

Pneumococcal Vaccines and the Elderly: Identifying Vaccine Candidates in the Primary Care Setting



FPEN



A White Paper from the Illinois Academy of Family Physicians

April 2005

Learning Objectives:

Upon completion of the program, participants should be able to:

1. Review the current Centers for Disease Control and Prevention recommendations for administering the pneumococcal polysaccharide vaccine (PPV) in the elderly
2. Identify candidates for PPV vaccination in the primary care setting
3. Understand efficacy and safety issues related to PPV administration
4. Identify candidates for re-vaccination

Sponsorship:

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Support:

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Vaccination has been suggested as a method to prevent the spread of pneumococcal disease for the past 90 years.¹ Advances in vaccine development during the ensuing decades have yielded the 23-valent pneumococcal polysaccharide vaccine (PPV), which has been licensed in the United States since 1983. This preparation contains a fixed quantity of the capsular polysaccharide for each of 23 common serotypes of the pneumococcus, *Streptococcus pneumoniae*, a ubiquitous human bacterial pathogen. These 23 capsular types represent at least 85% of the serotypes that cause invasive pneumococcal infections among adults in the United States.²

The role of the 23-valent PPV in preventing pneumococcal disease has been studied in a variety of patient populations, geographic locales, and clinical settings during the last 25 years. In 1997, results from

some of these studies led the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) to recommend vaccination with the 23-valent PPV for all persons aged 65 or older and for younger persons with medical conditions associated with increased risk of serious pneumococcal disease.² Since then, however, new studies and meta-analyses have renewed discussion about the efficacy of the vaccine in preventing invasive pneumococcal disease in select patient populations.³⁻⁸ In 2003, the Infectious Diseases Society of America issued updated practice guidelines for managing community-acquired pneumonia that consider these results within the context of prevention.⁹ In 2004, the *Family Practice Education Network* (FPEN), coordinated by the *Illinois Academy of Family Physicians* (IAFP), assembled a panel of public health experts to address these issues. By reviewing the literature and utilizing their own clinical experience, the Expert Panel has formulated recommendations for primary care providers regarding the use of PPV for elderly persons.

Streptococcus pneumoniae is a leading cause of many serious infections, including pneumonia, bacteremia and meningitis.¹⁰ These infections pose a heightened threat to elderly patients, and primary care providers (PCPs) are uniquely positioned to educate these patients and administer preventive measures. However, a recent survey of the literature indicates that many physician and patient barriers prevent optimal use of adult pneumococcal vaccination.¹¹ To help PCPs identify candidates for PPV vaccination and understand issues related to safety, efficacy, and re-vaccination, this FPEN publication reviews the current pneumococcal vaccination literature, highlighting risk factors for invasive pneumococcal disease, vaccination recommendations, and efficacy analyses. As such, this guideline offers the healthcare provider a succinct, stepwise, and proactive strategy to vaccinate appropriate patients against invasive pneumococcal disease.

Invasive Pneumococcal Disease: Epidemiology and Impact

Streptococcus pneumoniae causes many serious infections, including pneumonia, bacteremia, and meningitis. Epidemiologic analyses of invasive pneumococcal disease indicate that rates are highest among children under 2 years of age, followed by persons aged 65 and older.¹⁰ It has been estimated that community-acquired pneumonia causes 620,000 hospitalizations each year in the United States among adults over age 65.¹² Among this patient cohort, the combination of pneumonia and influenza is the fifth leading cause of death.¹³

Streptococcus pneumoniae is the etiologic agent most commonly identified in community-acquired pneumonia, and it is the leading cause of community-acquired pneumonia among older adults.^{6,14} The pathogen has also been identified as an etiologic age-related cause of pneumonia in residents of long-term care facilities, who are at a higher risk for invasive pneumococcal disease and death than are community-living older adults.^{15,16} Estimates indicate that the case-related fatality rate of invasive pneumococcal disease in adults increases with age, reaching 20% in the very elderly (e.g., ages 80 and greater).¹⁰ In the United States, the incidence of and mortality rate from invasive pneumococcal disease are greater in African-Americans than in Caucasians in all age groups.¹⁰

The Case for Vaccination with PPV

The case for vaccination against *S. pneumoniae* in older patients is strengthened by evidence related to treatment and outcomes. In 1998, persons aged 65 and older accounted for 56% of all deaths attributable to invasive pneumococcal disease in the United States, even though this population accounted for only 29% of the cases.¹⁰ Moreover, a multi-center study of 2287 patients with community-acquired pneumonia found that pneumonia-related deaths were 7.7 times more likely to occur within 30 days of presentation compared with pneumonia-unrelated deaths.¹⁷ Because of an increased likelihood of comorbidities and underlying conditions in elderly patients (e.g., renal failure, diabetes, liver conditions, cardiovascular disease), invasive pneumococcal infection poses a heightened health threat. Furthermore, recent trends in the United States indicate an increasing prevalence of antibiotic-resistant strains of *S. pneumoniae*,^{18,19} and the six serotypes that most frequently cause invasive drug-resistant pneumococcal infection in the United States (6B, 9V, 14, 19A, 19F, and 23F) are represented in the 23-valent PPV.²⁰

Current Recommendations for Prevention of Invasive Pneumococcal Disease

ACIP Recommendations. In 1997, the CDC's Advisory Committee on Immunization Practices issued a set of recommendations for the use of PPV in the prevention of pneumococcal disease.² These recommendations, which are summarized in Table 1, have been endorsed by numerous professional organizations, including the American Academy of Family Physicians, the American Academy of Pediatricians, the Canadian Task Force on Periodic Health Examination, and the US Preventive Services Task Force.¹¹ The ACIP has maintained these specific guidelines, without modification, since 1997.

Revaccination. Because pneumococcal polysaccharide vaccine does not induce immunologic memory, the ACIP recommends second doses of PPV for persons at highest risk of serious pneumococcal infection and those who are likely to have a rapid decline in pneumococcal antibody concentration. This includes patients with HIV infection and those receiving hemodialysis. In these suggested populations, the ACIP recommends a second dose of PPV after a minimum interval of 5 years from the time of initial dosing. For immunocompetent persons aged ≥ 65 years, a second dose may be administered if the patient received the vaccine ≥ 5 years previously and was aged < 65 years at the time of vaccination. The efficacy of revaccination is unknown; using the Strength of Evidence Categories defined in Table 1, the strength of evidence for all revaccination recommendations is "C." A recent study with healthy adults, ages 50-74, demonstrated that those who were revaccinated with PPV were more likely to report local injection site reactions (see next section for details) as compared with first vaccination.²¹ These reactions resolved within a median of three days, and this risk does not represent a contraindication to revaccination with PPV for recommended adults.

Vaccine Administration: Contraindications, Adverse Reactions, and Concurrent Administration with Other Vaccines

PPV is available under the brand name, Pneumovax[®] 23 (Merck & Co., Inc.; http://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_pi.pdf). It is administered intramuscularly or subcutaneously as a one-time 5-mL dose.

Table 1 ACIP Recommendations for PPV Administration

PPV should be administered to all persons in the following groups: Patient Category	Strength of Recommendation*
Immunocompetent persons aged ≥ 65 years	A
Immunocompetent persons aged ≥ 2 years with chronic cardiovascular disease, chronic pulmonary disease, or diabetes mellitus	A
Immunocompetent persons aged ≥ 2 years with alcoholism, chronic liver disease, or cerebrospinal fluid leaks	B
Immunocompetent persons aged ≥ 2 years with functional or anatomic asplenia	A
Immunocompetent persons aged ≥ 2 years who live in environments with high risk for disease (e.g., Alaskan natives and certain Native American populations)	C
Immunocompromised persons aged ≥ 2 years who are at high risk for infection	C

*Legend: Strength of Evidence for Categories of Recommendation

A = Strong epidemiologic evidence and substantial clinical benefit support the recommendation for vaccine use

B = Moderate evidence supports the recommendation for vaccine use

C = Effectiveness of vaccination is not proven, but the high risk for disease and the potential benefits and safety of the vaccine justify vaccination.

Source: Centers for Disease Control and Prevention. *MMWR* 1997;46 (No. RR-8):1-24. Available online at: <http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf>.

Precautions and Contraindications. According to the ACIP, PPV generally is considered safe based on clinical experience since 1977.² People with minor illnesses, such as a cold, may be vaccinated, although those who are moderately or severely ill or have a fever are encouraged to wait until recovery before being vaccinated.²² In addition to the immunocompromised

persons who have the conditions listed in Table 2, persons who have sickle-cell disease, a damaged spleen or no spleen, or kidney failure, and women who are pregnant or breast feeding, should consult with their physicians before receiving the vaccine. Vaccine use is contraindicated in persons who are hypersensitive to any component of the vaccine.²²

Table 2 PPV Vaccination in Immunocompromised Persons

The ACIP recommends the PPV for immunocompromised persons who have the following conditions:

- HIV infection, asymptomatic or symptomatic
- Leukemia
- Lymphoma
- Hodgkins disease
- Multiple myeloma
- Generalized malignancy
- Chronic renal failure
- Nephrotic syndrome
- Organ or bone marrow transplantation
- Chemotherapy (including long-term systemic corticosteroids)*

*Vaccination during chemotherapy or radiation therapy administration should be avoided; the interval between vaccination and initiation of immunosuppressive therapy should be ≥ 2 weeks.

Adverse Reactions. Local reactions at the site of injection include soreness, warmth, swelling, erythema, and induration; very rarely, recipients may experience a transient cellulitis-like reaction. The most common non-localized reaction to PPV is fever ≤ 102° F; other adverse experiences reported in clinical trials include malaise, fever > 102° F, nausea, vomiting, and headache. For a complete list of adverse reactions that have been reported in response to PPV administration, see the package insert for Pneumovax® 23.²²

Concurrent Administration with other Vaccines. Results suggest that the PPV can be safely administered concurrent with other vaccines, including influenza, with no increase in side effects or decreased antibody responses to either vaccine.^{23, 24} PPV and influenza vaccines, which are commonly given to elderly patients, can be concurrently injected into separate arms.

Source: Centers for Disease Control and Prevention. *MMWR* 1997;46 (No. RR-8):1-24. Available online at: <http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf>.

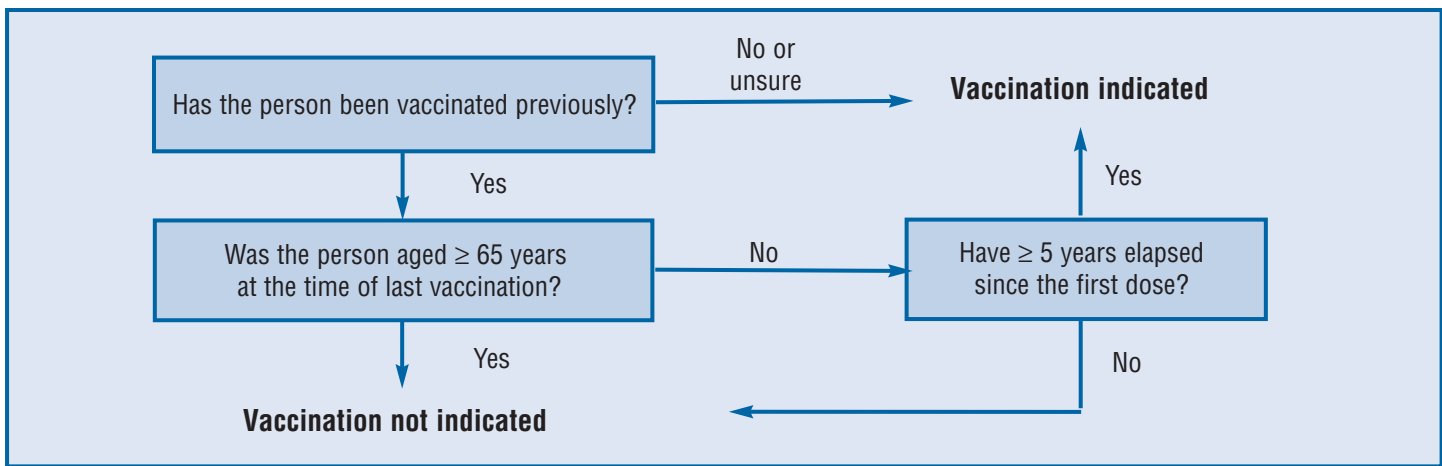


Figure 1 Algorithm for PPV vaccination of persons aged ≥ 65 years

Source: Centers for Disease Control and Prevention. *MMWR* 1997;46 (No. RR-8):13. Online at: <http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf>.

Vaccine Efficacy against Invasive Pneumococcal Disease

PPV efficacy in adults has been investigated in numerous settings, from observational studies to randomized, controlled clinical trials, in populations representing industrialized and non-industrialized countries. The results of these trials are variable, leading several investigators to conclude that benefit from pneumococcal vaccination may be population-dependent.^{1, 3} Reaching definitive conclusions about PPV efficacy has been hampered by numerous factors, including study design and power, patient selection, and variety in methods of reporting and diagnosis. For example, in 12 non-randomized, retrospective case-control/cohort studies in North American populations conducted between 1984 and 2001, the reported efficacy of PPV varied between -34% and +78%, where a negative efficacy indicates increased disease in the vaccine group.¹

Several meta-analyses of the randomized, controlled clinical trials have attempted to ascertain the benefits of PPV against various types of invasive pneumococcal disease (e.g., community-acquired pneumonia, bacteremia, meningitis) in high-risk patient populations, including the elderly.^{3-5, 8, 25} As with the non-randomized studies, results vary between the randomized, controlled clinical trials, thus leading researchers to inconsistent conclusions. For example, a 1994 assessment of 12 randomized trials by Fine, *et.al* concluded that PPV is efficacious at reducing bacteremic pneumococcal pneumonia in low-risk adults, but not for preventing pneumococcal infection-related or other medical outcomes in high-risk populations (e.g., the elderly and the immunocompromised).²⁵ In their 1999 analysis of 13 trials, however, Hutchison and colleagues reported that

PPV was efficacious against the specific serotypes included in the vaccine preparation, and they found no evidence that the vaccine was less efficacious for the elderly or those with chronic disease.⁸ Such conflicting conclusions have spawned meta-analyses by Moore, *et.al* (2000),⁴ Cornu, *et.al* (2001),⁵ Watson, *et.al* (2002),³ and Dear, *et.al* (2003),⁷ all of whom failed to find statistically significant benefit of PPV in terms of clinical outcomes for the subgroups of elderly patients in industrialized nations. The failure to show vaccine efficacy in the elderly and other at-risk groups, however, may reflect deficiencies in the study design and power of the individual trials.^{1, 3-5, 7} Therefore, existing studies point out the difficulties in assessing population-wide benefit of vaccination but do not rule out a vaccine benefit to patients at high-risk for pneumococcal infection.

Moreover, several recent large-scale studies in elderly persons suggest some preventive benefit from vaccination. A study of more than 250,000 elderly Swedish individuals demonstrated that the yearly incidence of hospital admissions for invasive pneumococcal disease was nearly halved in the study population vaccinated with PPV alone or PPV plus the influenza vaccine ($n = 77,018$), as compared to those who had been vaccinated against influenza alone or not at all ($n = 182,609$).²⁶ The study further suggested that the risk for invasive pneumococcal disease was more than halved in vaccinated (e.g., PPV, influenza, or both) individuals, as compared with the unvaccinated cohort. In a three-year observational retrospective study of more than 47,000 US adults aged ≥ 65 years,⁶ PPV was found effective for the prevention of pneumococcal pneumonia with bacteremia. However, the association between vaccination and the pneumococcal pneumonia without bacteremia could not be directly established in this study due to the lack of an etiologic agent identified with many cases of pneumonia.

Since 2000, a 7-valent protein-polysaccharide conjugate vaccine has been licensed in the United States for use against invasive pneumococcal disease in young children. Epidemiologic data gathered by the CDC indicate that the use of the conjugate vaccine in the indicated pediatric population may also be reducing the rate of invasive pneumococcal disease in adults.²⁷ The pediatric conjugate vaccine has not been tested for efficacy and safety in adults and is not indicated for the adult population. However, preliminary data suggest that the pediatric pneumococcal conjugate vaccine is recommended for children who have contact with high-risk adults.

The discussion about the population-wide efficacy of PPV continues to evolve, as larger and more comprehensive studies are conducted. Given that PPV provides some preventive benefit against invasive pneumococcal disease, and that the risk associated with PPV vaccination is minimal, professional societies continue to endorse the 1997 CDC ACIP guidelines for PPV use. Recommendations for vaccination of older persons have been supported by cost-effectiveness analyses, both for bacteremia²⁸ and non-bacteremic invasive pneumococcal disease.^{29, 30} Therefore, the Expert Panel concurs with the ACIP recommendations and supports vaccination of all persons in the US who are 65 years or older.

Conclusion

Invasive pneumococcal diseases are a common, and possibly life-threatening, set of conditions among individuals ages 65 and older. The Expert Panel concurs with current recommendations of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices to immunize all persons aged 65 and older with the 23-valent polysaccharide pneumococcal vaccine. Although population-wide studies of vaccine efficacy for all-cause pneumonia have not been conclusive, PPV is a safe and cost-effective preventive measure against the six serotypes of *Streptococcus pneumoniae* that most frequently cause invasive drug-resistant pneumococcal infection in the United States. The primary care provider is in a unique position to vaccinate immunocompetent and immunocompromised patients with PPV as recommended in these guidelines, as PPV may be administered concurrently with the influenza vaccine.

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Clinical Pearls

- PPV is a safe and cost-effective preventive measure against drug-resistant serotypes of *Streptococcus pneumoniae*.
- PPV should be administered to all immunocompetent persons aged ≥ 65 .
- PPV can be given to immunocompromised persons who have HIV infection, leukemia, and those on chemotherapy.
- A second dose of PPV may be administered ≥ 5 years from the time of initial dosing.
- PPV may be co-administered with the influenza vaccine.

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Pneumococcal Vaccines and the Elderly: Identifying Vaccine Candidates in the Primary Care Setting

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Content was useful, relevant, and timely to my profession	5	4	3	2	1
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In the space provided, indicate whether each item is True (T) or False (F).

- _____ 1. PPV vaccination protects against the six serotypes of *S. pneumoniae* that most frequently cause invasive, drug-resistant pneumococcal disease.
- _____ 2. PPV cannot be administered simultaneously with the influenza vaccine.
- _____ 3. PPV should be administered to all immunocompetent persons ages 65 and older.
- _____ 4. A second dose of PPV may be administered, provided that six months have elapsed from the time of initial dosing.
- _____ 5. PPV may be given to immunocompromised persons, such as those who have HIV infection, leukemia, lymphoma, and those on chemotherapy, although the vaccine may be less effective in these populations than in immunocompetent persons.

Thank you for filling out this post-test.

