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OBJECTIVES: To compare changes in vaccination rates (pneumococcal polysaccharide vaccine [PPSV]; tetanus, diphtheria, and pertussis [Tdap] vaccine; and influenza vaccine) among high-risk adults following an intervention (June 1, 2013, to January 31, 2015) that used the 4 Pillars Practice Transformation Program (4 Pillars Program).

STUDY DESIGN: Post hoc analysis of data from a randomized controlled cluster trial.

METHODS: Eighteen primary care practices received staff education, guidance for using the 4 Pillars Program, and support for a practice immunization champion. Paired t tests were used to compare vaccination rates separately for those with diabetes, chronic lung or chronic heart disease, or other high-risk conditions. Student’s t tests were used to compare vaccination rates across high-risk conditions. Generalized estimating equation modeling was used to determine the likelihood of vaccination.

RESULTS: Based on International Classification of Diseases, Ninth Revision, Clinical Modification codes, 4737 patients aged 18 to 64 years were identified as having diabetes (n = 1999), chronic heart disease (n = 658), chronic lung disease (n = 1682), or another high-risk condition (n = 764). PPSV uptake increased by 12.2 percentage points (PP), Tdap vaccination increased by 11.4 PP, and influenza vaccination increased by 4.8 PP. In regression analyses, patients with diabetes (odds ratio [OR], 2.2; 95% CI, 1.80-2.73), chronic lung disease (OR, 1.50; 95% CI, 1.21-1.87), or chronic heart disease (OR, 1.32; 95% CI, 1.02-1.71) were more likely to receive PPSV than those without the respective high-risk condition. Those with diabetes (OR, 1.14; 95% CI, 1.01-1.28) or chronic lung disease (OR, 1.14; 95% CI, 1.01-1.30) were more likely to receive an influenza vaccine than those without the respective condition. The likelihood of Tdap vaccination was not significantly associated with any of the chronic conditions tested.

CONCLUSIONS: An intervention including the 4 Pillars Program was associated with significant increases in vaccination of high-risk adults. However, the overall uptake of recommended vaccines for those with high-risk conditions remained below national goals.

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Using the 4 Pillars to Increase Vaccination Among High-Risk Adults: Who Benefits?
The purpose of this study was to compare the effect of the intervention on adult PPSV, influenza, and Tdap vaccination rates and likelihood of vaccination among adults aged 18 to 64 years with the 3 most common high-risk medical conditions (diabetes, chronic lung disease, and chronic heart disease) in a post hoc analysis.

**Methods**

The trial was approved by the Human Research Protection Office of the University of Pittsburgh. The methods have been published previously\(^{14}\) and are briefly presented herein.

**Sample Size and Sites**

Eligible primary care family medicine (FM) and internal medicine (IM) practices from a practice-based research network in Pittsburgh (FM PittNet), a clinical network in southwestern Pennsylvania (Community Medicine, Inc), and a safety-net clinical network in Houston were solicited for participation. When 25 sites (a sufficient number per sample size calculations for an RCCT) had agreed to participate, solicitation ceased. All sites used a common electronic health record (EHR), EpicCare. Eligibility requirements included having at least 100 patients 18 years or older, preliminary baseline vaccination rates less than 50% for at least 1 adult vaccine (influenza, pneumococcal, Tdap), and a willingness to make office changes to increase vaccination rates. Participating practices were stratified by location (urban, suburban, or rural) and discipline (FM or IM), then randomized. The practices in this analysis were the 18 private practices or residency sites in southwestern Pennsylvania and did not include 1 site in Pittsburgh, which dropped out, and 6 publicly funded practices in Houston, from which data on high-risk conditions were not available.

**4 Pillars Program and Intervention**

The 4 Pillars Program\(^{14,15}\) is founded on 4 evidence-based\(^ {16,17}\) key domains: Pillar 1: convenient vaccination services; Pillar 2: communication with patients about the importance of immunization and the availability of vaccines; Pillar 3: enhanced office systems to facilitate immunization; and Pillar 4: motivation through an office immunization champion (IC). The 4 Pillars Program includes background on the importance of protecting patients against vaccine-preventable diseases, barriers to increasing vaccination from both provider and patient perspectives, and strategies to eliminate those barriers. Practices were expected to implement strategies from each of the 4 pillars.

The intervention was designed using the diffusion of innovations theory\(^ {18}\) and included the 4 Pillars Program, provider education, and 1-on-1 coaching of the IC for each practice.

The IC was responsible for using the 4 Pillars Program to guide the practice's intervention activities, participating in the biweekly telephone call with a research liaison for coaching, ensuring that chosen strategies were being implemented, and working to maintain motivation of the staff.

The overall study included a 2-year RCCT in which the year 1 controls were crossed over into active intervention and the year 1 intervention groups became maintenance groups after the first year.\(^ {12-14}\) In this analysis, all patients from the 18 southwestern Pennsylvania sites were combined and vaccination among eligible high-risk patients was examined at the end of baseline (May 31, 2013) and the end of the intervention (January 31, 2015), at which time all sites had completed the intervention. The effects of the intervention among the types of high-risk conditions were compared in a post hoc analysis.

**Data Collection**

De-identified demographic data (date of birth, sex, race, health insurance coverage as a proxy for income); office visit dates; *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes for high-risk conditions, including immune and autoimmune diseases, cancers, chronic kidney diseases, diabetes, chronic lung diseases, and chronic heart diseases (codes 42, 135, 141-208.91, 250.0-250.93, 279-279.9, 282.6-284, 288-288.2, 393-398.99, 402.0-404.93, 410-412, 141-141.9, 416-416.9, 428-428.9, 438-438.9, 446-446.7, 491-496, 500-505, 506.4, 506.9, 508-508.9, 510-510.9, 513-519.9, 571-572.8, 585-586, 710-710.9, and 714-714.9) (see eAppendix Table [eAppendix available at ajmc.com]); and vaccination data (vaccines given and dates) were derived from de-identified EHR data extractions. A longitudinal database was created with only those patients who were aged 18 to 64 years at baseline and who had a visit each year during the study period, creating the cohort of individuals for study.

**Statistical Analyses**

Descriptive analyses were performed for patient demographic characteristics (age, sex, race, health insurance, high-risk condition). Age was used as a continuous variable, and racial groupings were non-Hispanic white and nonwhite. Patients with more than
TABLE 1. Cumulative Pneumococcal Polysaccharide, Tdap, and Influenza Vaccination Rates Among High-Risk Patients Aged 18 to 64 Years*  

<table>
<thead>
<tr>
<th>High-risk Group</th>
<th>Pneumococcal Polysaccharide Vaccine</th>
<th>Tdap Vaccine</th>
<th>Influenza Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes n = 1999</td>
<td>52.5</td>
<td>66.2</td>
<td>13.7*</td>
</tr>
<tr>
<td>Chronic lung disease n = 1682</td>
<td>42.5</td>
<td>54.0</td>
<td>11.5*</td>
</tr>
<tr>
<td>Chronic heart disease n = 658</td>
<td>46.4</td>
<td>58.5</td>
<td>12.1*</td>
</tr>
<tr>
<td>All other high-risk conditions n = 764</td>
<td>29.6</td>
<td>39.1</td>
<td>9.6*</td>
</tr>
<tr>
<td>All high-risk conditions n = 4737</td>
<td>43.5</td>
<td>55.7</td>
<td>12.2*</td>
</tr>
</tbody>
</table>

PPD indicates percentage point difference; Tdap, tetanus, diphtheria, and pertussis.  
*Percent vaccinated by end of baseline (5/31/2013).  
**Percent vaccinated by end of intervention (1/31/2015).  
** indicates P < .001; *** indicates P < .0001.

RESULTS

Among the 4737 patients aged 18 to 64 years who had a high-risk condition, the average age was 52.1 ± 10.2 years, with 54.2% female patients, 8.2% nonwhite patients, and 65.4% who were privately insured (data not shown). In this cohort, 42.2% of patients had diabetes, 35.5% had chronic lung disease, 13.9% had chronic heart disease, and 16.1% had another high-risk condition. Overall, 366 (7.7%) had 2 or more high-risk conditions.

Cumulative PPSV uptake at the end of intervention reached 55.7% for all high-risk patients. Specifically, 59% of those with chronic heart disease, 54% with chronic lung disease, 66% with diabetes, and 39% with another high-risk condition had received PPSV by the end of the intervention (Table 1). Overall cumulative pneumococcal vaccination rates significantly increased 12.2 PP from baseline; patients with diabetes had larger increases than those with chronic lung disease (P = .02), chronic heart disease (P = .032), or another high-risk condition (P = .009). Cumulative Tdap vaccination rates increased significantly for all high-risk patients by 11.4 PP from baseline, reaching nearly 50% at the end of the intervention. Vaccination rates for the various high-risk groups ranged from 46% to 51%. Only those with other high-risk conditions increased their rates significantly more than those with diabetes (12.7 PP vs 11.3 PP, respectively; P = .04). Annual influenza vaccination also increased significantly from baseline for those with diabetes, chronic lung disease, and other high-risk conditions, reaching 57% for all high-risk patients. There were no differences among high-risk groups for PP increases in influenza vaccination rates.

In regression analyses (Table 2), 2060 patients who had received PPSV before the study began (June 1, 2012) were excluded from the PPSV regression model; similarly, 1796 patients who had received...
Moreover, the improvement of 12.2 PP is notably higher than the 2014 national rate of 20%,4 and among those with diabetes and those with chronic lung disease were more likely to have received the influenza vaccine compared with those without these conditions, whereas those with chronic heart disease were not more likely to be vaccinated against influenza than those without.  

**DISCUSSION**

With a concerted effort, primary care practices were capable of modifying their offices' systems to significantly improve vaccination rates from baseline levels among high-risk adults younger than 65 years. For pneumococcal vaccine, these results (56%) are in stark contrast to the 2014 national rate of 20%,4 and among those with diabetes (66%), the rate surpasses the national goal of 60%.3 Moreover, the improvement of 12.2 PP is notably higher than secular trends of less than 2 PP per year recently observed among adults aged 19 to 64 years with high-risk conditions.4,19,20 Female sex, older age, and white race were related to higher likelihood of receipt of PPSV, similar to recent national data that indicate significantly lower rates among nonwhites compared with whites6 and higher rates among older than younger individuals.4 In this study, those with diabetes, chronic lung disease, or chronic heart disease were more likely to receive PPSV than patients without each respective high-risk condition. The risk of pneumococcal disease is increased for all 3 of these comorbidities21; thus, it is important to know if an intervention shown to be effective among all adults is similarly effective among high-risk adults or if a special intervention is necessary. These data indicate that high-risk adults do not require a separate intervention, as their increases in PPSV uptake approached increases reported in a study of all adults.14

Tdap vaccine uptake also increased significantly from baseline (by 11.4 PP to 49.4%). These values exceeded the 2015 national rate (20.1%), recent secular trends of 3 PP per year increased uptake for all adults older than 19 years,4,19,20 and the increases among all adults (6.2 PP) shown in a previous study.13 Interestingly, in this study, men with high-risk conditions were more likely to receive the Tdap vaccine, whereas increased rates among women might be expected given the recommendation for pregnant women22 and others who care for infants to receive the Tdap vaccine. Influenza vaccination increased significantly from baseline (3.1-5.9 PP) for those with any high-risk condition. Those with diabetes and those with chronic lung disease were more likely to have received the influenza vaccine compared with those without these conditions, whereas those with chronic heart disease were not more likely to be vaccinated against influenza than those without. Influenza vaccination rates for all groups were still considerably below Healthy People 2020 goals of 70%,3 a troubling finding given their high risk of influenza complications.

Barriers to adult vaccination include patient, provider, and health system issues, such as lack of awareness of the need for vaccination, competing priorities for the physician, and incomplete documentation of vaccination history.23 The Task Force on Community Preventive Services recommends provider reminders and a combination of interventions to increase vaccination coverage among high-risk adults.24 The 4 Pillars Program offers strategies...
Increasing Vaccination Among High-Risk Adults

to address each of these types of barriers, including assessing and communicating the need for vaccination by all members of the clinical staff, implementing best practice alerts in the EHR or other reminders to providers, offering simultaneous vaccination with other indicated vaccines, and using standing order protocols. In an RCCT, the 4 Pillars Program demonstrated modest improvements in vaccination rates for all 3 vaccines among all adults.14-15 Other studies have used similar multifaceted approaches to increasing pneumococcal and influenza vaccination25,26 with moderate success.

Limitations

The pneumococcal vaccine is recommended for cigarette smokers.21 We did not specifically include smokers without high-risk medical conditions and therefore do not know how their inclusion would have changed the vaccination estimates. The completeness and accuracy of ICD-9-CM coding was not verified, although EHRs were used. Other records (eg, pharmaceuticals as a proxy for diagnoses) were not evaluated to confirm or augment ICD-9-CM codes. Separate analyses of uncommon ICD-9-CM codes were not done due to funding and time limitations. The population is limited to the greater Pittsburgh region and may not be generalizable to other populations. This is a post hoc analysis derived from an RCCT. The primary purpose of the analysis was to compare the effect of the intervention on groups of adults with common high-risk conditions rather than demonstrate its effectiveness against no program; hence, before-and-after analyses were conducted.

CONCLUSIONS

An intervention including the 4 Pillars Program, staff education, and support for a practice-based IC was associated with significant increases in PPSV, Tdap, and influenza vaccination among high-risk adults aged 18 to 64 years over a 2-year study. These findings further support the use of evidence-based strategies as part of a comprehensive, practice-based effort to address low vaccination rates among adults with high-risk medical conditions. Providers should be aware that the systems that are being successfully used to improve vaccination of non–high-risk patients may be equally effective for vaccinating patients with high-risk conditions.

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REFERENCES


Full text and PDF at www.ajmc.com
### eAppendix Table. High-risk Conditions, *ICD-9* Codes, and Number of Patients

<table>
<thead>
<tr>
<th>High-risk Condition</th>
<th>ICD-9 codes</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>250.0-250.93</td>
<td>1999</td>
</tr>
<tr>
<td>Chronic lung diseases</td>
<td>491.0-496; 500-505; 506.4; 506.9; 508-508.9; 510-510.9; 513-519.9</td>
<td>1682</td>
</tr>
<tr>
<td>Chronic heart diseases</td>
<td>393-398.99; 402.0-404.93; 410-412; 414.0-414.9; 416.0-416.9; 428.0-428.9;</td>
<td>658</td>
</tr>
<tr>
<td>Subtotal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \geq 2 ) (diabetes, lung disease, heart disease)</td>
<td></td>
<td>(366)</td>
</tr>
<tr>
<td>Other high-risk conditions, ie, HIV, other immune disorders, autoimmune disorders,</td>
<td>42; 135; 141-208.91; 279-279.9; 282.6-284; 288-288.2; 438-438.9; 446-446.7; 571-572.8; 585-586; 710-710.9; 714-714.9</td>
<td>764</td>
</tr>
<tr>
<td>cancers/malignancies, sickle cell disease, kidney disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>4737</td>
</tr>
</tbody>
</table>