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MMWR: Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥ 65 Years: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Key Points for Healthcare Professionals

New Recommendation

- In August 2014, the Advisory Committee on Immunization Practices (ACIP) voted to recommend pneumococcal conjugate vaccine (PCV13, Prevnar-13[®]) for all adults 65 years or older. This dose is in addition to the existing recommendation of one dose of pneumococcal polysaccharide vaccine (PPSV23, Pneumovax[®]23).
- PCV13 was licensed by the Food and Drug Administration for use in adults 50 years or older in 2011.
- Both PCV13 and PPSV23 provide good protection against invasive forms of infection caused by vaccine-type pneumococci. Although PPSV23 protects against more *Streptococcus pneumoniae* serotypes than PCV13, studies do not consistently show effectiveness against vaccine-type non-bacteremic pneumococcal pneumonia. PCV13 provides moderate levels of protection against vaccine-type non-bacteremic pneumococcal pneumonia. PCV13 helps to fill the gap in protection against non-bacteremic pneumococcal pneumonia.
- In June 2014, the results of a large randomized placebo-controlled trial evaluating efficacy of PCV13 against community-acquired pneumonia among adults 65 years or older (CAPiTA trial) became available. (*Community Acquired Pneumonia Immunization Trial in Adults (CAPITA) Abstract # 0541. 2014. at <https://pneumonia.org.au/public/journals/22/PublicFolder/ABSTRACTBOOKMASTERforwebupdatd20-3-14.pdf>.)
 - The results of the CAPiTA trial among approximately 85,000 adults 65 years or older demonstrated 45% efficacy of PCV13 against vaccine-type non-bacteremic pneumococcal pneumonia and 75% efficacy against vaccine-type invasive pneumococcal disease.*

Recommendation Details

- Both PCV13 and PPSV23 should be routinely administered in series to all adults 65 years or older.
- For pneumococcal vaccine-naïve adults:
 - Adults 65 years of age or older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed 6 to 12 months later by a dose of PPSV23.

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- If PPSV23 cannot be given during the 6 to 12 month time window, the dose of PPSV23 should be given during the next visit after 12 months. PPSV23 should not be given less than 8 weeks after the PCV13 dose.
- The two pneumococcal vaccines should not be administered at the same visit.
- For adults previously vaccinated with PPSV23:
 - Adults 65 years of age or older who have previously received one or more doses of PPSV23 should also receive a dose of PCV13 if they have not yet received it.
 - A dose of PCV13 should be given at least 1 year after the receipt of the most recent PPSV23 dose.
 - For those for whom an additional dose of PPSV23 is indicated (i.e., persons with functional or anatomic asplenia and immunocompromised persons), this subsequent PPSV23 dose should be given 6 to 12 months after PCV13 and at least 5 years since the most recent dose of PPSV23.
- ACIP considered multiple factors when determining the optimal interval between a dose of PCV13 and PPSV23, including immune response, safety, the risk window for protection against disease caused by serotypes unique to PPSV23, as well as the timing for the next visit to the provider.
 - The minimum acceptable interval between PCV13 followed by PPSV23 should be 8 weeks.
- Recommendations for routine use of PCV13 in adults at increased risk for pneumococcal disease remain unchanged.
 - Adults 19 years of age or older with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a dose of PCV13 first followed by a dose of PPSV23 at least 8 weeks later.
 - Adults at increased risk for pneumococcal disease who received PCV13 at 64 years or younger should not receive another dose of PCV13 at 65 years or older.

Safety

- Safety of PCV13 was evaluated in approximately 6,000 PPSV23-naïve and PPSV23-experienced adults aged 50 years and older. (*US Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee (VRBPAC) adult indication briefing document: Prevnar 13. Silver Spring, MD2011.*)
- Overall incidence of serious adverse events reported within 1 month of an initial study dose of PCV13 or PPSV23 did not differ between the 2 vaccines and ranged from 0.2% to 1.7%.

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- Common adverse reactions reported with PCV13 were pain, redness, and swelling at the injection site; limitation of movement of the injected arm; fatigue; headache; chills; decreased appetite; generalized muscle pain; and joint pain. Similar reactions were observed in adults who received PPSV23.

Administering Multiple Vaccines at the Same Visit

- PCV13 and PPSV23 should not be administered at the same visit.
- PCV13 should be given before PPSV23 because the optimal immune response is achieved when PCV13 is given first followed by PPSV23.
- Patients can receive either of the pneumococcal vaccines at the same time as inactivated influenza vaccine.
- There are no current data on concomitant administration of PCV13 with other vaccines such as the tetanus, diphtheria, acellular pertussis (Tdap) vaccine or zoster vaccine. However, CDC recommends that, to avoid missed opportunities, other inactivated vaccines and live vaccines can be given at the same visit. But if not administered at the same visit, then other non-pneumococcal vaccines should be given at least 1 month later.

Insurance Coverage

- Most private health insurance covers pneumococcal vaccines.
- At this time, Medicare part B typically covers only the first dose of pneumococcal vaccine for older adults and pays 100% of the cost of covered pneumococcal vaccines.
- Patients should check with their insurance provider for details on whether there is any cost to them and for a list of in-network vaccine providers.
- If your patients have insurance that supplements Medicare Part B, they should check with them to see if their plan covers both recommended pneumococcal vaccinations.

Evaluation of Implementation and Impact of PCV13 Recommendation

- The implementation and impact of the recommendation for PCV13 use among adults 65 years or older will be assessed, including uptake of PCV13 and PPSV23, and impact on PCV13-type invasive pneumococcal burden and community-acquired pneumonia.
- Indirect effects of PCV13 use among children, if similar to those seen after PCV7 introduction, may further reduce the remaining burden of adult pneumococcal disease caused by PCV13-

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types.

- If PCV13 use among children virtually eliminates PCV13 serotypes from circulating in the United States, there may not be long-term utility of routine use of PCV13 among adults.
- The recommendations for routine PCV13 use among adults 65 years or older will be re-evaluated in 2018 and revised as needed.

Pneumococcal Disease in Adults

- *Streptococcus pneumoniae* (pneumococcus) remains a leading cause of serious illness, including bacteremia, meningitis, and pneumonia among older adults in the United States.
- Each year in the United States, about 520,000 adults 65 years or older get pneumococcal disease and about 18,000 of them die.
- During the next few years, PCV13 could provide protection against 20-25% of invasive pneumococcal infections and approximately 10% of all community acquired pneumonia in older adults.
- Use of PCV7 and PCV13 among children in the United States has reduced pneumococcal infections among children (direct effects) and adults (indirect effects).

Additional Points

- Most adults are not aware that they need vaccines, and your strong recommendation is critical in ensuring that they have the best protection against serious diseases like pneumonia.
 - Only 60% of adults 65 years or older have received PPSV23.
 - Because the recommendation for PCV13 use in adults 65 years or older is new, data on coverage are not yet available.
- In addition to pneumococcal vaccination, adults need vaccines to protect against influenza, tetanus, pertussis, and shingles. They may also be recommended to get additional vaccines, such as hepatitis A and B and MMR, based on health conditions, occupation, lifestyle, locations of travel, and other risk factors.
- As a standard of practice, clinicians should routinely assess patient immunization status at every visit and recommend necessary vaccines. For vaccines a clinic doesn't stock, clinicians should refer patients to local healthcare professionals who do offer the vaccine and confirm that they have received the recommended vaccination. Vaccines should be documented in immunization information systems (aka immunization registries) to ensure that patients get the right vaccines at the right time and to ensure that all of a patient's clinicians know which vaccines their patients have received.

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- Adult immunization resources
 - For healthcare professionals: www.cdc.gov/vaccines/hcp/patient-ed/adults/
 - For patients: www.cdc.gov/vaccines/adults
 - Immunization schedule: www.cdc.gov/vaccines/schedules/hcp/adult.html
- Pneumococcal disease and vaccine resources
 - Disease: www.cdc.gov/pneumococcal/clinicians
 - Vaccine: www.cdc.gov/vaccines/vpd-vac/pneumo
 - ACIP Recommendations: www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html
 - Adult-specific guidance: www.cdc.gov/vaccines/vpd-vac/pneumo/vac-PCV13-adults.htm
- Influenza disease and vaccine resources
 - Disease: <http://www.cdc.gov/flu/weekly/fluactivitysurv.htm>
 - Vaccine: <http://www.cdc.gov/flu/professionals/vaccination/index.htm>
 - ACIP Recommendations: <http://www.cdc.gov/flu/professionals/acip/index.htm>
 - Table: Influenza Vaccines: <http://www.cdc.gov/flu/protect/vaccine/vaccines.htm>
 - Mobile App for Clinicians: <http://www.cdc.gov/flu/apps/cdc-influenza-hcp.html>