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Pneumococcal Vaccination Guidance for Nursing Home Residents: Recommendations from AMDA's Infection Advisory Committee

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Abstract

Efforts at preventing pneumococcal disease are a national health priority, particularly in older adults and especially in post-acute and long-term care settings (PA/LTC). The Advisory Committee on Immunization Practices (ACIP) recommends that all adults ≥ 65, as well as adults aged 18–64 with specific risk factors, receive both the recently introduced polysaccharide-protein conjugate vaccine against 13 pneumococcal serotypes (PCV13) as well as the polysaccharide vaccine against 23 pneumococcal serotypes (PPSV23). Nursing facility licensure regulations require facilities to assess the pneumococcal vaccination status of each resident, provide education regarding pneumococcal vaccination, and administer the appropriate pneumococcal vaccine when indicated. Sorting out the indications and timing for PCV13 and PPSV23 administration is complex, and presents a significant challenge to healthcare providers. Here, we discuss the importance of pneumococcal vaccination for older adults, detail AMDA – The Society for Post-Acute and Long-Term Care Medicine (The Society)’s recommendations for pneumococcal vaccination practice and procedures, and offer guidance to PA/LTC providers supporting the development and effective implementation of pneumococcal vaccine policies.

Keywords

Nursing Home; Pneumococcal Vaccines; Pneumococcal Infections; Aged; Policy

BACKGROUND

The Advisory Committee on Immunization Practices (ACIP) has long recommended pneumococcal vaccination for older adults and those with certain chronic health conditions [1]. In 2014, ACIP released updated recommendations that call for the combined use of two separate pneumococcal vaccines [2]. Since their release, AMDA - The Society for Post-Acute and Long-Term Care Medicine (The Society) has fielded a number of inquiries from providers, facilities and surveyors regarding application of the ACIP recommendations to post-acute and long-term care (PA/LTC) settings. Questions received have focused on the impact of pneumococcal disease and pneumococcal vaccination in PA/LTC populations; financial coverage of the vaccine; and operational issues. Operational queries have included questions surrounding appropriate intervals for vaccination, whether nursing homes were required to offer either and/ or both vaccines, whether standing orders are allowed, and how to address lack of access to past vaccination history.

The Society strongly supports pneumococcal vaccination consistent with ACIP and Centers for Disease Control and Prevention (CDC) recommendations. The Society also understands the need to respond to the various questions raised about pneumococcal vaccination in PA/LTC settings. To that end, The Society’s Infection Advisory Committee (IAC) conducted

an environmental scan. This included assembling and thematically grouping questions received from September 2014 through May 2016. In addition, the IAC conducted a limited number of detailed interviews with select stakeholders, including state survey agency representatives, PA/LTC practitioners, and members of other professional societies. General information from survey citations was reviewed and pertinent literature and website reviews were conducted.

Based on this work, the IAC developed a series of educational and implementation tools to assist PA/LTC providers when assessing residents for pneumococcal vaccination needs. To further assist with guideline compliance, the materials present multiple clinical vignettes for practitioners [3]. Here, we present the results of these efforts, The Society's policy statement, and introduce the tools developed.

PNEUMOCOCCAL DISEASE SERIOUSLY IMPACTS THE HEALTH OF OLDER ADULTS

Streptococcus pneumoniae (pneumococcus) remains a serious health threat in the United States, and one that is potentially preventable [2]. The leading bacterial cause of community acquired pneumonia (CAP), *Streptococcus pneumoniae* accounts for 20 to 60% of cases [4]. However, *Streptococcus pneumoniae* causes a variety of other infections as well, such as bacterial otitis media typically seen in children and invasive pneumococcal disease. The term invasive pneumococcal disease (IPD) refers to any infection of a normally sterile site by *Streptococcus pneumoniae*. Examples of IPD include bacteremia, meningitis, arthritis, and endocarditis. IPD represents roughly one quarter of all pneumococcal infections and the incidence of IPD increases with age [5].

Before the advent of antibiotics in the early 1900's, IPD was nearly always fatal [6]. The development of sulfa drugs, penicillin and subsequent antibiotics occasioned a significant reduction in pneumococcal-related morbidity and mortality [7]. Antibiotics became the mainstay of treatment for pneumococcal disease. Despite the overall reduction in mortality from pneumococcal disease, certain populations such as those ≥ 65 years of age as well as younger individuals with specific chronic medical conditions continue to experience high pneumococcal-related mortality rates [8–10].

Many factors contribute to the increased susceptibility of older adults to pneumococcal disease. Age-related changes in immune function, including immunosenescence, impaired splenic function and changes in the respiratory tract appear to play a role [11,12]. Residence in a post-acute or long-term care facility increases risk as evidenced by several documented outbreaks or clusters of pneumococcal disease [13–17]. Medication use, including polypharmacy, is also common in the treatment of older adults. Prescribed medications may include immunosuppressive drugs and central nervous system (CNS) active agents that can increase risk of aspiration and/or respiratory depression and further increase the risk of pneumococcal infection. The increased susceptibility and mortality among specific populations as well the emergence of antibiotic resistant strains drove the consideration of methods for primary prevention, namely the development of pneumococcal vaccines [4,7].

PNEUMOCOCCAL VACCINES AND ACIP RECOMMENDATIONS

Pneumococcal polysaccharide vaccine (PPSV) was first commercially developed and licensed for use in 1977 as a 14-valent vaccine (PPSV14). In 1983, a 23-valent vaccine (PPSV23) was licensed (Table 1), and in 1984 the ACIP recommended the PPSV23 for adults 65 and those with chronic illness at increased risk of pneumococcal disease [1]. This recommendation extends to nearly all adults residing in PA/LTC facilities. The vaccine reduced the incidence of invasive pneumococcal disease in immunocompetent adults. However, limited studies led to questions about the effectiveness of PPSV23 in high-risk adults [18]. Unfortunately this hampered uptake of the vaccine throughout the 1990's and early 2000's, and ultimately prompted a search for a more effective vaccine.

In 2000, a new 7-valent pneumococcal vaccine, the pneumococcal conjugate vaccine (PCV7), was licensed for use in the pediatric population (<18 years of age) [19]. PCV7 reduced the rate of pneumococcal-related illness in children. Remarkably, administration of PCV7 to children also correlated with a marked reduction in the rate of hospitalizations due to pneumonia in older adults, even though this population did not receive the vaccine directly [20]. Of note, the effect decline in hospitalization rates for pneumonia was greatest among people 85 years [21]. Adoption of PCV7 has also been associated with a reduction in adult mortality from IPD [22]. In 2010, PCV7 was replaced with an expanded PCV13 vaccine. Given the reports of improved effectiveness of the conjugate vaccines, the *Community Acquired Pneumonia Immunization Trial in Adults (CAPITA)* was launched in the Netherlands, a country in which PPSV23 had not been administered widely [23]. The CAPITA study randomized almost 85,000 adults 65 years of age (>26,000 were 75 years or older) to receive either PCV13 or placebo. PCV13 reduced vaccine-type invasive pneumococcal disease by 75% and vaccine-type community acquired pneumonia by 45%. Unfortunately, the study did not include a comparison to PPSV23, so could not answer the question of which vaccine is more effective at preventing pneumococcal-related illnesses.

Several studies of PCV13 and PPSV23 affirm that even very frail individuals benefit from pneumococcal vaccination. Immunogenicity studies comparing PCV13 and PPSV23 in frail elderly patients have been conducted in both nursing home and hospital settings. Subjects recruited in these studies included very frail elderly individuals with significant levels of dependency and cognitive impairment. Regardless of setting, subjects were able to mount a significant antibody response, including those with no detectable baseline levels of immunity [24,25]. A placebo controlled study of PPSV23 conducted in 1006 Japanese nursing home residents found a significant reduction in pneumococcal and all cause pneumonia rates. This study also reported a striking 35% absolute risk reduction in deaths from pneumococcal pneumonia [26]. While PCV13 may elicit a stronger immune response [27,28], the incidence of infections caused by the strains covered by the vaccine have declined [2]. In contrast, while PPSV23 may be less immunogenic, it offers protection against more strains [27,28].

In 2014, weighing the totality of evidence available to date, the ACIP recommended the use of both vaccines in adults 65 years or older in addition to those with chronic health conditions [2]. The ACIP determined that use of both vaccines provided benefit surpassing

that of either one alone. The 2014 ACIP recommendations included complex recommendations for intervals between vaccine administration. In 2015, the ACIP simplified the vaccine interval recommendations [29] with the intent to improve vaccine uptake as well as bring current recommendations into congruence with CMS coverage policies [30]. Table 2 lists current ACIP recommendations and Figure 1 shows the recommended dosing intervals for PCV13 and PPSV23 administration [29]. Figure 2 provides an algorithm to help guide determination of vaccine administration in vaccine-naïve adults based on age, high- and low-risk conditions [31]. Depending on their indications, adults may receive up to 3 doses of PPSV23 during their lifetime (2 doses at age <65 years; 1 dose at age ≥ 65 years), all of which should be given 5 years apart.

REGULATORY ATTEMPTS TO IMPROVE PNEUMOCOCCAL VACCINATION RATES IN PA/LTC FACILITIES

Several regulatory initiatives have been undertaken to improve pneumococcal vaccination rates in PA/LTC populations. In 2002, the United States Department of Health and Human Services (DHHS) issued orders allowing the use of standing order programs in nursing homes for influenza and pneumococcal vaccination [32]. Research had shown standing order programs to be effective in improving immunization rates and in 2000, the ACIP had recommended their use in a variety of clinical settings [33,34]. Despite their explicit allowance, standing order programs were not widely adopted, and influenza and pneumococcal vaccination rates remained well below targets. This led the Centers for Medicare & Medicaid Services (CMS) to issue a new immunization standard (F334) in 2005 as part of the nursing facility conditions of participation [35]. This regulation requires PA/LTC facilities to assess the influenza and pneumococcal vaccination status of each resident, provide education about the vaccines and offer the vaccines to all eligible residents [36]. Additional 2009 updates to the PA/LTC facility infection control guidance (F441) emphasized the importance of vaccination by directing surveyors to investigate whether facilities have systems in place to ensure immunization of residents when assessing a facility's overall infection control practices [36]. In July 2012, CMS began public reporting of a set of new quality measures. Included in these measures were two pertaining to pneumococcal vaccination: the percentage of short and long stay residents who have been assessed and appropriately given the pneumococcal vaccine [37].

By explicitly allowing and promoting standing order programs, promulgating immunization standards, tightening the survey investigative protocol for pneumococcal vaccination, and initiating public reporting of pneumococcal vaccination rates, CMS has made it clear that pneumococcal vaccination is a high priority. CMS expects facilities to have effective and current pneumococcal vaccination programs in place as part of their infection control activities.

BARRIERS TO PNEUMOCOCCAL IMMUNIZATION IN NURSING HOMES

The United States DHHS Healthy People 2020 Program has established a 90% pneumococcal vaccination rate goal for all adults (> 18 years) who reside in PA/LTC facilities. While pneumococcal vaccination rates among nursing home residents have

improved from 67% in 2006, they have since stagnated around 80%. Moreover, concerns have been raised about the accuracy of this data, and it is possible that vaccination rates may be lower than those reported [38,39]. There are many potential barriers to vaccination in general including poor access to vaccines, lack of education, healthcare worker behaviors and attitudes, cultural factors and cost [40,41]. A full discussion of such barriers is beyond the scope of this paper. However there are several key points relevant to pneumococcal vaccination of PA/LTC residents that deserve comment.

First, PA/LTC practitioners have voiced skepticism regarding the benefits of pneumococcal vaccinations. PA/LTC practitioners appropriately recognize frailty as a characteristic of PA/LTC residents and a potential attenuator of vaccine response [24,31,42]. Pneumococcal disease poses a serious health threat to residents and one in which prevention, by necessity, must play a prominent role. The data presented above provides evidence supporting the use of pneumococcal vaccine even in frail populations. While not as effective compared to use in younger and/or healthier populations, pneumococcal vaccination still provides a significant benefit to frail recipients. The Society has established a clear policy statement on pneumococcal vaccination in the PA/LTC setting, detailed in the following section.

Second, obtaining an accurate vaccine history is a challenge. Despite the prevalence of electronic health records, transfer of important vaccination information remains suboptimal and poses challenges as recently highlighted in the National Quality Forum's 2015 report, *Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations* [43]. Facilities should seek ways to improve communication about a resident's vaccination status at admission and discharge. Third, there have been questions regarding reimbursement from Medicare for pneumococcal vaccines. As PCV13 and PPSV23 are ACIP recommended vaccines, CMS has issued statements of coverage for both vaccines as a Part B benefit [23]. Fourth, and the most challenging barrier, is the complexity of vaccine recommendations. Given the complexities of current ACIP pneumococcal vaccination recommendations and the unique features of PA/LTC settings, it is understandable that pneumococcal vaccinations pose a challenge to many PA/LTC providers. As noted, ACIP recommendations have been simplified and algorithms such as the ones in Figures 1 and 2 exist to guide practitioners in selecting the right vaccine for each resident. Still, facilities will need to be familiar with specific indications for the vaccine and perform a thoughtful assessment of each resident.

POLICY STATEMENT, RECOMMENDATIONS AND TOOLS FROM THE SOCIETY'S INFECTION ADVISORY COMMITTEE (IAC)

AMDA – The Society for Post-Acute and Long-Term Care Medicine (The Society) strongly supports pneumococcal vaccination of PA/LTC residents and the need for continued efforts to improve pneumococcal vaccination rates. Box 1 details The Society's policy statement regarding pneumococcal vaccination developed by the Infection Advisory Committee (IAC) and adopted by The Society.

The Society has created a series of educational and implementation tools to assist PA/LTC providers when assessing residents for pneumococcal vaccination needs. Available at the

Society's website and found in Appendices 1–3, these tools were developed by the IAC and approved by The Society's Board. They are introduced here with the aim of supporting provider efforts to improve pneumococcal vaccination rates among the PA/LTC population.

The tools include:

- A *Pneumococcal Vaccination Guidance* document formatted using a frequently asked question approach. The *Guidance* addresses common pneumococcal vaccination questions, and presents a series of common clinical vignettes designed to help providers select appropriate vaccination strategies. (see Appendix 1)
- A *Pneumococcal Vaccination Coverage* document that also uses a frequently asked question approach to answer questions about CMS coverage of pneumococcal vaccinations. (see Appendix 2)
- A *Resident Pneumococcal Vaccination Assessment Note* which helps nursing home staff complete the required resident pneumococcal vaccination assessment through use of a template note. (see Appendix 3)

The tools are available free of charge to assist PA/LTC providers and facilities. They can be found in the online appendix, as well as through The Society website [[Pneumococcal Vaccination Guidance for PA / LTC Facilities](#)]. The Society plans to update these materials as ACIP recommendations change. Finally, The Society welcomes feedback on this material in an effort to make improvements and to continue to support PA/LTC practitioners and facilities in their efforts to vaccinate their residents as an effective means to reduce the risk of infection with *S. pneumoniae* and improve clinical care.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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BOX 1

**AMDA - THE SOCIETY FOR POST-ACUTE AND LONG-TERM CARE
MEDICINE POLICY STATEMENT ON PNEUMOCOCCAL VACCINATION**

- The Society strongly advocates that Post-Acute and Long-Term Care (PA/LTC) facilities and providers establish *and* maintain a pneumococcal vaccination program that provides residents with access to current Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC) recommended pneumococcal vaccinations.
- Such a program would include a requirement to assess PA/LTC residents for their pneumococcal vaccination status and to administer and document appropriate pneumococcal vaccinations in accordance with current ACIP and CDC guidance, unless the PA/LTC resident declines or has a medical contraindication or allergy,
- In addition, The Society recommends PA/LTC facilities and providers demonstrate an ongoing commitment to Quality Assessment and Performance Improvement by evaluating and addressing their pneumococcal vaccination programs if vaccine acceptance rates fall below U.S. Department of Health and Human Services goals.

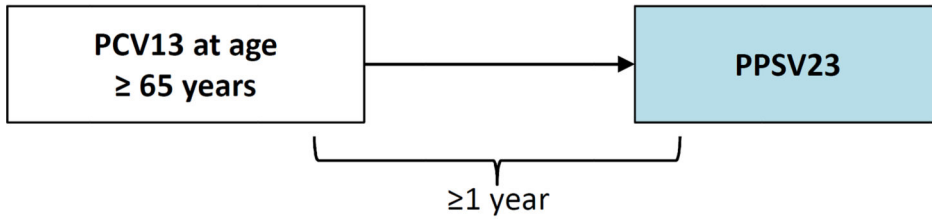
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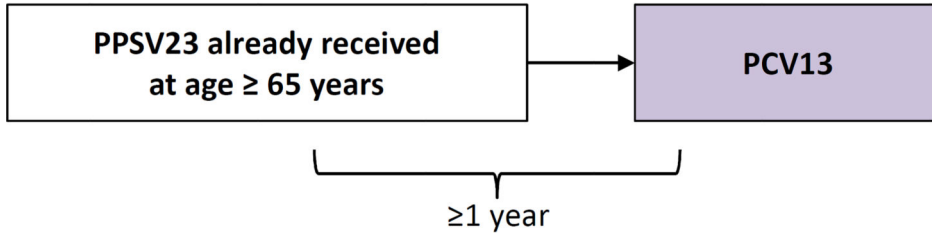
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Pneumococcal vaccine-naïve persons aged ≥ 65 years



Persons who previously received PPSV23 at age ≥ 65 years



Persons who previously received PPSV23 before age 65 years and who are now aged ≥ 65 years

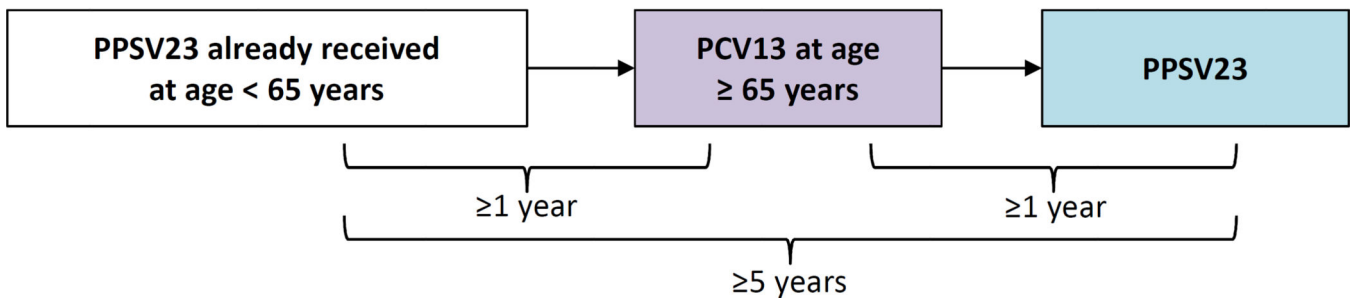


Figure 1. Advisory Committee on Immunization Practices (ACIP) recommended intervals for sequential use of PCV13 and PPSV23 for immunocompetent adults aged ≥ 65 years. **For adults aged ≥ 65 years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants, the recommended interval between PCV13 followed by PPSV23 is 8 weeks. For those for whom previously received PPSV23 when aged <65 years and for whom an additional dose of PPSV23 is indicated when aged ≥ 65 years, this subsequent PPSV23 dose should be given 1 year after PCV13 and 5 years after the most recent dose of PPSV23. Depending on their indications, adults may receive up to 3 doses of PPSV23 during their lifetime (2 doses at age <65 years; 1 dose at age ≥ 65 years), all of which should be given 5 years apart. These materials were adapted from [29].

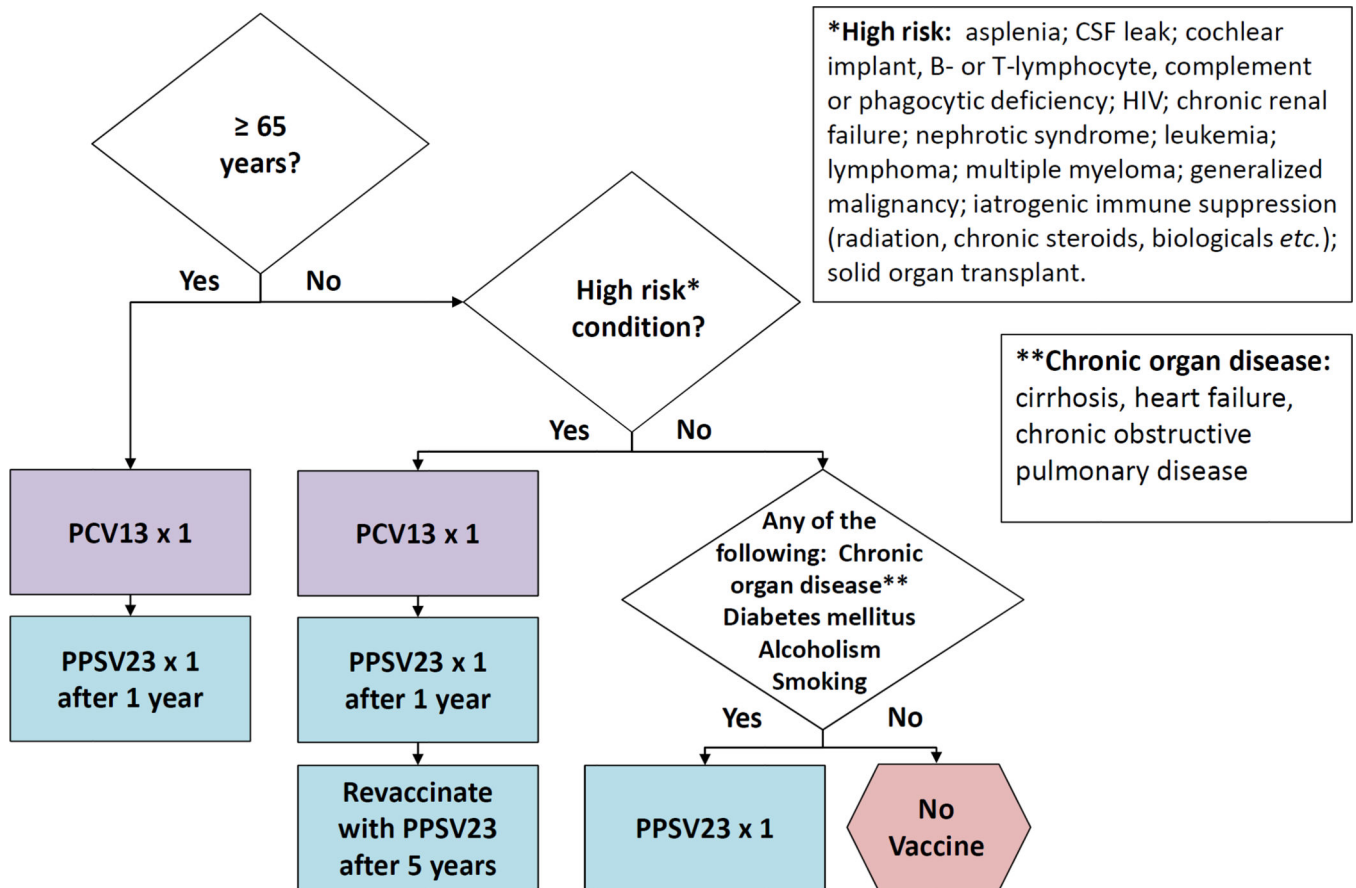


Figure 2. Algorithm for Pneumococcal Immunization for Adults. These recommendations, based on [2,5], are for adults who have not previously received a pneumococcal vaccine. Figure adapted with permission from [31].

TABLE 1

Pneumococcal Vaccines Available in the United States

Vaccine	Vaccine Type and Content	Brand Name (Manufacturer)	Comments
PPSV 23	Pneumococcal polysaccharide – contains cell capsule antigens from 23 pneumococcus subtypes	Pneumovax 23 (Merck)	First pneumococcal vaccine. Licensed in 1983.
PCV 13	Pneumococcal conjugate – contains cell capsule antigens from 13 pneumococcus subtypes combined with diphtheria antigen	Prevnar 13 (Wyeth / Pfizer)	Approved by FDA in 2010. Conjugate formulation was developed to enhance immunogenicity.
PCV 7	Pneumococcal conjugate – contains cell capsule antigens from 7 common pneumococcus subtypes combined with diphtheria antigen	Prevnar 7 (Wyeth / Pfizer)	Licensed for children only. Not used in older adults.

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TABLE 2

Summary of the Advisory Committee on Immunization Practices recommended intervals, by risk and age groups, for adults with indications to receive to PCV13 and PPSV23.

Risk group/Underlying medical condition ^a	Intervals for PCV13–PPSV23 ^b sequence, by age group		Intervals for PPSV23–PCV13 ^b sequence, by age group	
	19–64 years	65 years	19–64 years	65 years
No underlying chronic conditions	NA ^c	1 year	NA ^c	1 year
Immunocompetent persons				
Chronic heart disease				
Chronic lung disease				
Diabetes mellitus	NA	1 year	NA	1 year
Alcoholism				
Chronic liver disease, cirrhosis				
Cigarette smoking				
Immunocompetent persons				
Cerebrospinal fluid leak	8 weeks	8 weeks	1 year	1 year
Cochlear implant				
Persons with functional or anatomic asplenia				
Sickle cell disease/other hemoglobinopathy	8 weeks	8 weeks	1 year	1 year
Congenital or acquired asplenia				
Immunocompromised persons				
Congenital or acquired immunodeficiency	8 weeks	8 weeks	1 year	1 year
Human immunodeficiency virus infection				
Chronic renal failure				
Nephrotic syndrome				
Leukemia				
Lymphoma				
Hodgkin disease				
Generalized malignancy				
Iatrogenic immunosuppression				
Solid organ transplant				
Multiple myeloma				

^aAdapted from [29]

^bPCV13, polysaccharide-protein conjugate vaccine against 13 pneumococcal serotypes; PPSV23, polysaccharide vaccine against 23 pneumococcal serotypes.

^cNA, not applicable. Sequential use of PCV13 and PPSV23 is not recommended for these age and risk groups.