

Call to Action on Pneumococcal Disease: Review of Vaccination Evidence and Outcomes of Webcast Programs

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Miller Medical Communications LLC assisted with preparing this content.

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Financial Disclosures:
Dr Grogg is on the speakers' bureaus for Sanofi, MedImmune, Novartis, and Pfizer, and he is a consultant for Novartis, Merck, and Pfizer.
Ms Schultz has nothing to disclose.

Support: This supplement is supported by an independent educational grant from Pfizer.

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Submitted February 13, 2015;
final revision received
April 16, 2015; accepted
April 22, 2015.

In 2015, the Advisory Committee on Immunization Practices issued updated recommendations for the use of 13-valent pneumococcal conjugate vaccine (PCV13) and 23-valent pneumococcal polysaccharide vaccine (PPSV23) to immunize adults aged 19 to 64 years with risk factors and all adults aged 65 years or older. Despite these recommendations, rates of vaccination among adults remain low. Federal and state initiatives have been launched to encourage health care providers to incorporate vaccination screening and recommendations in practice. Several resources are available to improve vaccination rates, including implementing electronic medical records; engaging non-physician staff in assessing vaccination history and administering immunizations; adopting standing order protocols; and implementing strong recommendations to patients regarding needed immunizations. However, even in the face of compelling evidence-based research, implementing changes in practice is challenging. The American Osteopathic Association implemented a 2-part Web program called the Call to Action on Pneumococcal Disease. Although some changes in attitudes and intent to change were demonstrated by this initiative, there were no statistically significant increases in self-reported actual adoption of standing order protocols or increases in adult pneumococcal immunization. Nonetheless, some lessons were learned, and these results support the need for ongoing efforts in this area of medicine.

J Am Osteopath Assoc. 2015;115(6 suppl 2):S6-S25
doi:10.7556/jaoa.2015.071

This supplement is supported by an independent educational grant from **Pfizer**.

A substantial gap exists in adult pneumococcal disease immunization (APDI) compared with recommended rates. The Centers for Disease Control and Prevention (CDC) has consistently found that pneumococcal vaccination coverage among adults is below target levels set by Healthy People 2020.¹ Thus, the gap between actual and target rates leaves much room for improvement.

The American Osteopathic Association (AOA) is cognizant of the performance gap in APDI and is partnering with Healthy People 2020, including the position on vaccine-preventable disease in general and pneumococcal disease specifically. Osteopathic physicians (ie, DOs) represent a large segment of medical professionals, and approximately 60% are engaged in primary care specialties in which they may be most effective in improving pneumococcal vaccination rates among adults.

In 2007, the AOA conducted a survey-based study to describe the practices of office-based primary care DOs and to compare them with those of allopathic physicians (ie, MDs).² The responders, including 220 DOs and 111 MDs, were asked to indicate areas of practice in which additional information would be most useful.² Adult vaccines were identified as the third-highest area of interest for both physician groups, preceded only by electronic medical records (EMRs) and pediatric vaccinations.² In another survey specifically designed to assess educational needs,³ to which more than 1000 DOs responded, preventive

health services was identified as the fifth-highest overall area of interest. When practice settings of the responders were analyzed, however, preventive health services was identified as 1 of 2 highest-ranked areas (along with obesity) among DOs practicing internal medicine and fourth-highest among urban-based DOs.³

As a result, the AOA issued a Call to Action on Pneumococcal Disease, which addressed several factors of interest:

- Adult immunization is an area of DOs' self-reported interest.
- Implementing this initiative builds on the AOA's existing partnership with Healthy People 2020.
- Compelling evidence suggests that the implementation of standing order protocols (SOPs) drives increases in vaccination rates for vaccine-preventable diseases.
- The opportunity is available to make DOs more aware of the facts relating to pneumococcal disease, help them understand what they can do to affect overall population health by increasing APDI rates, and give them the opportunity to take a leadership role in their practices by embracing SOPs and thus directly impact patient care by increasing pneumococcal vaccination rates.

To address DOs' educational needs that underlie the identified practice gaps and to serve as the outline for development of content for educational interventions, the objectives of the Call to Action were to describe how to (1) implement and man-

age SOPs for APDI within practice settings, (2) evaluate adult patients who are candidates for receiving APDI on the basis of current recommendations, and (3) increase provider recommendations for APDI to patients who should be vaccinated. In the present article, we discuss epidemiology of pneumococcal infections, pneumococcal vaccines, vaccination recommendations, patient concerns, and barriers to immunization, followed by a summary of the methods and outcomes from the Call to Action.

Epidemiology of Pneumococcal Infections

Worldwide, *Streptococcus pneumoniae* is a leading cause of pneumonia and other illnesses, including bacteremia and meningitis, and is a major cause of sinusitis and otitis media.^{4,5} Immunocompetent adults with certain underlying conditions, adults with functional or anatomic asplenia, and immunocompromised adults face increased risk of contracting pneumococcal disease (Table 1). In the United States, *S pneumoniae* accounts for approximately 175,000 hospitalizations per year and is responsible for 36% of community-acquired pneumonia cases and 50% of hospital-acquired pneumonia cases.⁶ It is a common complication of influenza and measles, and it is associated with a mortality rate of 5% to 7% among the general population and as high as 80% among elderly patients.⁶

According to US data collected in 2004, there were approximately 400,000 patients who were admitted to

Table 1.
Groups at Risk for Pneumococcal Disease

Risk Group	Medical Condition or Other Indication
Immunocompetent persons	Chronic heart disease (excluding hypertension) ^a Chronic lung disease ^b Diabetes mellitus Cerebrospinal fluid leaks Cochlear implant Alcoholism Chronic liver disease, including cirrhosis Cigarette smoking
Persons with functional or anatomic asplenia ^c	Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, splenic dysfunction, or splenectomy
Immunocompromised persons ^c	Congenital or acquired immunodeficiencies ^d HIV infection Chronic renal failure Nephrotic syndrome Leukemias Lymphomas Hodgkin disease Generalized malignancy Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids or radiation therapy Solid organ transplantation Multiple myeloma

^a Including congestive heart failure and cardiomyopathies.

^b Including chronic obstructive pulmonary disease, emphysema, and asthma.

^c A second dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23) is recommended 5 years after the first dose for persons with functional or anatomic asplenia and for immunocompromised persons.

^d Includes B-(humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

Source: Centers for Disease Control and Prevention (CDC); Advisory Committee on Immunization Practices. Updated recommendations for prevention of invasive pneumococcal disease among adults using the 23-valent pneumococcal polysaccharide vaccine (PPSV23). *MMWR Morb Mortal Wkly Rep.* 2010;59(34):1102-1106.

the hospital with pneumococcal pneumonia.⁷ Adults aged 65 years or older accounted for 80% of hospitalizations for pneumonia.⁷ Overall, there were 22,000 deaths resulting from pneumococcal disease, including 19,000 deaths from pneumonia.⁷ Adults aged 65 years or older accounted for 18,000 deaths,

with 91% of those deaths attributable to pneumococcal pneumonia.⁷

The CDC issued a report documenting its findings concerning *S pneumoniae* on the basis of data collected in 2013.⁸ The surveillance area covered more than 30 million people from different areas of the country.⁸ The report

defined invasive pneumococcal disease as the isolation of *S pneumoniae* from a normally sterile site.

Pneumonia with bacteremia accounted for 2152 cases per 100,000 population, amounting to 67% of cases, and bacteremia without focus and meningitis accounted for approximately 623 cases (19%) and 204 cases (6%) per 100,000, respectively.⁸

The report also estimated that invasive disease resulting from *S pneumoniae* accounted for 33,500 cases nationally (10.6 per 100,000), with an estimated 3500 fatalities (1.1 per 100,000).⁸ The CDC Healthy People 2020 Update includes the objective of reducing the rate of pneumococcal infections among adults aged 65 years or older to 31 per 100,000, which was exceeded in 2013 when the reported rate was 30 per 100,000.⁸

Pneumococcal Meningitis

Pneumococcal infections account for 13% to 19% of all cases of bacterial meningitis.⁶ Between 3000 and 6000 cases of pneumococcal meningitis occur annually, and approximately 25% of patients diagnosed with pneumococcal meningitis also have pneumonia.⁶ The fatality rate is 30%, but it may be as high as 80% among elderly patients.⁶ Survivors commonly experience neurologic sequelae. Patients who have had a cochlear implant may be at increased risk of pneumococcal meningitis.

Health Care Utilization and Cost of Disease

Data gathered in 2004 showed that almost 4 million cases of pneumococcal infections were reported, resulting

in nearly 5 million outpatient visits and 4.1 million outpatient prescriptions.⁷ In addition, 445,000 patients were hospitalized with pneumococcal disease; of that number, more than 90% had a diagnosis of pneumonia.⁷ Pneumococcal pneumonia accounted for 19,000 deaths, with approximately 16,000 deaths among adults aged 65 years or older.⁷ Pneumococcal infections resulted in 24,000 nursing home stays.⁷

The annual direct cost of pneumococcal disease was \$3.7 billion (2004 dollars), not including the loss of productivity and work loss; adults aged 65 years or older accounted for almost half of the cost (*Figure 1*). The loss in productivity because of death and disability was estimated to be \$3.1 billion.⁷ The total annual cost of pneumococcal disease was \$7.7 billion, with adults accounting for 84% of this amount.⁷ The costs among adults aged 18 to 64 years accounted for 34% but increased to 52% when including productivity and work loss.⁷

Pneumococcal Vaccines

As early as the 1890s, attempts were made to develop vaccines for pneumococci.⁹ These efforts focused on the development of purified pneumococcal capsular polysaccharides to immunize humans, and 2 vaccines were developed in the 1930s and 1940s to prevent pneumococcal infections. Although penicillin became the treatment of choice for pneumococcal disease, the increasing prevalence of strains of pneumococci that are resistant to penicillin led to renewed efforts to develop effective vaccines.

Pneumococcal Conjugate Vaccines

In 2000, the 7-valent pneumococcal conjugate vaccine (PCV7), which protected against 7 types of pneumococci, was introduced. Griffin et al¹⁰ examined pneumococcal data before the introduction of PCV7 and from 2007 through 2009 (well after its introduction) and observed declines in hospitalization rates. However, the incidence of pneumococcal disease from non-PCV7 serotypes increased, and in February 2010, the Advisory Committee on Immunization Practices (ACIP) recommended the introduction of the 13-valent pneumococcal conjugate vaccine (PCV13), which contains the 7 serotypes in PCV7 as well as 6 additional serotypes.¹¹ In late 2011, PCV13 was approved by the US Food and Drug Administration for use among adults aged 50 years or older. In 2012, the ACIP recommended the use of PCV13 and the 23-valent pneumococcal polysaccharide vaccine (PPSV23) for adults aged 19 years or older with immunocompromising conditions.

Tomczyk et al¹² cited the results of randomized, multicenter immunogenicity studies conducted in the United States and Europe on the efficacy of PCV13. Participants were immunocompetent adults aged 50 years or older who received a single dose of PCV13 or PPSV23. In adults aged 60 to 64 years and aged 70 years or older, PCV13 elicited opsonophagocytic activity geometric mean antibody titers that were comparable with, or higher than, responses elicited by PPSV23.¹² Opsonophagocytic activity geometric mean antibody titers

elicited by PCV13 in adults aged 50 to 59 years for all 13 serotypes were comparable with the corresponding geometric mean antibody titers elicited by administration of PCV13 in adults aged 60 to 64 years.¹² Persons who received PPSV23 as the initial study dose had lower opsonophagocytic antibody responses after subsequent administration of a PCV13 dose 1 year later than those who had received PCV13 as the initial dose.¹²

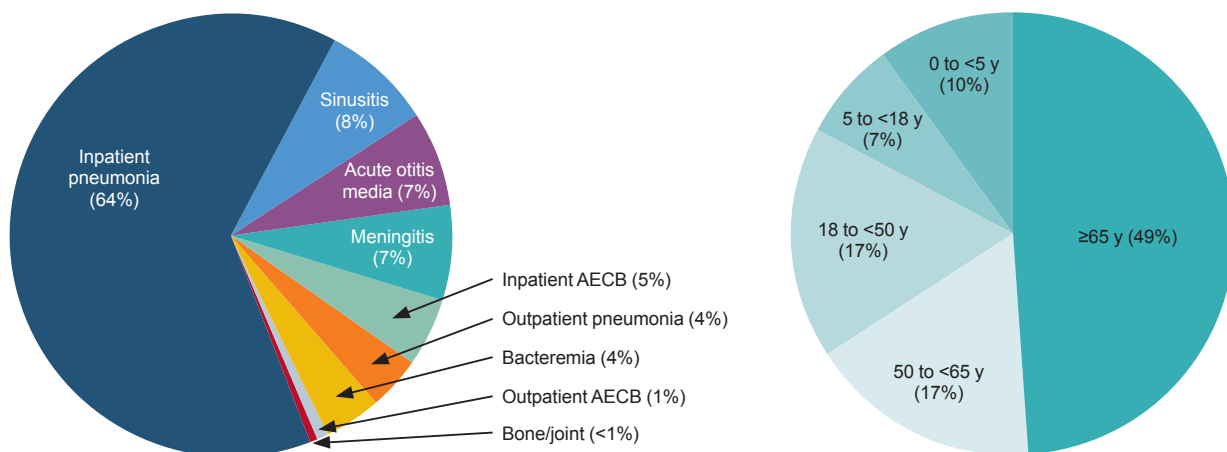
In June 2014, the results of a trial of PCV13 against community-acquired pneumonia among adults aged 65 years or older showed a moderate level of evidence supporting the use of PCV13 vaccination for older adults.¹² More recently, Bonten et al¹³ found strong evidence that the use of PCV13 among older adults was effective in preventing hospitalizations from pneumococcal pneumonia, adding that it did not prevent community-acquired pneumonia from any cause.¹³

According to current recommendations,¹² both PCV13 and PPSV23 should be routinely administered in a series to all adults aged 65 years or older. The recommendation for the use of PCV13 among adults in this age group will be reevaluated in 2018.¹² Recommendations from the ACIP for routine use of PCV13 in adults aged 19 years or older who have immunocompromised conditions, functional or anatomic asplenia, cerebrospinal fluid leak, or cochlear implants remain unchanged.

Safety Issues, Contraindications, and Precautions

Health care providers should be aware that PCV13 is contraindicated

Costs Without Productivity and Work Loss: \$3.7 Billion



Costs With Productivity and Work Loss: \$7.7 Billion

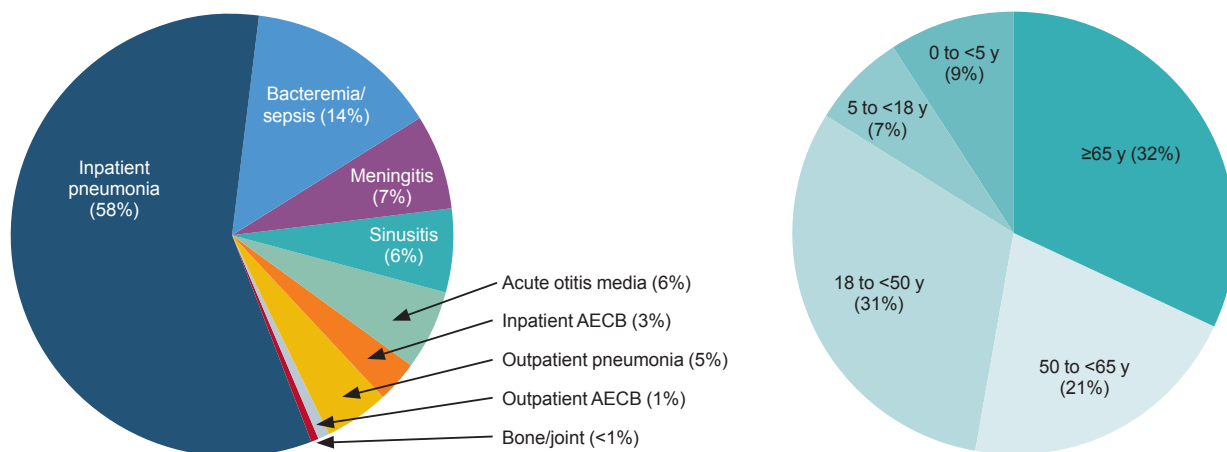


Figure 1.

Costs by disease categories and age for pneumococcal disease, comparing direct medical costs and total costs, including work loss and productivity costs. *Abbreviation:* AECB, acute exacerbation of chronic bronchitis. Reprinted from *Vaccine*, vol 29, ed 18, Huang et al, Healthcare utilization and cost of pneumococcal disease in the United States, 3398-3412, 2011, with permission from Elsevier.⁷

for people who (1) have had an anaphylactic reaction to a diphtheria-toxoid containing vaccine (because the antigens in PCV13 are conjugated to diphtheria CRM197 protein) or (2) have a history of anaphylactic hypersensitivity to any vaccine component.¹⁴ Precautions for PCV13 include moderate or severe acute illness with or without fever. The PCV13 packaging does not contain latex. The ACIP recommends that “the presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines”; the definition of “moderate or severe acute illness” is left to the discretion of the provider.

PPSV23

The first polysaccharide pneumococcal vaccine was introduced in the United States in 1977; it contained antigens from 14 different types of pneumococcal bacteria.¹⁵ In 1983, a PPSV23 was introduced and replaced the 14-valent vaccine; PPSV23 contains polysaccharide antigen from 23 types of pneumococcal bacteria that cause 88% of pneumococcal disease.

Safety Issues, Contraindications, and Precautions

This vaccine is contraindicated for individuals who have had a severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component. As is the case with PCV13, precautions for PPSV23 include moderate or severe acute illness with or without fever, at the discretion of the provider.

ACIP 2015 Recommendations for Use of PCV13 and PPSV23 in Adults

According to 2015 recommendations from the ACIP¹⁶ on the use of PCV13 and PPSV23, the following are recommended (*Figure 2*):

- When indicated, only a single dose of PCV13 should be given to adults.
- For adults vaccinated with PPSV23 at or after age 65 years, no additional dose of PPSV23 is indicated.
- When both PCV13 and PPSV23 are indicated, PCV13 should be administered first; PCV13 and PPSV23 should not be administered during the same visit.
- When indicated, PCV13 and PPSV23 should be administered to adults whose pneumococcal vaccination history is incomplete or unknown.
- For adults aged 65 years or older who have not received PCV13 or PPSV23, PCV13 should be administered followed by PPSV23 in 6 to 12 months.
- For adults aged 65 years or older who have not received PCV13 but have received a dose of PPSV23 at age 65 years or older, PCV13 should be administered at least 1 year after the dose of PPSV23 received at age 65 years or older.
- For adults aged 65 years or older who have not received PCV13 but have received 1 or more doses of PPSV23 before age 65 years, PCV13 should be administered at least 1 year after the most recent dose of PPSV23; another dose of PPSV23 should be administered 6 to 12 months after PCV13, or as soon as possible if this time window has passed, and at least 5 years after the most recent dose of PPSV23.
- For adults who have received PCV13 but not PPSV23 before age 65 years, PPSV23 should be administered 6 to 12 months after PCV13 or as soon as possible if this window has passed.
- For adults who have received PCV13 and 1 or more doses of PPSV23 before age 65 years, PPSV23 should be administered 6 to 12 months after PCV13, or as soon as possible if this time window has passed, and at least 5 years after the most recent dose of PPSV23.

Although the ACIP recommends waiting 6 to 12 months after administration of PCV13 to older adults before PPSV23 is given, the Centers for Medicare & Medicaid Services (CMS) requires at least 11 months between doses before they will pay for the vaccine.¹⁷

The ACIP also recommends pneumococcal immunization for adults aged 19 through 64 years with immunocompromising conditions or anatomical or

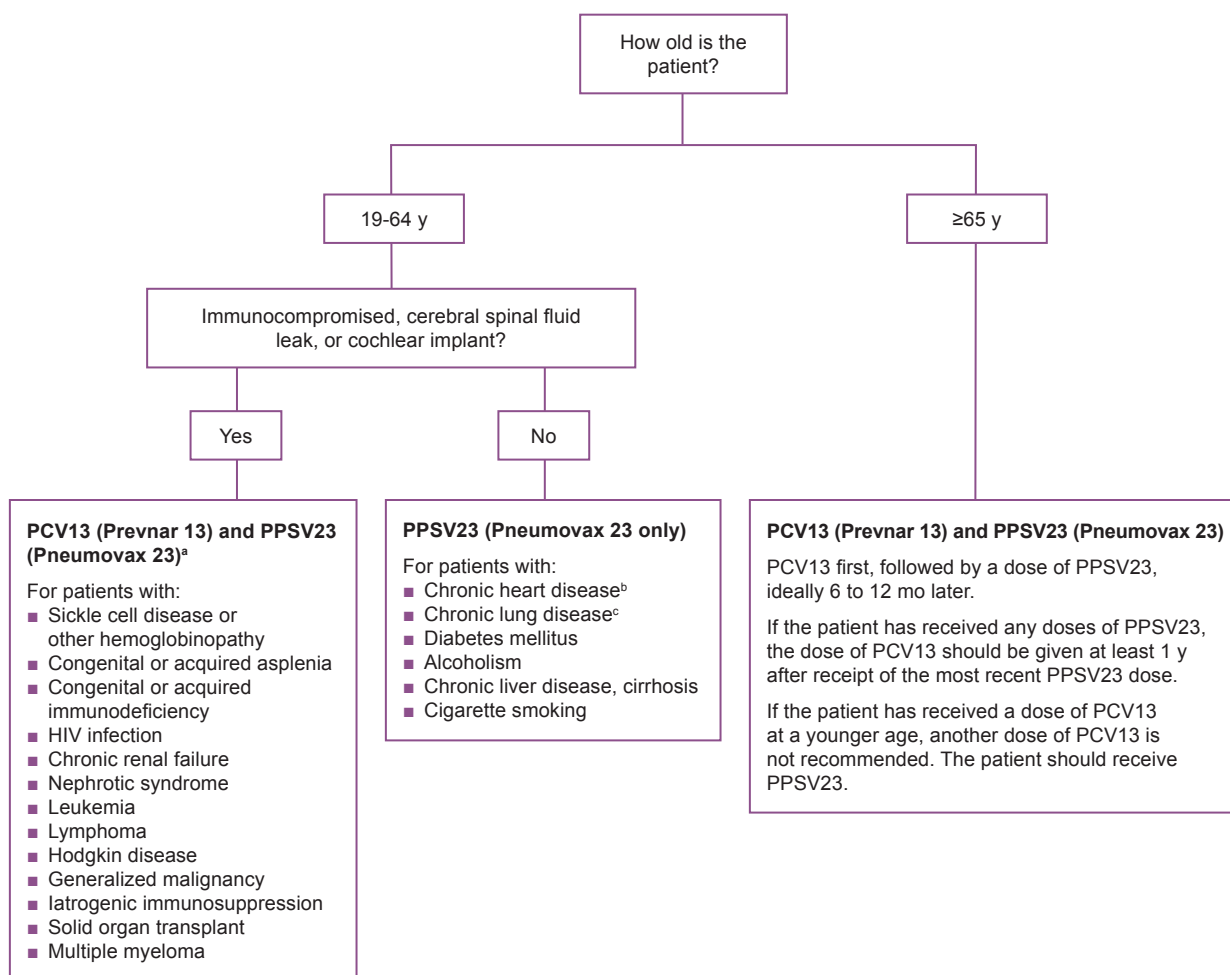


Figure 2.

Pneumococcal vaccination of high-risk adults.^{12,16,18} Provided courtesy of Dale W. Bratzler, DO.

^aAll patients aged 19 through 64 years who are immunocompromised or who have functional asplenia should receive PCV13 followed by PPSV23 at least 8 weeks after their PCV13 dose.

These patients should also be revaccinated with PPSV23 at least 5 years after their first PPSV23 dose. Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders. Diseases requiring treatment with immunosuppressive drugs, including long-term corticosteroids and radiation therapy. ^bIncluding congestive heart failure and cardiomyopathies (excluding hypertension).

^cIncluding chronic obstructive pulmonary disease, emphysema, and asthma. *Abbreviations:* PCV13, 13-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine.

functional asplenia, as listed in *Table 1*. For these patients, health care providers should administer pneumococcal vaccines at least 2 weeks before immunosuppressive therapy or an elective splenectomy and as soon as possible to adults who have newly diagnosed asymptomatic or symptomatic HIV infection.

For these patients with immunocompromising conditions or anatomical or functional asplenia as defined in *Table 1*, the recommendations for immunization are as follows (*Figure 3*)¹⁸:

- For patients who have not received either PCV13 or PPSV23, PCV13 should be administered followed by PPSV23 at least 8 weeks after PCV13; a second dose of PPSV23 should be given at least 5 years after the first dose.
- For patients who have not received PCV13 but have received 1 dose of PPSV23, PCV13 should be administered at least 1 year after PPSV23; a second dose of PPSV23 should be given at least 8 weeks after PCV13 and at least 5 years after the first dose of PPSV23.
- For patients who have not received PCV13 but have received 2 doses of PPSV23, PCV13 should be administered at least 1 year after the most recent dose of PPSV23.
- For patients who have received PCV13 but not PPSV23, PPSV23 should be given at least 8 weeks after PCV13; a second dose of PPSV23 should be given at least 5 years after the first dose.

- For patients who have received PCV13 and 1 dose of PPSV23, a second dose of PPSV23 should be given at least 5 years after the first dose of PPSV23.

For adults aged 19 through 64 years with cerebrospinal fluid leaks or cochlear implants, PCV13 should be administered followed by PPSV23 at least 8 weeks after PCV13.¹⁸

For immunocompetent adults aged 19 through 64 years with chronic heart disease (including congestive heart failure and cardiomyopathies, excluding hypertension), chronic lung disease (including chronic obstructive lung disease, emphysema, and asthma), chronic liver disease (including cirrhosis), alcoholism, or diabetes mellitus, PPSV23 should be administered.¹⁸ Also, PPSV23 should be given to adults aged 19 through 64 years who smoke cigarettes or reside in nursing homes or long-term care facilities.

In addition, routine pneumococcal vaccination is not recommended for American Indians/Alaska Natives or other adults unless they have the indications as above; however, public health authorities may consider recommending the use of pneumococcal vaccines for American Indians/Alaska Natives or other adults who live in areas with high risk for invasive pneumococcal disease.¹⁶

Addressing Patient Concerns

Although many patients will comply with the offer of vaccination, patients have

the right to refuse. If a patient declines vaccination, the practitioner should continue to discuss the issue and focus on concerns that may cause reticence to vaccinate. In particular, the practitioner should revisit data about the safety of the vaccines, inform the patient that there are preservative-free preparations of the vaccine, and, if needed, counsel the patient that herd immunity reduces the risk of disease within the community. If a patient refuses the administration of a vaccine, the result of this failure to vaccinate will increase the patient's vulnerability to that disease.

Patients with chronic diseases and other risk factors not included above may present special issues for the practitioner. The information that follows has been summarized from the Immunization Action Coalition website,¹⁹ which also contains useful information about administering the vaccine.

Dialysis Patients

An adult dialysis patient who is younger than 65 years needs a dose of PPSV23 followed by a second dose 5 years later. When the patient reaches age 65 years, he or she will need another dose. If the patient was aged 65 years when first vaccinated, a single dose of PPSV23 is recommended.

Patients With Preexisting Pneumococcal Disease

Even patients who have had pneumococcal disease should receive PPSV23 because the vaccine will immunize them against the 23 serotypes known to produce illness and may reduce the risk of pneumococcal disease later in life.

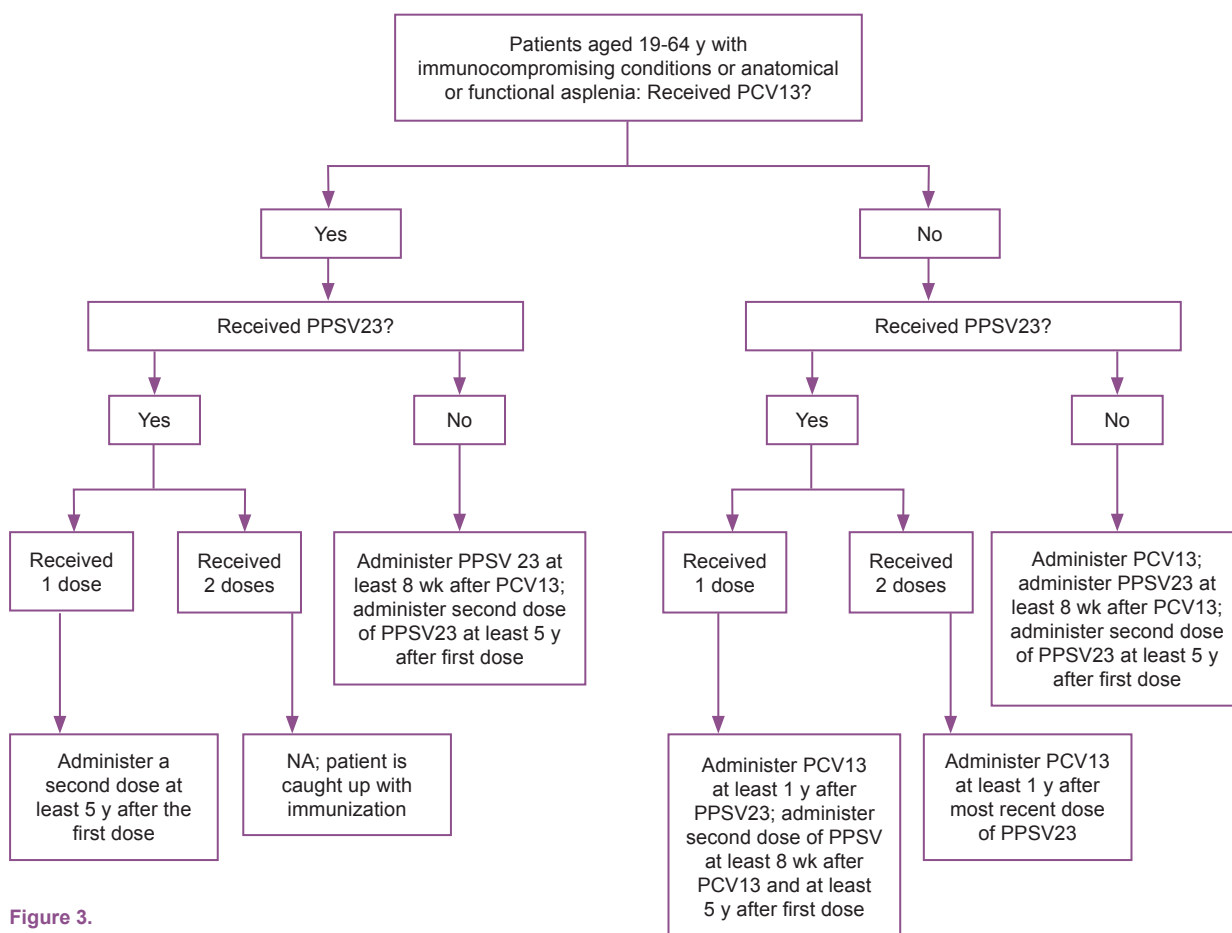


Figure 3. Flowchart of pneumococcal vaccination recommendations for patients aged 19 to 64 years with immunocompromising conditions or anatomical or function asplenia.¹⁸ *Abbreviations:* NA, not applicable; PCV13, 13-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine.

Pregnant Women

The PPSV23 vaccine is recommended for pregnant women if a risk factor for pneumococcal disease is present.

Patients to Receive

Immunomodulatory Therapy

Patients with conditions that will be treated with immunomodulatory therapy (eg, rheumatoid arthritis, inflammatory bowel disease, psoriasis) should have their vaccination status updated in line

with current ACIP recommendations before beginning this therapy, as there is an increased risk of serious infections with these agents.

Improving Vaccination Rates

Barriers

According to the CDC, immunization rates among adults are considerably below optimal levels.^{20,21} The CDC sum-

marized the results of data from the 2011 National Health Interview Survey, including data for pneumococcal vaccines, and showed low levels of improvement in the use of many vaccines. Among adults at high risk aged 19 to 64 years, the rate of pneumococcal vaccination increased 1.6%; for adults aged 65 years or older, the rate increased by 2.6%.²⁰ These rates are substantially below the Healthy People 2020 Goals for these age groups (Table 2).

In the United States, adults are seen periodically, if not regularly, in health care systems. The gap between actual and target rates of APDI is a result of several barriers, including the following:

- **Systems barriers**—Absence of structure for ensuring adult vaccinations; lack of regular well-care visits for adults; switching of providers and medical plans; provision of care by subspecialists who do not consider immunizations their responsibility; inconsistent reimbursement; lack of health care insurance or access to a provider; inadequate vaccine storage.²¹
- **Health care providers**—Lack of awareness of current ACIP recommendations; not recommending vaccines to patients who need them; not assessing immunization status; lack of communication among staff members about patients' vaccination needs; lack of feedback on performance in this area.²¹
- **Patients**—Discrepancies between a physician's perception and a patient's actual reasons for not wanting to receive vaccinations; common myths related to vaccinations.²²
- **Practice settings**—Outpatient private practice, where there may be a low priority given to vaccines compared with other medical needs and lack of inquiry about a patient's vaccination status; hospitals, where there may be a lack of adequate documentation and communication among health care providers;

Table 2.
Vaccination Rates Against Pneumococcus by Age Group

Age Group, y	Healthy People 2020 Goal	Actual Immunization Rates (2011)
19-64	60%	20.1%
≥65	90%	62.3%

Source: Centers for Disease Control and Prevention (CDC). Noninfluenza vaccination coverage among adults—United States, 2011. *MMWR Morb Mortal Wkly Rep.* 2013;62(4):66-72.¹⁹

public health clinics, where there may be a lack of commitment to vaccination, lack of information about vaccines in languages patients can understand and at the appropriate reading level, and lack of Internet access; extended care facilities, where there may be lack of a systematic approach to vaccination and lack of monitoring.²³

For these reasons, many adults remain unvaccinated. Thus, improving practices by health care providers and in practice settings are key components to increasing vaccination rates.

The knowledge gap reported by health care providers regarding ACIP vaccine recommendations is surprisingly large. In a survey conducted in the United States of 100 primary care physicians and 100 nurse practitioners, physician assistants, and registered nurses, almost 50% reported that they did not rely on CDC or ACIP vaccination guidelines.²⁴ Numerous knowledge gaps regarding specific vaccine recommendations were also documented in a national survey of primary care practitioners.²² When presented with different case scenarios in which knowledge of pneumococcal disease vaccination

or revaccination needed to be demonstrated, all practitioners showed substantial knowledge gaps. Many of the respondents reported having no method in place to keep themselves up to date on changes in pneumococcal immunization practices, and most respondents rated themselves to be not particularly effective in keeping up to date regarding changes in pneumococcal disease prevention recommendations.

The survey findings and the accompanying qualitative provider interviews also uncovered lack of knowledge about smokers younger than 65 years needing to receive the pneumococcal vaccine, confusion about who is considered immunocompromised, confusion on revaccination of patients who received the first vaccine before age 65 years, uncertainty about what to do when immunization status is unknown, and incorrect beliefs about vaccine effectiveness.²²

A related performance gap occurs when providers do not assess immunization status and do not provide missing immunizations. Nowalk et al conducted 2 studies^{25,26} of immunization rates among adults aged 65 years or older. One study²⁶ noted the high frequency of missed opportunities to vaccinate against pneumococcal disease

as compared with vaccination against influenza, as well as a low rate of patient refusal to be vaccinated when the opportunity was offered. The authors also noted that providers' failure to discuss vaccination and to vaccinate during acute care visits as well as the low frequency of preventive visits contributed to the high rate of missed opportunities to vaccinate. In addition, a report issuing the results of a survey conducted by the Infectious Diseases Society of America noted that 47% of providers reported always or almost always reviewing the patients' immunization history; only one-third reported providing the missing immunizations.²⁷

Tools to Improve Rates

The Guide to Community Preventive Services (Community Guide) is a free resource to help practitioners choose programs and policies to improve health and prevent disease. The information in the Community Guide is assembled by the nonprofit, volunteer Community Preventive Services Task Force, whose members are appointed by the director of the CDC. This task force conducts systematic reviews of many public health issues, including assessing and improving low vaccination rates.²⁸ The task force's goals are evidence-based and focus on using more interventions that have been shown to work, using fewer interventions that have been shown not to work, and encouraging more research into interventions without ample evidence to say whether they work.

The task force has issued a series of recommendations designed to improve vaccination rates (Table 3) and

rated interventions as recommended, recommended against, or insufficient evidence. Based on these findings, the practical components of an effective program for medical practices should include (1) using EMRs, (2) engaging nonphysician staff in assessing vaccination history and administering vaccines, (3) adopting SOPs, and (4) implementing strong provider recommendations to vaccinate.

Use of EMRs

The Health Information Technology for Economic and Clinical Health (HITECH) Act, which was signed into law in 2009, includes detailed plans for adopting the use of EMRs.²⁹ The CMS has developed a program that involves 3 stages of meaningful use of electronic technology; the term *meaningful use* indicates that certified electronic health technology be used in ways that can be measured qualitatively and quantitatively.²⁹ The CMS rules include incentives and penalties, some of which have a deadline in 2015.

A systematic review³⁰ published in 2011 showed that EMR implementation contributed marginally to improved patient health. Although primary care physicians had positive impressions of EMR as a driver in improving the quality of care, the review³⁰ found that the results of measured quality indicators were mixed, as was the impact of EMRs in other clinical care settings. The review³⁰ also cautioned that primary care physicians need to allow time for staff training when rolling out EMR systems but added that savings occurred over time.

Electronic medical record systems include functions that remind practitioners when patients are due for vaccinations and provide the capacity to document patients' vaccination records. Loo et al³¹ published the results of a study showing that EMR reminders alone led to major improvements in providing pneumococcal vaccinations for patients aged 65 years or older, with as many as twice the number of patients being vaccinated after the implementation of an EMR system.³¹ This study³¹ also supported the use of a team-based approach to deliver care.

Involving Nonphysician Staff

Implementing the participation of nonphysician staff to improve immunization levels involves using a consistent and thorough approach to change existing practice, including the following:

- Incorporate immunization into nurse screening along with other metrics (eg, smoking status and pain level).
- Track immunization information of new patients.
- Provide educational data in waiting rooms and examination rooms.
- Encourage nurses and physicians to review immunization status at each visit.
- Ensure that all clinical staff strongly recommend scheduled immunizations.

Lau et al²¹ conducted a systematic review of the effectiveness of quality improvement interventions designed to increase pneumococcal vaccination

Table 3.
Community Preventive Services Task Force
Recommendations for Increasing Appropriate Vaccinations

Intervention	Recommendation	
	Status	Date
Enhancing Access to Vaccination Services		
Home visits to increase vaccination rates	Recommended	March 2009
Reducing client out-of-pocket costs	Recommended	October 2008
Vaccination programs in women, infant, and children settings	Recommended	March 2009
Increasing Community Demand for Vaccinations		
Client or family incentive rewards	Recommended	April 2011
Client reminder and recall systems	Recommended	February 2008
Client-held paper immunization records	Insufficient evidence	March 2010
Clinic-based education when used alone	Insufficient evidence	February 2011
Community-wide education when used alone	Insufficient evidence	March 2010
Community-based interventions implemented in combination	Recommended	June 2010
Monetary sanction policies	Insufficient evidence	April 2011
Vaccination requirements for college attendance	Recommended	June 2009
Provider- or System-Based Interventions		
Health care system-based interventions implemented in combination	Recommended	December 2010
Immunization information systems	Recommended	July 2010
Provider assessment and feedback	Recommended	February 2008
Provider education when used alone	Insufficient evidence	March 2010
Provider reminders	Recommended	June 2008
Standing orders	Recommended	June 2008

Source: Adapted from Increasing appropriate vaccination. Guide to Community Preventative Services website. <http://www.thecommunityguide.org/vaccines/index.html>. Accessed April 21, 2015.

rates among adults. They concluded that team change (in which nurses were assigned responsibility for administering vaccinations), patient outreach, and clinician reminders were especially effective in improving vaccination rates.

Involving office staff thus can enhance care and prevent morbidity and mortality. Tracking the number of patients immunized, especially in the

context of a team approach, can be rewarding to staff members. Additionally, the use of a team approach allows a nonphysician to emerge as an immunization champion.

SOPs

An SOP for vaccination may be defined as a system in which nonphysician medical personnel assess a patient's immu-

nization status and administer vaccines according to an approved protocol without direct physician involvement. Standing order protocols are currently in use in inpatient and outpatient facilities and community pharmacies in most states.

A task force assembled by the Community Guide found strong evidence to recommend the use of SOPs for vaccination.²⁸ In its systematic review,

the task force looked at data from 29 studies conducted from 1997 to 2009.²⁸ The results of the systematic review showed a median increase in vaccination rates of 24%—an increase of 17% when SOPs were used alone and an increase of 31% when SOPs were used with other interventions.²⁸ Standing order protocols were effective in increasing vaccination rates in a wide range of clinical settings and among a variety of providers and patient populations; SOPs increased influenza and pneumococcal vaccine delivery to adults. The results found no evidence of harm in using SOPs to improve vaccination rates.

The Immunization Action Coalition is another key resource available to clinicians interested in implementing SOPs for vaccination. This coalition (<http://www.immunize.org>) provides educational materials for health care professionals and the public to improve safe and effective immunization. The Immunization Action Coalition also facilitates communication about the safety, efficacy, and use of vaccines and has worked with the CDC to educate health care professionals about vaccine recommendations. Its website includes examples of SOPs for pneumococcal vaccines for teenagers and adults. These practical and concise 1-page documents identify patients who need vaccination by age and comorbidities (according to ACIP recommendations), specify when to administer PPSV23 and PCV13, include contraindications and precautions, contain information on reporting to the Vaccine Adverse Event Reporting System, and have a space for the medical director's signature.

Stinchfield³² identified the implementation of SOPs that allow nonphysicians to vaccinate and strong provider recommendations for vaccination as the most effective strategies to overcome barriers to vaccine uptake. The effectiveness of SOPs in increasing vaccination rates for influenza and pneumococcal disease is well established in the inpatient setting.³³ In outpatient settings, SOP use improved influenza vaccination rates among a general elderly patient population,³⁴ among cardiovascular patients at a lipid clinic,³⁵ and among pregnant women.³⁶ In a study of patients in dialysis clinics, SOP use significantly increased pneumococcal and hepatitis B vaccination rates.³⁷

The use of SOPs is endorsed by the CDC and the ACIP,³⁸ the Task Force for Community Preventive Services,³⁹ and the Southern California Evidence-Based Practice Center-RAND.⁴⁰ In 2002, regulations from the CMS prohibiting SOPs for medication administration were modified to exclude influenza and pneumococcal immunizations.⁴¹ Studies have demonstrated that SOPs are more effective in increasing vaccination rates than clinician or patient reminder systems.^{42,43}

Still, the use of SOPs for adult immunization remains low. A nationwide survey⁴⁴ of physicians that analyzed the responses of 900 physicians who reported immunizing adults in their practice found that the strength of agreement about the effectiveness of SOPs was a key predictor for their adoption. These results suggest that 2 aspects of the "Awareness-to-Adherence" model of physician adoption of vaccines—awareness of and agreement with the

effectiveness of the SOP—were associated with the use of SOPs.⁴⁴ A further analysis⁴⁵ of this sample of primary care physicians revealed that only 23% reported using SOPs consistently for both influenza and pneumococcal vaccination. The use of SOPs for pneumococcal vaccination alone was rare.⁴⁵ Physicians in practices with SOPs for both vaccines reported greater awareness of ACIP recommendations and CMS regulations and were more likely to agree that SOPs are an effective way to boost vaccination coverage. Implementation of SOPs for influenza and pneumococcal vaccines was associated with several practice-level factors as well, including more effective practice teamwork, presence of an immunization champion, and greater availability of clinical assistants with more advanced training than that of medical assistants.⁴⁵

Access to physician assistants or licensed nursing personnel was a significant correlate of SOPs for pneumococcal vaccine. Physicians in practices with access to these more highly trained personnel were twice as likely to have SOPs for pneumococcal and influenza vaccines. This association may be related to the complexity of pneumococcal vaccination and recommendations for high-risk patients.⁴⁵

Additionally, the presence of an EMR system was similarly associated with SOPs for pneumococcal vaccination compared with SOPs for influenza vaccination. Electronic medical records make it easier for practitioners to track immunization histories and flag patients who should be vaccinated.⁴⁶ The Medicare Incentive Program for EMR usage may

further facilitate the use of SOPs and thus increase adult vaccination rates.⁴⁷

In addition, the CDC administers the AFIX program, which is designed to educate health care personnel about—and provide resources on—improving immunization practices.⁴⁸ An outcome-oriented program, AFIX is used nationwide by public and private vaccination providers and is recommended by governmental and nongovernmental vaccine programs and medical professional societies. The program includes the following steps, which are provided in more detail in *Table 4*⁴⁸:

- Assessment of the immunization coverage of public and private providers
- Feedback of diagnostic information to improve service delivery
- Incentives to motivate providers to change immunization practices or recognition of improved or high performance
- eXchange of information among providers

The Comprehensive Clinic Assessment Software Application is a tool that assesses immunization coverage and practices in clinical settings that provide immunizations. This software is designed to be used in conjunction with the AFIX program and has immunization data entry and immunization information systems data import capabilities. After immunization data are entered or imported into the application, data can be analyzed and reports generated to focus on areas that are successful and those that need improvement.

Implementing Strong Provider Recommendations

Adult patients rely on provider recommendations when deciding whether to get immunized, especially for pneumococcal vaccine. A survey of more than 2000 adults indicated that lack of physician recommendation was among the most common reasons for not receiving immunizations.²⁴ Conversely, the reason most frequently given by unvaccinated respondents for not being vaccinated was that they did not know they needed it.⁴⁹ In a survey of persons aged 65 years or older, health care provider recommendation emerged as the most important factor associated with influenza and pneumococcal vaccine status. Even among patients with a negative attitude toward vaccination, most were vaccinated if their provider recommended it.⁵⁰

Legal Issues

In 2002 the CMS eliminated the requirement for a physician signature for flu and pneumococcal vaccinations for hospitals, long-term care facilities, and home health agencies that provide care for Medicare and Medicaid patients.⁵¹ The risk of litigation for pneumococcal immunizations, along with influenza and the combined tetanus, diphtheria, and pertussis vaccines, is small because these vaccines are covered by the federal no-fault National Vaccine Injury Compensation Program and claims must be filed with the US Court of Federal Claims. However, knowledge of vaccine reactions is essential; information about vaccine reactions is available at <http://www.immunize.org/handouts/vaccine-reactions.asp>.

The Patient Protection and Affordable Care Act requires health plans to cover preventive services and eliminates cost sharing for adults aged 65 years or older and for adults aged 19 to 64 years who are at risk for pneumococcal disease.⁵² For individuals or families who have enrolled in a new health plan on or after September 23, 2010, the plan is required to cover the cost of vaccines recommended by the ACIP before September 2009 with no copayments or other cost-sharing requirements when those services are delivered by an in-network provider. In addition, new health plans will be required to cover new ACIP recommendations made after September 2009 without cost-sharing in the next plan year that occurs 1 year after the date of the recommendation.

Moving From Evidence to Practice: An Ongoing Process

Physicians are deluged by a constant volume of new information about improving their practices.⁵³ Barriers include the challenge of finding the time to stay current with the quantity of relevant published research and organizational, peer group, and individual barriers. The gap between evidence-based innovations and actual clinical practice is the subject of considerable research, including exploring aspects of behavior that are modifiable, identifying barriers and facilitators of change, and estimating how to disseminate and implement strategies.

Table 4.
Steps of the AFIX Program for Educating Health Care Personnel on Immunization Practices⁴⁸

Step	Description
A: Assessment of the immunization coverage of public and private providers	To determine the immunization rate for a defined group of patients by evaluating medical records To diagnose possible service delivery problems To increase awareness
F: Feedback of diagnostic information to improve service delivery	To inform immunization providers about their performance To create the awareness that can facilitate behavioral change To provide feedback with precision, without judgment, and with confidentiality
I: Incentives to motivate providers to change immunization practices or recognition of improved or high performance	To incite appropriate action that varies by provider and stage of progress To provide opportunities for partnership and collaboration
X: eXchange of information among providers	To allow individual providers access to the experience of others To motivate performance improvement To coordinate resources and efforts

Consensus exists that all participants in health care systems will need to collaborate in this complex effort, and organizational and behavioral changes are essential to this process.⁵⁴ In 2002, a meta-analysis⁵⁵ of interventions to increase the use of adult immunizations and cancer screening showed that the most important interventions focused on organizational change, including the use of specific clinics devoted to prevention, planned care visits for prevention, and designated nonphysician staff to perform specific activities.

Improving Vaccination Rates Among DOs

The primary aim of the AOA's Call to Action on Pneumococcal Disease was to increase the percentage of adults vaccinated against pneumococcal disease in DO practices by (1) increasing the number of DO practices that use

SOPs for APDI and (2) increasing the frequency of use of existing SOPs for APDI in those outpatient DO practices that have already adopted them.

The secondary aims of this initiative were (1) to provide information that will enable DOs to assess who should be immunized for pneumococcal disease based on the ACIP's 2015 recommendations, (2) to increase the use of patient education interventions about APDI in DO practices, and (3) to increase the proportion of DO practices in which physicians and staff actively recommend pneumococcal vaccination to all patients who should be immunized on the basis of ACIP guidelines.

Design of the Call to Action Initiative

The intended primary audience for the Call to Action was the cohort of DOs who are primary care physicians or those who practice family medicine.

The goal was to have 250 members of this group enroll and complete the program. The protocol for this educational outcomes measurement study was reviewed and approved by an independent institutional review board registered with the US Food and Drug Administration and the Office of Human Research Protection. At the end of the first 30-minute on-demand webcast, which was available on a dedicated Web portal, participants were asked if they were interested in watching a second webcast that focused on SOP and the value of active physician participation in recommending APDI. In addition, participants were asked to enroll in the initiative and participate in a series of surveys that would track the effectiveness of the education in promoting changes in practice.

Some physicians participated in this initiative without watching the first webcast; we believe they were aware of the

gap in practice and therefore chose to enroll. The second webcast was also available for those who did not participate in the surveys. *The Journal of the American Osteopathic Association* also offered online surveys directly relating to the content of the educational activity and were designed to assess the degree of knowledge transfer (immediate learning) and intent to change that occurred. Participants in all surveys were informed that their responses would be treated anonymously and reported in aggregate only. Those formally enrolled in the initiative were also asked to participate in a final survey that included the same questions on the first survey as well as questions regarding barriers to implementing changes in practice related to APDI. This survey invitation was sent out approximately 3 months after the second webinar to allow time for implementation of changes in practice.

All survey responses were downloaded in Excel format (Microsoft Corporation) and sent to the investigators (S.E.G. and J.S.). The Postgraduate Institute for Medicine conducted the statistical analysis and initial interpretation of the data. Personally identifiable information obtained from the pre- and postsurveys for the second educational session was removed before analysis; these data were compared using both aggregate and matched-pair analysis. Only the AOA and the primary investigator (S.E.G.) had access to the list of participants to determine the matched-pair participants.

Summarizing Survey Data

A total of 255 individuals participated in the presurvey for the initiative, which

established baseline knowledge and practice among this group of DOs. A total of 170 participants took part in the second webcast, 107 completed the initial survey, and 18 completed the 3-month follow-up survey.

Data obtained from the surveys included demographic information (including specialty areas and ages of patients seen in practice), perceived barriers to implementing SOP, participation by nonphysician personnel in immunization processes, and knowledge of ACIP recommendations for pneumococcal vaccines. Questions were directly linked to the learning objectives for this initiative. In general, the results demonstrated the effectiveness of the educational design for the webcasts in producing immediate learning and intent to change. However, the data also showed a large remaining gap in reaching the Healthy People 2020 goal for immunizing adults older than 65 years.

Demographics

Data showed that 69% of the participants in the baseline presurvey conducted before the first webinar and 73% of those completing the postsurvey were in primary care specialties and, thus, were most likely to address immunization status. In addition, both survey populations had a similar number of years in practice, although the postsurvey group had a slightly higher percentage of clinicians with more than 10 years in practice. Participants in webinar 2 reported an average patient load of 55 adults older than 19 years per week.

Prevalence of

Pneumococcal Vaccination

The data showed a large deficit in meeting the Healthy People 2020 goal for APDI immunization for adults older than 65 years, which is 80%. Slightly more than 70% of respondents reported APDI rates in their practice at 50% or lower.

Barriers to Improving

Immunization Rates

Among participants with SOPs in place, the total percentages of pre- and postsurvey respondents identifying barriers was 50%. However, the number of perceived barriers per participant decreased in the postsurvey group (presurvey: 71% with more than 2 barriers identified; postsurvey: 40%), perhaps indicating that participants were able to implement SOPs because they encountered fewer barriers.

Among the presurvey responses, a high percentage of participants identified the lack of regular well-care visits for adults and reliable immunization history as well as reimbursement issues and patient resistance as major barriers. This finding was true regardless of whether the participant had SOPs in place or not. In the postsurvey responses, reimbursement issues and patient resistance were the only barriers to exceed 20% by those who had SOPs in place. Although the low number of postsurvey responses makes it difficult to draw any statistically reliable conclusions, the results suggest that seeing patients during regular well-care visits may correlate with SOP adoption.

Physician Recommendation for Pneumococcal Immunization

Although statistical analysis did not support demonstration of change in physician recommendations, the actual numbers showed a slight trend toward adopting this strategy in practice. However, the results of routine review of immunization history for adult patients older than 50 years during every visit suggest a trend toward implementing this strategy after participating in the educational initiative. The lack of statistical significance for these findings may be a result of the small number of participants.

SOPs for Pneumococcal Immunization

According to webinar 2 results, most participants intended to support adopting a strategy of engaging nonphysician participation in APDI SOPs, indicating a statistically significant demonstration of gains in competence (defined as the ability/likelihood to engage in a strategy while still within the educational activity). As many as 107 clinicians intended to support this strategy frequently or always, which could affect as many as 5885 patients per week. Among postsurvey participants, there appeared to be an increase in the perception of the effectiveness of APDI SOPs for adult patients, which would support greater adoption of SOPs by these practitioners. However, because greater adoption of SOPs did not occur, it is possible that barriers to implementation might have negatively affected adopting SOPs. This apparent lack of change between pre- and postsurvey responses to use SOPs to provide pneumococ-

cal vaccination for adults older than 65 years supports the conclusion that the study did not reach its primary end point of increasing the adoption of SOP for APDI.

Review of Vaccination Status During Each Patient Visit

According to webinar 2 participants, postsurvey results showed a statistically significant shift ($P < .05$) toward agreement with the strategy of the physician or clinical staff reviewing vaccination status for each patient and strongly recommending vaccination when indicated. If implemented, this strategy could impact 6215 patients per week. These results also indicate that some of the learning objectives for this webinar and initiative were met.

Tobacco Use

Among presurvey respondents, 29% either disagreed or mildly agreed with the evidence-based assertion that “all tobacco users younger than 65 years should be educated about APDI and encouraged to receive the pneumococcal vaccine,” indicating ambivalence about this recommendation. This ambivalence appears to have decreased in the postsurvey, with 18% either in disagreement or mild agreement; however, statistical analysis of the matched pairs did not reveal statistically significant findings, possibly because of the small number of matched pairs. However, participants in the entire initiative appeared to have increased awareness of the need to educate tobacco users in the importance of protecting themselves against pneumococcal disease.

ACIP Recommendations for Pneumococcal Vaccination

The presurvey responses to the question, “Which patients under 65 years of age would you consider including in [APDI] standing orders?” indicated a lack of awareness of the current recommendations for immunizing some patients younger than 65 years; this deficit continued in postsurvey responses and indicate a need for more education on this point.

Limitations

The Call to Action was an educational outcomes study that relied on self-reported data rather than objective information on current physician practices. Self-reported data are subject to respondent bias and inaccuracy. However, they can provide an indication of the state of attitudes and likelihood of engaging in the desired behaviors. Although there were sufficient participants in the overall educational initiative (webinars 1 and 2) to produce reliable statistical data with regard to learning and competence, the limited number of participants in the 3-month postsurvey affected the lack of demonstration of substantial improvement in adoption of SOPs. The possibility also existed for response bias in favor of change among postsurvey respondents, indicating that participants may have been more eager to claim change than to admit that no change occurred.

Overall, the results were mixed. Future studies must carefully evaluate methods for effectively recruiting and engaging learners over the course of an initiative, including ways to increase participation in the final postsurvey where

actual practice change is assessed. Consideration should also be given to evidence sources other than voluntary participant surveys for demonstration of current practice. Also, one suggested area of future study is the impact of the provisions of the Patient Protection and Affordable Care Act requiring insurers to cover preventive care.

We hope that the Call to Action has offered persuasive evidence of the need for improving APDI rates. Although we agree with Lau et al²¹ that stronger interventions need to be devised and evaluated to meet national vaccination goals, we believe that the information provided herein will provide a good starting point to reach our objective.

Conclusion

Pneumococcal disease, including pneumonia, meningitis, sinusitis, and otitis media, is a major cause of serious illness. Although immunization is an effective means of preventing pneumococcal disease, data collected by the CDC show low immunization rates among adults, especially among low-income and minority adults. According to the CDC, health care providers have a key role in improving immunization rates. Strategies to improve vaccination rates include the use of EMRs, engaging nurses and other nonphysician staff in assessing vaccination history and administering vaccines, adopting SOPs, and increasing communication of provider recommendations. These changes are designed to increase the priority of vaccinations throughout health care practices by heightening awareness and empowering staff.

Analysis of data gathered from participants before and after the 2 webinars was not conclusive because of the low number of postsurvey participants; however, these results did show some indications of change in attitude and, potentially, in practice. The AOA will continue to be a resource for its members to increase the number of adults vaccinated against pneumococcal disease.

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