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Using the 4 Pillars™ to Increase Vaccination among High-risk Adults: Who Benefits?

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Abstract

Objective: Compare changes in vaccination rates (pneumococcal polysaccharide (PPSV), influenza, and tetanus, diphtheria and pertussis (Tdap) vaccines) among high-risk adults following an intervention (6/1/2013–1/31/2015) using 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 of a practice immunization champion. Paired t-tests were used to compare vaccination rates were compared separately for those with diabetes, chronic lung or chronic heart disease or other high-risk conditions. Student's t-tests were used to compare across high-risk conditions. Generalized estimating equation modeling was used to determine likelihood of vaccination.

Results: Based on ICD9 codes, 4,737 patients 18–64 years old were identified as having diabetes (n=1,999), chronic heart disease (n=658), chronic lung disease (n=1,682) or another high-risk condition (n=764). PPSV vaccination increased 12.2 percentage points (PP), Tdap vaccination increased 11.4 PP and influenza vaccination increased 4.8 PP. In regression analyses, patients with diabetes (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 influenza vaccination than those without the respective condition.; 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. Overall uptake of recommended vaccines for those with high-risk conditions remained below national goals.

Summary:

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Using the 4 Pillars™ Practice Transformation Program, primary care practices can increase vaccination among high-risk adults who are historically a low vaccine uptake group.

Keywords

High-risk adults; pneumococcal vaccine; primary care; adult vaccination

Introduction

Adults with certain chronic medical conditions are at higher risk of complications from some vaccine-preventable diseases because these conditions are known to compromise the immune response to infection or increase vulnerability to the effects of infection.[1,2,3] For example, among adults 18–64 years old, rates of pneumococcal pneumonia are 3.0 to 9.8 times higher for those with chronic heart disease, lung disease or diabetes compared with healthy adults; for invasive pneumococcal disease, rates are 3.6 to 7.7 times higher.[3] Not only are vaccination rates for this group woefully low – 20.3% for pneumococcal polysaccharide vaccine (PPSV) in 2014[4] - and far from the Healthy People 2020 goal of 60%,[5] there are significant disparities in rates by race,[6] health insurance status, and frequency of contact with a medical provider.[7] Although the 2013 influenza vaccination rate among high-risk adults (49.5%) was higher than among those without high-risk conditions (32.9%),[8] this value is also below the U.S. goal of 70%.[5] Tetanus, diphtheria and pertussis vaccine (Tdap) uptake among all adults 19 years and older was 20.1% in 2014.[4]

Recent research on interventions to improve vaccination among high-risk adults is scant. Two studies focused on specialized high-risk populations (dialysis patients[9] and American Indians with diabetes[10]) and successfully increased PPSV uptake to 65.5% and 92%, respectively through extensive provider and patient education and outreach to patients, including home vaccination visits. Among dialysis patients[9] and veterans with spinal cord injuries,[11] multi-component interventions resulted in increases in influenza uptake of 4–5 percentage points.

We undertook a 2-year study of 18 primary care practices to test the effectiveness of an intervention designed to increase uptake of adult vaccines using the 4 Pillars™ Practice Transformation Program (4 Pillars™ Program). This program is a step-by-step guide for medical practices to implement evidence-based strategies for increasing vaccinations in primary care (4pillarstransformation.pitt.edu). These strategies are applicable for many practice settings and populations. Overall findings from the randomized controlled cluster trial (RCCT) and pre-post studies have been published.[12–14] 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 18–64 years with the three 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 previously published[15] 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 a randomized controlled cluster trial (RCCT)) agreed to participate, solicitation ceased. All sites used a common electronic medical record (EMR), EpicCare. Eligibility requirements included having at least 100 patients ≥18 years of age, preliminary baseline vaccination rates for at least one adult vaccine (influenza, pneumococcal, Tdap) <50%, and a willingness to make office changes to increase vaccination rates. Participating practices were stratified by location (urban, suburban or rural), and discipline (internal or family medicine) and randomized. Practices in this analysis were the 18 private practices or residency sites in Pittsburgh and did not include one drop out site in Pittsburgh and six publicly funded practices in Houston because data on high-risk conditions were not available from the latter.

4 Pillars™ Practice Transformation Program and Intervention

The 4 Pillars™ Program has been previously described[13,15] and is founded on four 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; 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 Diffusion of Innovations theory,[18] and included the 4 Pillars™ Program, provider education, and one-on-one 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. These results have been published. [12–14] In this analysis, all patients from the 18 Pittsburgh sites were combined and vaccination among eligible high-risk patients was examined at the end of baseline (5/31/2013) and the end of the intervention (1/31/2015) 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, ICD-9 codes for high-risk conditions including immune and autoimmune diseases, cancers, chronic kidney diseases, diabetes, chronic lung diseases and chronic heart diseases (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; 714–714.9; see supplemental Table), and vaccination data (vaccines given and dates) were derived from deidentified electronic medical record (EMR) data extractions. A longitudinal data base was created with only those patients who were 18–64 years at baseline and who had a visit each year during the study period, creating a 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. Racial groupings were Non-Hispanic white and non-white. Patients with more than one of these three high-risk conditions were included in each of their respective disease groups for analysis. PPSV and Tdap would typically be administered once during project period, thus PPSV and Tdap rates are presented as cumulative rates at the end of baseline (5/31/2013) and end of intervention (1/31/2015). For influenza vaccine, the analytical periods were 6/1/2012 to 5/31/2013 for baseline and 6/1/2014 to 1/31/2015 for the intervention year. Proportions were reported for categorical variables and means and standard deviations were reported for continuous variables. The primary outcome measures were the cumulative PPSV and Tdap vaccination rates and influenza vaccination rates reported at the end of baseline and the end of the intervention and percentage point (PP) differences. Student's paired t-tests were performed to test for two-year differences in influenza vaccination rates and cumulative PPSV and Tdap vaccination rates. In addition, the weighted average vaccination rates were compared between high-risk conditions for each vaccine using Student's t-test.

Multi-level generalized estimating equation modeling, which accounts for the clustered nature of the data, i.e., patients are clustered within practices, was conducted using vaccination status for each vaccine as the binary outcome variable. Those who were vaccinated with PPSV or Tdap prior to the trial were excluded from the regression analyses. To determine which factors were related to PPSV, Tdap and influenza vaccine uptake, the regression models also accounted for heterogeneity in demographic characteristics (including age, sex, race, and health insurance). Statistical significance of two-sided tests was set at a type I error (alpha) equal to 0.05. All analytical procedures were performed using SAS® 9.4 (SAS Institute, Cary, NC, USA).

Results

Of the 4,737 patients ages 18–64 years who had a high-risk condition, average age was 52.1±10.2 years, with 54.2% female patients, 8.2% non-white patients and 65.4% who were privately insured (data not shown); 42.2% percent 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 two or more of these high-risk conditions.

Cumulative PPSV vaccination rates among those not vaccinated at the end of baseline reached 56% for all high-risk patients; 59% of those with chronic heart disease, 54% of those with chronic lung disease; 66% of those with diabetes and 39% of those 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=0.020), chronic heart disease (P=0.032) or another high-risk condition (P=0.009). Cumulative Tdap vaccination rates among those not vaccinated at the end of baseline increased significantly for all high-risk patients by 11.4 PP from baseline, reaching nearly 50% for all high-risk patients at the end of the intervention. Vaccination rates for the various 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=0.040). 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 rates.

In regression analyses (Table 2), 2,060 patients who had received PPSV before the study began (6/1/2012) were excluded from the PPSV regression model; similarly, 1,796 patients who had received Tdap vaccine before the study began were excluded from the Tdap regression model. The odds of pneumococcal vaccination were significantly associated with older age (OR=1.02; 95% CI=1.01-1.02), white race (OR=1.45 (95%CI=1.02-2.06), having diabetes (OR=2.22; 95% CI=1.80-2.73), chronic lung disease (OR=1.50; 95% CI=1.21-1.87) and chronic heart disease (OR=1.32; 95% CI=1.02-1.71). The odds of Tdap vaccination were significantly inversely associated with being female (OR = 0.83, 95% CI=0.70, 0.99, referent = males). The odds of receipt of influenza vaccine were associated with being female (OR=1.24, 95% CI=1.12, 1.37), with being older (OR=1.03, 95%CI=1.03, 1.04), with having diabetes (OR=1.14; 95% CI=1.01-1.28), and with having chronic lung disease (OR=1.14; 95% CI=1.01–1.30).

Discussion

With a concerted effort, primary care practices were capable of modifying their offices' systems to significantly improve vaccination rates of high-risk adults under age 65 years from baseline levels. For pneumococcal vaccine, these results are in stark contrast to the 2014 national rate of 20%[4] and among those with diabetes and chronic lung disease, they surpass the national goal of 60%.[5] Moreover, the improvement of 12.2 PP is notably higher than secular trends of less than 2 PP per year recently observed among adults 19–64 years of age 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 indicating significantly lower rates among non-whites compared with whites,[6] and higher rates among older than younger individuals.[4] In this study, those with diabetes, chronic lung or chronic heart disease were more likely to receive PPSV than patients without those respective high-risk conditions. The risk of pneumococcal disease is increased for all three of these co-morbidities,[21] 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 increases in PPSV uptake approached increases reported in a study of all adults.[22]

Tdap vaccine uptake also increased significantly from baseline and exceeded both the 2015 national rate (20.1%), and recent secular trends of 3 PP/year increased uptake for all adults over age 19 years,[4,19,20] as well as the increases among all adults (6.2 PP) shown in a previous study.[12] Interestingly, in this study, men with high-risk conditions were more likely to receive Tdap vaccine when increased rates among women might be expected given the recommendation for pregnant women[23] 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 compared to those without these conditions were more likely to have received influenza vaccine; 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%,[5] a troubling finding given their high-risk of influenza complications.

Barriers to adult vaccination include patient, provider and health system issues including, lack of awareness of the need for vaccination, competing priorities for the physician, and incomplete documentation of vaccination history.[24] The Task Force on Community Preventive Services recommends provider reminders and a combination of interventions to increase vaccination coverage among high-risk adults.[25] The 4 Pillars™ Practice Transformation Program offers strategies 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 EMR or other reminders to providers, offering simultaneous vaccination with other indicated vaccines and using standing order protocols. In a RCCT, the 4 Pillars™ Program demonstrated modest improvements in all three vaccines among all adults.[12–14] Other studies have used similar, multi-faceted approaches to increasing pneumococcal and influenza vaccination,[26,27] with moderate success.

Limitations

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 coding was not verified, although electronic medical records were used. Other records (e.g., pharmaceuticals as a proxy for diagnoses) were not evaluated to confirm or augment ICD codes. Separate analyses of uncommon ICD codes were not done due to

funding and time limitations. The population is limited to the greater Pittsburgh region and surrounding communities and may not be generalizable to other populations. This is a *post hoc* analysis derived from a randomized controlled cluster trial. 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™ Practice Transformation Program, staff education and support for a practice-based immunization champion was associated with significant increases in pneumococcal, Tdap and influenza vaccination of high-risk adults ages 18–64 years over a two-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.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1.

Cumulative pneumococcal polysaccharide vaccine, Tdap vaccine and influenza vaccination rates among high-risk patients ages 18–64 years

	Pneumococcal Polysaccharide Vaccine			Tdap Vaccine			Influenza Vaccine		
High-risk Group	**End of Baseline, % vaccinated**	**End of Intervention, % vaccinated**	**PP difference**	**End of Baseline, % vaccinated**	**End of Intervention, % vaccinated**	**PP difference**	**End of Baseline, % vaccinated**	**End of Intervention, % vaccinated**	**PP difference**
Diabetes n=1,999	52.5	66.2	13.7*	36.7	48.0	11.3*	53.7	58.6	5.0†
Chronic lung disease n=1,682	42.5	54.0	11.5*	39.2	49.9	10.7*	51.2	55.3	4.2†
Chronic heart disease n=658	46.4	58.5	12.1*	34.8	46.0	11.3*	56.4	59.4	3.1
All other high-risk conditions n=764	29.6	39.1	9.6*	38.7	51.4	12.7*	51.4	57.3	5.9†
All high-risk conditions n=4,737	43.5	55.7	12.2*	37.9	49.4	11.4*	52.1	56.8	4.8*

Note: End of Baseline = 5/31/2013 and End of Intervention = 1/31/2015. Represents individual patients not diagnoses as there are 366 individuals with 2 or more high-risk diagnoses. Those vaccinated with PPSV or Tdap at the end of baseline were not included in the analyses.

*$P<0.001$

**$P<0.01$

†$P<0.05$

Table 2.

Odds of receipt of pneumococcal polysaccharide vaccine, Tdap vaccine and influenza vaccine for high-risk patients ages 18–64 years, adjusted for demographics and comorbidity using logistic regression.

	Pneumococcal polysaccharide vaccine N=2,677		Tdap vaccine N=2,941		Influenza vaccine N=4,737	
Variable	**Odds Ratio (95% CI)**	***P* value**	**Odds Ratio (95% CI)**	***P* value**	**Odds Ratio (95% CI)**	***P* value**
Female, ref. = male	1.16 (0.98, 1.37)	0.086	0.83 (0.70, 0.99)	**0.034**	1.24 (1.12, 1.37)	**<0.001**
Age (years)	1.02 (1.01, 1.02)	**<0.001**	1.00 (0.99, 1.00)	0.333	1.03 (1.03, 1.04)	**<0.001**
White race, ref. = non-white	1.45 (1.02, 2.06)	**0.036**	0.99 (0.72, 1.36)	0.953	1.20 (1.00, 1.45)	0.055
Medicaid, self-pay, uninsured, ref. = commercial insurance	1.21 (0.97, 1.50)	0.084	0.82 (0.65, 1.04)	0.106	1.04 (0.91, 1.78)	0.602
Diabetes, ref. = no diabetes	2.22 (1.80, 2.73)	**<0.001**	0.84 (0.68, 1.03)	0.093	1.14 (1.01, 1.28)	**0.039**
Chronic lung disease, ref. = no chronic lung disease	1.50 (1.21, 1.87)	**<0.001**	0.84 (0.68, 1.04)	0.115	1.14 (1.01, 1.30)	**0.038**
Chronic heart disease, ref. = no chronic heart disease	1.32 (1.02, 1.71)	**0.036**	0.83 (0.64, 1.09)	0.182	1.11 (0.97, 1.30)	0.168