouraged to use their state’s immunization registry. When assessing a resident with an uncertain pneumococcal vaccination history, it is reasonable to ask the resident, family members and possibly the resident’s primary care practitioner. If your state has an immunization registry, it may also helpful to query the registry. **However, vaccination should not be delayed for any extended period of time in an effort to track down past records. If vaccination records are not readily available, the resident should be offered and administered vaccine as indicated.** Extra doses of the vaccine are not harmful. The choice of vaccine would be the same as if the resident had reported never having the vaccine, namely PCV13 followed by PPSV23.
3. Is there a minimum administration time interval between PCV13 and PPSV23?
   Yes - The minimum interval between administration of PCV13 and PPSV23 should be at least 8 weeks. Current (2015) current ACIP and CDC guidance recommend a 12 month or longer interval between the two vaccines in order to simplify the vaccine administration guidelines and to coordinate with current CMS payment policies. While not recommended, it is not medically contraindicated to administer the two vaccines at intervals more than 8 weeks and less than 12 months.

4. We have a resident in our facility over the age of 65 who reports she/he was vaccinated for pneumococcal disease prior to turning age 65 and more than one year ago. The resident (or resident’s family member) reports the vaccine received was Pneumovax (PPSV23). Does this resident need another pneumococcal vaccination?
   Yes – Individuals who receive PPSV23 prior to age 65 should receive PCV13 upon turning 65. The PCV13 vaccine should be administered = 12 months following the prior PPSV23. In addition, a second, one time booster dose of PPSV23 should be administered at an interval that is 5 years following the first PPSV23 and at least one year following PCV13.

5. We have a resident admitted to our facility who reports she/he was vaccinated for pneumococcal disease prior to 2014 and after the age of 65. It is one year later. The resident (or resident’s family member) is uncertain which vaccine they had. Does this resident need another pneumococcal vaccination? If so, which one?
   Yes – PCV13 was not routinely recommended for adults = 65 years prior to 2014. Thus an individual who reports having a pneumococcal vaccination prior to 2014 is most likely to have had PPSV23. PCV13 should be administered at an interval of 12 months following PPSV23.

6. We have a resident in our facility over the age of 65 who reports having had PCV13 a year ago. The resident did not have any pneumococcal vaccination prior to age 65. Does this resident need another pneumococcal vaccination? If so, which one?
   Yes – Individuals = 65 years should receive PCV13 followed by PPSV23 12 months later. This resident has had PCV13 already and should now be offered PPSV23.
7. We have a resident in our facility over the age of 65. The resident reports having had PPSV23 several years ago, before turning 65 years of age. This resident received PCV13 one year ago. Does this resident need another pneumococcal vaccine? If so, which one?
   Yes – Individuals, who received PPSV23 prior to age 65, should receive a second dose of PPSV23 after the age of 65. This one time booster should be administered at an interval of = five years following the first PPSV23 and = one year following the PCV13.

8. We have a resident in our facility over the age of 65 who has had both pneumococcal vaccines since the age of 65. Do they need further boosters every five years?
   No – Current ACIP guidelines do not recommend booster doses for either PCV13 or PPSV23 if the individual has already received both vaccines after age 65.

9. We have a resident in our facility who received a dose of PCV13 before age 65. The resident is now = 65 years. Does the resident need another dose of PCV13?
   No – Only one dose of PCV13 is recommended for adults. If PCV13 is given before the age of 65, a repeat dose (or booster dose) is not necessary.

10. Where can we find out if a resident has had any pneumococcal vaccines?
    Despite the increasing availability of electronic health records and technology, obtaining an accurate vaccination history remains a major logistical challenge. If a resident is not able to provide information about their past medical history, providers may turn to family members, designated decision-makers, the resident’s primary care physician or state immunization registries. However, it is important to recognize that vaccination should not be delayed for any extended period of time in an effort to query these sources. If vaccination information is not readily available, providers should offer and administer pneumococcal vaccination as indicated.
11. What is a reasonable time period, following admission, for assessment and administration of pneumococcal vaccines?
Administration of pneumococcal vaccine should ideally be done as soon as possible following admission to a facility. It is recognized that the immediate admission period is one of high complexity and potentially complicated by resident instability. For these reasons, a flexible approach should be taken regarding timing of vaccination. The assessment of a resident regarding their immunization status (and determination of vaccine need) should be initiated at the time of admission and completed by day 14 (first MDS assessment period). The vaccine should be administered and documented as soon as possible following the assessment. Administration could potentially be delayed due to issues of medical instability. In any event, it is reasonable to expect administration and documentation of pneumococcal vaccine by the first quarterly assessment OR patient discharge, WHICHEVER COMES FIRST.
Figure 1 – Conditions or Risk Factors in Which Pneumococcal Vaccination Is Recommended in Individuals Less than 65 Years of Age

<table>
<thead>
<tr>
<th>Condition or Risk Factor</th>
<th>Recommended Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PCV13</td>
</tr>
<tr>
<td>Chronic Heart Disease, Chronic Lung Disease, Asthma</td>
<td>✓</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>✓</td>
</tr>
<tr>
<td>Chronic Liver Disease; Cirrhosis</td>
<td>✓</td>
</tr>
<tr>
<td>Alcoholism</td>
<td>✓</td>
</tr>
<tr>
<td>Cigarette Smoking</td>
<td>✓</td>
</tr>
<tr>
<td>Cochlear Implant, Cerebrospinal Fluid Leak</td>
<td>✓</td>
</tr>
<tr>
<td>Sickle Cell Disease; Hemoglobinopathy</td>
<td>✓</td>
</tr>
<tr>
<td>Congenital or Acquired Asplenia</td>
<td>✓</td>
</tr>
<tr>
<td>HIV; Congenital or Acquired Immunodeficiency</td>
<td>✓</td>
</tr>
<tr>
<td>Chronic Renal Failure; Nephrotic Syndrome</td>
<td>✓</td>
</tr>
<tr>
<td>Lymphoma; Leukemia; Hodgkin Disease</td>
<td>✓</td>
</tr>
<tr>
<td>Generalized Malignancy</td>
<td>✓</td>
</tr>
<tr>
<td>Immunosuppression from Chemotherapy, Long Term Steroids, Radiation Therapy</td>
<td>✓</td>
</tr>
<tr>
<td>Solid Organ Transplants, Multiple Myeloma</td>
<td>✓</td>
</tr>
</tbody>
</table>

*A one-time booster dose* is recommended 5 years after the first dose of PPSV23. The booster should be given ≥ 1 year after PCV13.
Figure 2 - Current ACIP Interval Recommendations for Pneumococcal Vaccinations (September 2015) (CDC Simplified Flow Chart for Pneumococcal Vaccinations) http://www.cdc.gov/mmwr/pdf/wk/mm6434.pdf

New ACIP interval recommendations for pneumococcal vaccinations

Sep 2015

http://www.cdc.gov/mmwr/pdf/wk/mm6434.pdf

Figure courtesy CDC MMWR 2015
Timeline of ACIP & CMS Pneumococcal Vaccination Recommendations

Nov 1977 → 14-valent pneumococcal polysaccharide vaccine (PPSV14) is licensed.

June 1983 → 23-valent pneumococcal polysaccharide vaccine (PPSV23) is licensed. PPSV23 replaces PPSV14.

May 1984 → ACIP recommends pneumococcal polysaccharide vaccine in adults ≥ 65 years.

Feb 2000 → 7-valent pneumococcal conjugate vaccine (PCV7) is licensed for use in children.

Oct 2002 → DHHS issues role allowing standing orders for pneumococcal vaccinations.

Oct 2005 → CMS issues role that mandates nursing facilities offer pneumococcal vaccination to residents.

Feb 2010 → 13-valent pneumococcal conjugate vaccine (PCV13) is licensed. PCV13 replaces PCV7.

June 2012 → ACIP recommends PCV13 in immunocompromised adults ≥19 years.

Sept 2014 → ACIP recommends PCV13 to all adults ≥ 65 years.

Dec 2014 → CMS issues payment decision indicating they will cover vaccines if ≥ one year apart.

Sept 2015 → ACIP recommends simplified intervals for PCV13 and PPSV23.
References


Resources

1. General Information on Pneumococcal Disease
   http://www.cdc.gov/pneumococcal/index.html
2. CMS Modifications to Medicare Part B Coverage of Pneumococcal Vaccinations – December 2014
3. CDC Contacts for Immunization Registry Records
   http://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html
4. CDC Manual for the Surveillance of Vaccine-Preventable Diseases
5. Current Vaccine Information Statements
   http://www.cdc.gov/vaccines/hcp/vis/index.html
6. Immunization Action Coalition Pneumococcus Question and Answers

Immunization Action Coalition Sample Standing Orders Policy for Pneumococcal Disease