PREVENTING CHRONIC DISEASE
PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

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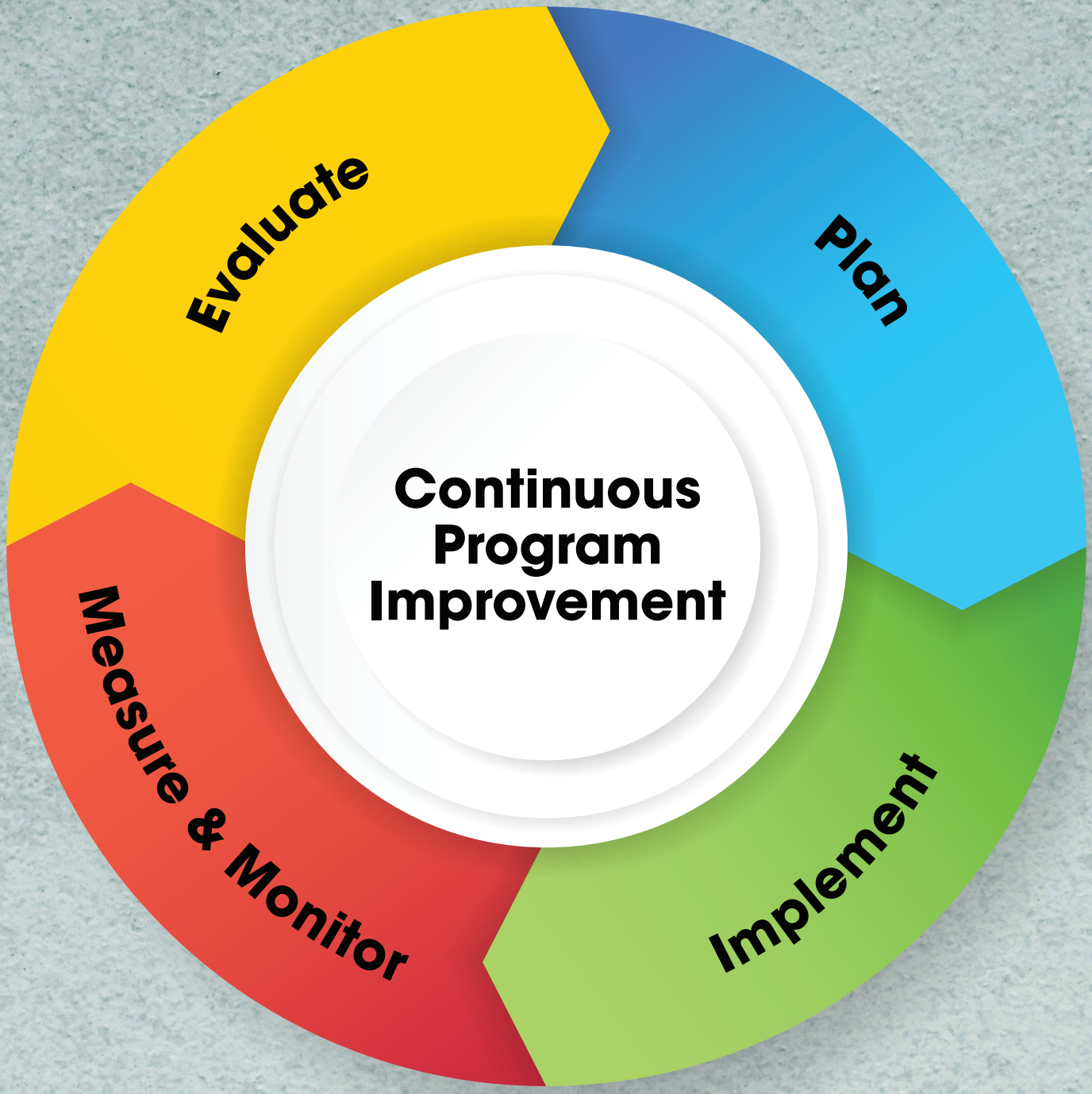

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Preventing Chronic Disease (PCD) is a peer-reviewed public health journal sponsored by the Centers for Disease Control and Prevention and authored by experts worldwide. PCD was established in 2004 by the National Center for Chronic Disease Prevention and Health Promotion with a mission to promote dialogue among researchers, practitioners, and policy makers worldwide on the integration and application of research findings and practical experience to improve population health.

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PROGRAM EVALUATION BRIEF

Teacher Physical Education Practices and Student Outcomes in a Sample of Middle Schools Participating in the Presidential Youth Fitness Program

Isabela Ribeiro Lucas, PhD[1]; Carole Harris, PhD[1]; Sarah Lee, PhD[2]; Jane Wargo, MA[3]; Seraphine Pitt Barnes, PhD, MPH, CHES[2]; Tina J. Kauh, PhD[4]; Ronaldo Iachan, PhD[1]

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PEER REVIEWED

Summary

What is already known on this topic?

Multicomponent school-based physical education (PE) programs can improve children's health and academic outcomes. An examination of the Presidential Youth Fitness Program (PYFP) on student's outcomes and PE practices had not been conducted until the present evaluation.

What is added by this report?

PYFP was associated with an increase in student aerobic capacity during a semester. PYFP students had significantly higher aerobic capacity at the end of the semester than did comparison students.

What are the implications for public health practice?

PYFP is a free and voluntary program that can be implemented in schools across the country and can positively affect PE practices and student outcomes.

Abstract

Obesity and lack of physical activity among children and adolescents are public health problems in the United States. This Presidential Youth Fitness Program (PYFP) evaluation measured program implementation in 13 middle schools and its effect on physical education practices, student fitness knowledge, and student physical activity and fitness levels. PYFP, a free program with the potential to positively affect student health and fitness outcomes, was designed to improve fitness education practices that are easily integrated into existing physical education programs. We used a 2-group (13 PYFP and 13 comparison schools) quasi-experimental design to collect FitnessGram assessments, accelerometry data, and surveys of students, physical education teachers, and administrators. Although the program was positively associated with student cardiovascular endurance and physical activity gains during the semester, schools underused professional development courses and fitness recognition resources.

Introduction

Obesity and lack of physical activity among children and adolescents are public health problems in the United States (1,2). The *2018 Physical Activity Guidelines Advisory Committee Scientific Report* confirms a strong association between higher physical activity levels and better health outcomes, including cardiorespiratory and muscular fitness, bone health, and weight status (3). Because school-aged children spend more than half of their waking hours in school (4) and engage in 20% to 30% of their total physical activity at school (5), schools are ideal settings in which to implement interventions to increase physical activity. Multicomponent school-based physical education (PE) programs improve children's health and academic outcomes (6,7), and a standards-based PE curriculum helps students develop the knowledge and skills needed to achieve and maintain health-enhancing levels of physical activity and fitness (8).

The Presidential Youth Fitness Program (PYFP) was created in 2012 by a public–private partnership between the President's Council on Sports, Fitness and Nutrition, the Centers for Disease Control and Prevention, the National Fitness Foundation, the Society of Health and Physical Educators, and The Cooper Institute. A process evaluation of PYFP showed positive results (9), but the ef-

fectiveness of PYFP on key outcomes was not examined. The objective of this study was to describe findings from a PYFP outcomes evaluation.

Purpose and Objectives

PYFP has hypothesized 4 key components to increase health-related fitness and knowledge among students and improve the effectiveness of PE: 1) use of FitnessGram (www.cooperinstitute.org/fitnessgram), a criterion-based fitness assessment that compares student measurements with a set of health-related standards; 2) a focus on fitness education to promote cardiovascular and muscular health; 3) professional development for PE teachers; and 4) recognition for students who achieve Healthy Fitness Zone standards.

We conducted the evaluation in 26 middle schools in the United States from October 2017 through June 2018 with the purpose of addressing the following questions: To what degree was PYFP implemented? Did PYFP implementation lead to integration of fitness education into physical education, improve fitness testing practices, or have a positive effect on PE and physical activity policies, practices, or environments? Did PYFP affect fitness knowledge, physical activity levels, or fitness among students?

Intervention Approach

On the basis of evidence that fitness assessment and education might influence fitness levels (10), PYFP aims to improve teacher fitness education practices and student knowledge, physical activity levels, and fitness with no cost to schools. PYFP schools included in this evaluation voluntarily applied for a grant from the National Fitness Foundation in 2014 or 2015 to participate in PYFP and, as part of the program, received FitnessGram software licenses, teacher textbooks and online training, and student recognition items.

Evaluation Methods

The evaluation was based on systems thinking theory, which focuses on linkages and interactions among system components (in this study, components of PYFP) and assesses intended and unintended outcomes (11). We used mixed-methods, a 2-group quasi-experimental design. A power analysis indicated that a sample of 22 schools (11 PYFP schools and 11 control schools) would be appropriate. We used the following data sources:

- surveys of students, PE teachers, and school administrators,
- 2 components of the FitnessGram assessment (the 20-meter Progressive Aerobic Cardiovascular Endurance Run [PACER], designed to assess aerobic capacity, and measurements of height and weight to calculate body mass index [BMI, kg/m^2]), collected at the beginning (baseline) and end (follow-up) of a PE semester, and
- accelerometry data collected at the beginning (baseline) and end (follow-up) of a PE semester.

We conducted baseline assessments from October 2017 through April 2018 and follow-up assessments from January 2018 through June 2018. ICF's institutional review board and the US Office of Management and Budget approved the study.

School selection. Of 293 public middle schools that received National Fitness Foundation Round 2 (2014–2017) or Round 3 (2015–2018) grants for PYFP, 43 met inclusion criteria (≥50% students receive free or reduced-price lunch; >150 students are enrolled in 6th and 7th grades [combined]) and were eligible to participate. We contacted 28 PYFP schools after our team received approval from their districts; 5 declined, 10 did not respond, and 13 enrolled. PYFP and comparison schools (matched on size, percentage of students receiving free or reduced-price lunch, geography, and racial/ethnic distribution) participated voluntarily. To achieve the target sample, we selected at least 4 PE classes per school. Study participation required parental consent and student assent.

Participants. We recruited 4 schools in addition to our targeted 22 schools to prepare for potential attrition, resulting in 26 schools (13 PYFP, 13 comparison) from 9 geographically diverse states (Iowa, Illinois, Indiana, Kentucky, Maine, Michigan, North Carolina, Tennessee, Washington). Forty-eight PE teachers (23 PYFP, 25 comparison) completed online surveys; 2,702 students (1,435 PYFP, 1,267 comparison) completed paper-and-pencil surveys; and 569 students (290 PYFP, 279 comparison) provided accelerometry data. We obtained height and weight measurements for 2,440 students (1,174 PYFP, 1,266 comparison) and PACER measurements for 2,616 (1,375 PYFP, 1,241 comparison) students.

Data collection. A trained, designated liaison in each school obtained parental permission, assisted with the logistics of FitnessGram assessments, distributed accelerometers, and implemented student surveys (completed once at the end of the semester). We provided various incentives (eg, fitness equipment, money, gift cards, nonmonetary prizes) to participating schools, liaisons, and students at various levels of participation. PE teachers conducted baseline FitnessGram assessments at PYFP schools, and trained

ICF staff conducted them at comparison schools; ICF conducted all follow-up FitnessGram assessments. Students wore ActiGraph accelerometers (model GT3XP-BTLE), positioned on the waist, for 7 days at baseline and 7 days at follow-up.

Teacher-level data: degree of PYFP implementation and teacher-specific volume of PE. We measured the degree of PYFP implementation by calculating program dose scores for the following: the proportion of students who received FitnessGram assessments, the number of professional development courses completed by PE teachers (4 were offered), the number of fitness education activities (ie, integration of fitness education into physical education), and use of fitness recognition (certificates awarded to students who score in the Healthy Fitness Zone in at least 5 FitnessGram assessment categories). We developed a scoring algorithm for these data; possible dose scores for each program component ranged from 0 to 4 (for a maximum of 16); higher scores indicate a greater degree of implementation. We measured PE volume for each teacher as the number of PE minutes offered between baseline and follow-up to control for the effect of the program in the regression models.

School-level data: physical activity/physical education policies, practices, and environment. We calculated a score for the physical activity/physical education environment from the following items in the PE teacher and administrator surveys: 1) the number of physical activity opportunities outside of PE time, 2) school environmental supports for physical activity/physical education teacher practices, and 3) administrative support. Total possible scores ranged from 0 to 19; higher scores indicate more positive environments.

Student-level outcomes. Outcomes were fitness knowledge (as measured in the student survey), BMI percentile (12), PACER scores (20-meter laps were converted to 1-mile run or walk times to estimate aerobic capacity [maximum oxygen consumption, Vo_{2max}]) (13), and intensity of physical activity (time in moderate-to-vigorous physical activity [MVPA]), determined from accelerometer data and child-based cut points (14).

Analysis

We used Stata version 11 (StataCorp) and SAS version 9.4 (SAS Institute Inc) for all analyses. We calculated descriptive statistics and performed bivariate analysis for school-level, teacher-level, and student-level data. We used multilevel linear models for clustering of students within classrooms for average MVPA (during and outside of PE), Vo_{2max}, and BMI percentile. The regression models included students with complete baseline and follow-up data for each outcome: MVPA (n = 387), Vo_{2max} (n = 1,985), and BMI (n = 1,783). Because baseline Vo_{2max} differed between groups, we analyzed follow-up scores by using a group interaction term. We found no group differences at baseline for BMI and MVPA, so we examined change from baseline to follow-up. On the basis of a sensitivity analysis, we included in MVPA analyses data from students with accelerometry data for 3 or more days of 8 hours per day (55% of all observations). We excluded from BMI analyses students whose BMI was greater than 70 (n = 7) or whose height decreased from baseline to follow-up (n = 361). Vo_{2max} analyses excluded PE classes with documented deviations from the measurement protocol (9 classes; 210 students).

Results

Student demographic characteristics did not differ significantly between groups for school enrollment, percentage of students who receive free or reduced-price lunch, or race (Non-Hispanic black and non-Hispanic white), but PYFP schools had a significantly greater percentage of Hispanic students than comparison schools (11% vs 7%; $P = .01$) (Table).

Degree of PYFP implementation. Of the program dose scores, the highest scores were received for FitnessGram assessments (3.9 of 4 points), followed by integration of fitness into PE (2.9 of 4 points). The lowest score was for completion of professional development courses (1.2 of 4 points); only 6 teachers completed 2 or more courses. Almost 40% of teachers reported time devoted to fitness education increased after PYFP implementation, and PYFP teachers reported greater use of student physical activity logs (44% vs 16%) and individual feedback on students' physical activity plans (52% vs 32%) than comparison teachers.

Most administrators (92%) reported that PYFP had a positive effect on school climate; 85% agreed that PYFP added value to PE, physical activity programs, and students by improving PE quality. However, only 22% of PE teachers reported that PYFP had increased opportunities for physical activity breaks during school, and only 17% indicated that physical activity increased during PE.

Student outcomes. Student surveys showed no significant differences in knowledge between groups. Most students in both groups knew the importance of exercising 5 days or more per week, knew that 60 minutes of daily exercise is needed for good health, learned how to be fit in PE classes, and learned about setting fitness goals to improve fitness scores.

Student BMI percentiles were not significantly different between groups at baseline or follow-up, and change from baseline to follow-up was not significantly different between groups. MVPA levels were not significantly different between groups at baseline or follow-up (Figure), but the MVPA of PYFP students increased significantly more than the MVPA of comparison students ($P =$

.04). In multivariate models, changes in MVPA and BMI from baseline to follow-up did not differ significantly by group after adjusting for age, sex, teacher-specific volume of PE, baseline values, and physical activity/physical education environment score. Younger students ($P = .03$) and students who were offered higher volumes (frequency and length) of PE ($P = .03$) had significantly lower BMI than older students and those with lower PE volumes. No predictors were significantly associated with the MVPA model.

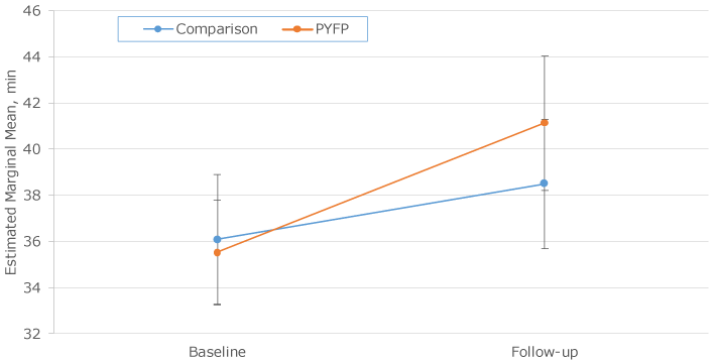

Figure. Minutes of daily moderate-to-vigorous physical activity levels at baseline and follow-up, by group, in an evaluation of student outcomes in a sample of middle schools participating in the Presidential Youth Fitness Program (PYFP), 2017–2018. The evaluation comprised 13 PYFP schools and 13 comparison schools. Error bars indicate 95% confidence intervals.

In the bivariate analysis, baseline Vo_{2max} was modestly but significantly higher among PYFP students than comparison students, whereas change in Vo_{2max} from baseline to follow-up was significantly higher among comparison students. After we adjusted for student age, student sex, teacher-specific PE volume, baseline Vo_{2max}, and physical activity/physical education environment, the regression model for Vo_{2max} at follow-up showed significant group effects, with higher scores at follow-up for PYFP students than comparison students ($P < .001$), but no group differences for the change-over-time model. Being younger ($P = .01$) and having higher baseline Vo_{2max} ($P < .001$) were significant predictors for follow-up Vo_{2max}.

Implications for Public Health

This evaluation was the first to assess the effect of PYFP on student health and fitness and to use comparison schools. Findings indicated school administrators and teachers strongly supported PYFP and attributed substantial improvements in PE courses and PE/PA environments to the program. Moreover, the positive associations between PYFP and student cardiovascular endurance at follow-up provided evidence for the health benefits of the program. Because PYFP's components are consistent with the recommendations and evidence described in the National Physical Activity Plan (15) and the Comprehensive School Physical Activity Program (16), and they involve little or no cost to participating schools, PYFP should be considered a strong and practical strategy to improve student physical activity levels. Interestingly, degree of PYFP implementation was not significantly associated with student outcomes, and professional development courses and fitness recognition resources were underused, which suggests more research is needed to determine the amount of training required for teachers and the role of student recognition in promoting student fitness achievements.

Our study has several limitations. We did not randomly assign schools to PYFP or comparison conditions. PYFP schools had voluntarily started the program 2 or 3 years before the evaluation, and the evaluation was designed to examine PYFP *as implemented*. Thus, a selection bias may have been present. The use of matched comparison schools and statistical controls was intended to minimize the influence of factors known to affect student fitness (eg, race/ethnicity, sex, age), but they might not have eliminated the influence of known and unknown factors. In addition, our study was retrospective, so reports by school personnel might have been influenced by memory bias. Lack of random assignment and the retrospective design preclude the ability to determine cause and effect. Because of the time required to obtain approvals and recruit schools, the study period was limited to 1 semester. A longer study period might have produced different findings.

PYFP is a free program with the potential to positively affect student health and fitness outcomes. Strategies to support greater and more consistent use of PYFP resources, such as professional development, and program enhancements to address implementation barriers should be considered.

Acknowledgments

This evaluation was supported through a partnership between the National Fitness Foundation, the Centers for Disease Control and Prevention (contract no. 200-2014-61102), and The Robert Wood Johnson Foundation (grant no. 74475). We are grateful for the statistical support from Donoria Evans and Yangyang Deng, our data collectors and recruiters, and school administrators and physical education teachers. No copyrighted material, surveys, instruments, or tools were used in this article.

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Table

Table. Summary of Findings in Study of Teacher Physical Education Practices and Student Outcomes in a Sample of Middle Schools Participating in the Presidential Youth Fitness Program, 2017–2018

Characteristic	PYFP Schools (n = 13)	Comparison Schools (n = 13)	*P* Value[a]
Demographic Characteristics of Schools			
Total school enrollment, mean no. of students	459	553	.22
Students who receive free or reduced-price lunch, %	64	60	.29
Non-Hispanic white, %	75	75	.90
Non-Hispanic black, %	9	9	.50
Hispanic, %	11	7	.01
Physical Education Implementation[b]			
Degree of implementation, as measured by program dose scores, mean (range)			
No. of teachers who completed online survey	23	25	—
Overall program dose, no. of points scored from 0–16	10.4 (5–15)	—	—
FitnessGram assessments, no. of points scored from 0–4	3.9 (3–4)	—	—
Integration of fitness education into physical education, no. of points scored from 0–4	2.9 (1–4)	—	—
Fitness recognition, no. of points scored from 0–4	2.4 (0–4)	—	—
Professional development courses completed by physical education teachers, no. of points scored from 0–4	1.2 (0–4)	—	—
Integration of fitness education into physical education[c]			
Time devoted to fitness education during physical education increased with PYFP	9 of 23 (39%)	—	—
Physical education teacher allocates >50% of physical education time to fitness education	11 of 23 (48%)	12 of 25 (48%)	—
Fitness testing practices			
Physical education teacher required students to keep a log of physical activity outside of physical education class	10 of 23 (43%)	4 of 25 (16%)	.36
Physical education teacher provided students with feedback on individuals student physical activity plans	12 of 23 (52%)	8 of 25 (32%)	.45
Physical activity/physical education policies, practices, and environment			
Administrators reporting that PYFP had a positive effect on school climate	12 of 13 (92%)	—	—
Administrators agreeing that PYFP added value to physical education and physical activity programs by improving PE quality	11 of 13 (85%)	—	—
Physical education teachers reporting increased opportunities for physical activity breaks during school	5 of 23 (22%)	—	—

Abbreviation: —, not applicable; BMI, body mass index; PE, physical education; PYFP, Presidential Youth Fitness Program; SE, standard error.
[a] *P* values determined by Levene test for equality of variances for demographic characteristics; by Pearson χ^2 test for fitness testing practices; by Wald test for fitness knowledge; and by 2-sample *t* test for student BMI percentile and student Vo_{2max}.
[b] Teacher-level variables; online surveys were completed by teachers once during semester.
[c] Fitness education covers such concepts as the importance of health-related fitness and physical activity for good health.
[d] Student-level variables; paper-and-pencil surveys were completed by students once during semester; BMI and Vo_{2max} were measured at beginning and end of semester.
[e] Determined by bivariate analysis of PACER scores; 20-m laps were converted to 1-mile run/walk times to estimate aerobic capacity (maximum oxygen consumption, Vo_{2max}) (12). Vo_{2max} is measured in mL of oxygen used in 1 minute per kg of body weight (mL/kg/min).

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Table. Summary of Findings in Study of Teacher Physical Education Practices and Student Outcomes in a Sample of Middle Schools Participating in the Presidential Youth Fitness Program, 2017–2018

Characteristic	PYFP Schools (n = 13)	Comparison Schools (n = 13)	*P* Value[a]
Physical education teachers reporting increased physical activity during physical education	4 of 23 (17%)	—	—
Student Outcomes[d]			
Fitness knowledge			
No. of students answering survey questions on knowledge	1,435	1,267	—
Exercise ≥5 days per week for good health, %	70	70	.32
Exercise ≥60 min per day for good health, %	59	59	.34
Learned how to be fit in their physical education classes, %	81	83	.48
Learned about setting goals in physical education to improve fitness scores, %	69	72	.14
Student BMI percentile			
No. of students for whom height and weight data were available	792	1,188	—
Baseline assessment, mean (SE)	71.4 (1.0)	69.1 (0.8)	.09
Follow-up assessment, mean (SE)	71.4 (1.0)	69.8 (0.8)	.22
Change between baseline and follow-up, mean (SE)	0.03 (0.32)	0.67 (0.24)	.11
Student Vo_{2max}[e]			
No. of students for whom data were available	951	1,239	—
Baseline assessment, mean (SE)	41.8 (0.2)	41.0 (0.2)	<.001
Follow-up assessment, mean (SE)	42.1 (0.2)	42.2 (0.2)	.64
Change between baseline and follow-up, mean (SE)	0.26 (0.1)	1.19 (0.09)	<.001

Abbreviation: —, not applicable; BMI, body mass index; PE, physical education; PYFP, Presidential Youth Fitness Program; SE, standard error.
[a] *P* values determined by Levene test for equality of variances for demographic characteristics; by Pearson χ^2 test for fitness testing practices; by Wald test for fitness knowledge; and by 2-sample *t* test for student BMI percentile and student Vo_{2max}.
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PROGRAM EVALUATION BRIEF

A Faith-Based Intervention to Reduce Blood Pressure in Underserved Metropolitan New York Immigrant Communities

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PEER REVIEWED

Summary

What is already known on this topic?

Minority populations, including Asian Americans, face disparities in hypertension compared with non-Hispanic whites, underscoring the need for culturally adapted programs in settings that reach Asian American communities.

What is added by this report?

We collaborated with our community partners to culturally adapt and implement an evidence-based community blood pressure monitoring program for Asian Americans (Asian Indian, Korean, Filipino, Bangladeshi) in metropolitan New York and New Jersey in 2015 and 2016 across 12 faith-based organizations.

What are the implications for public health practice?

Faith-based programs targeting Asian Americans may be a replicable, low-cost, sustainable way to increase health-related self-efficacy and for decreasing blood pressure among Asian Americans with diagnosed hypertension.

Abstract

Minority populations, including Asian Americans, face disparities in hypertension compared with non-Hispanic whites. This underscores the need for culturally adapted programs in settings that reach Asian American communities, such as faith-based organizations. We worked collaboratively with community partners to culturally adapt and implement an evidence-based community blood pressure monitoring program for Asian Americans (Asian Indians, Koreans, Filipinos, and Bangladeshis) in metropolitan New York during 2015 and 2016. The program included regularly scheduled volunteer-led screening and counseling events with congregants at faith-based organizations. Among participants with complete 6-month data (n = 348), health-related self-efficacy significantly improved after 6 months, and systolic and diastolic blood pressure was significantly reduced in some subgroups; reductions were highest in participants who self-reported a previous diagnosis of hypertension. Among Asian Americans, faith-based programs may be a replicable, low-cost, sustainable way to increase health-related self-efficacy and decrease blood pressure, specifically among individuals with self-reported hypertension.

Introduction

Nearly one-third of the US adult population has hypertension (1). Minority populations, including African Americans, Latinos, and Asian Americans, face disparities in hypertension and related cardiovascular disease (CVD) outcomes compared with non-Hispanic whites (1–3). Despite these findings, there is limited research on interventions to address high blood pressure in community settings among minority groups such as Asian Americans. Furthermore, research suggests that declines in CVD mortality rates observed in the broader US population in the past decade are not reflected for Asian Americans, indicating that current activities may not be reaching these groups (4,5).

Keep on Track (KOT), a program developed by the New York City Department of Health and Mental Hygiene (NYC DOHMH), is a volunteer-run, community-based blood pressure monitoring program that aims to lower blood pressure in community-dwelling adults. KOT was first successfully implemented and evaluated through senior center programming in New York City. The involvement of peer volunteers was central to the program (6).

Faith-based organizations (FBOs) may be effective settings for implementing health promotion and prevention strategies in Asian American communities. A 2012 Pew Research Center survey found that Asian Americans report a high level of FBO engagement but also report substantial differences in religious affiliation within and across subgroups (7). Research suggests that FBOs are successful in delivering health promotion programs because of their roles as trusted community centers and their ability to leverage infrastructure and social capital resources (eg, health ministries, regular congregant contact) for such programs (8,9). However, there are limited studies on faith-based health promotion interventions among Asian American communities (8,10,11).

Purpose and Objectives

The Racial and Ethnic Approaches to Community Health For Asian Americans (REACH FAR) project, led by a coalition composed of academic, government, and community-based organizations, culturally adapted and implemented the KOT program for 4 Asian American faith-based communities in metropolitan New York City and New Jersey during 2015 and 2016 (12). We present program findings, overall and stratified by Asian American subgroup and hypertension status at baseline.

Intervention Approach

The REACH FAR KOT program approach was informed by prior work in senior centers (6) and drew from social cognitive theory, which integrates Bandura's construct of self-efficacy and the factors that influence the confidence a person has to make a behavioral change (13). Our program began in September 2015 and was implemented in 12 FBOs in New York City and New Jersey: 3 Sikh gurdwaras, 2 Bangladeshi mosques, 3 Filipino churches, 3 Korean churches, and one Bangladeshi FBO-co-located senior center. Sites were selected on the basis of pre-existing relationships with coalition partners. During the engagement stage of the implementation process, community partners met with FBO leadership and key congregation members to introduce the program and develop an implementation plan aligned with each FBO's organizational structure. Recruited FBOs received a site honorarium for participation and signed a memorandum of understanding agreement that outlined program and evaluation activities. Next, NYC DOHMH–trained bilingual consultants recruited a team of FBO volunteers (ie, congregation members already active in existing health or wellness committees) to implement and deliver the program at each site. Recruited volunteers (96 individuals across the 12 sites) participated in a 2-day NYC DOHMH train-the-trainer program, which included topics on understanding the health effects of hypertension, program logistics, and operational duties.

Volunteers advertised the REACH FAR KOT program launch through FBO communication channels, including fliers, newsletters, listservs, and congregation leadership announcements. At each launch event, volunteers conducted a free blood pressure screening for all interested congregation members aged 18 to 85 years and recorded blood pressure measurements on a tracking card. After the screening, volunteers provided in-language, culturally tailored lifestyle counseling on maintaining healthy blood pressure and weight management, which included reviewing healthy eating tips and examples of healthy plates using common cultural foods (14). KOT volunteers also provided health coaching to participants to enhance their confidence in overcoming access barriers and their ability to ask and understand information about hypertension during clinical encounters. Participants were provided with translated blood pressure "passports" that documented measurements, medications, and questions that participants were encouraged to share with providers. Congregation members who had a blood pressure reading of 140/90 mm Hg or higher were advised to follow up with their primary care physician or were provided a referral to care. Post-launch, volunteers held regular screening events open to the entire congregation; returning congregants' blood pressure measurements were tracked on the same screening record card kept at the FBO site. The frequency of regularly held screening events post-launch depended on the FBO site's preference and capacity. For example, 1 site held KOT events every 2 weeks, while other sites held events quarterly.

All KOT program participants were invited to enroll in the KOT program evaluation through recruitment events held before or after regular FBO services. Pregnant women were not eligible to participate. People who consented to participate completed surveys at baseline and 6 months post-launch administered by program evaluation staff and received a gift card incentive. All activities were approved by the New York University School of Medicine institutional review board.

Evaluation Methods

Outcomes, assessed at baseline and 6-month follow-up, were 1) systolic and diastolic blood pressure (SBP and DBP), 2) a blood pressure screening in the last 6 months, 3) a doctor's visit in the last 6 months, and 4) health-related self-efficacy.

Blood pressure measurements were taken by trained volunteers at the initial KOT event and each subsequent screening event by using the Omron Model BP785 (Omron Corporation). Because multiple blood pressure readings were not consistently taken, the first blood pressure measurements were used for all analyses.

Baseline and 6-month surveys assessed blood pressure outcomes (blood pressure screening history, diagnosis of hypertension, and blood pressure medication use); demographics (age, sex, nativity, ethnicity); physiologic measures (self-reported height and weight); and health-related self-efficacy. A health-related self-efficacy scale was adapted from Bandura to measure health-related decision-making behaviors (13). Eight questions specific to health-related self-efficacy were confidence in 1) making decisions regarding health, 2) asking about health issues, 3) going to the doctor alone, 4) picking up the telephone to find out where to go for care, 5) knowing where to get medical attention, 6) needing others to accompany you, 7) finding your way around the city on public transportation, and 8) having the right to use family income to take care of medical needs. Scores ranged from 1 to 4, and 4 represented highest self-efficacy. We used alternative World Health Organization-recommended cut-off points to assess body mass index (15).

Differences in means (SBP, DBP, health-related self-efficacy) were assessed using *t* tests; differences in proportions (blood pressure screening or doctor's visit within 6 months) were assessed using χ^2 tests. Analyses were conducted for all participants and stratified by Asian American subgroups as well as self-reported hypertension at baseline. Self-reported hypertension was determined by asking the question, "Has a doctor or other health professional ever told you that you have high blood pressure?" We also stratified by elevated blood pressure at baseline (SBP ≥160 mm Hg and/or DBP ≥100 mm Hg) as a conservative proxy for including those with uncontrolled hypertension. Changes in SBP and DBP were assessed longitudinally by examining the slope of blood pressure change over time across multiple readings and using generalized estimating equations among all participants (with readings at points in addition to baseline and follow-up). Finally, we descriptively analyzed program data to determine program feasibility, including average number of screening events and number of people screened per event.

Results

A total of 1,653 congregants were screened across all sites and screening events. A subset of participants were enrolled, consented, and completed a baseline survey (n = 719). A total of 348 participants (48.4%) completed follow-up surveys (Asian Indian = 66, Bangladeshi = 52, Filipino = 47, Korean = 168, Other/Not reported = 15). Participants were predominantly aged 55 years or more, female, and foreign-born (Table 1). Obesity was higher among South Asian Americans (Asian Indians and Bangladeshis) than among Filipino and Korean American congregants. Self-reported hypertension and having a regular place of care varied across the Asian American subgroups.

On average, 10.5% of congregants participated across the 12 sites, varying from 4.6% of congregants at Bangladeshi sites to 54.7% of congregants at Filipino sites. Sites held an average of 9 screenings across the 6-month period (range, 2–12). Across sites, an average of 25 congregants were screened per event, and each screening event lasted 4 hours. Since the launch, the KOT program has been maintained at 11 of 12 sites. When comparing individuals who completed 6-month follow-up with those who did not complete follow-up, Korean Americans were significantly more likely to complete than other subgroups, as were women (overall and Asian Indian) and older participants (overall and Korean).

Between baseline and 6 months, mean SBP decreased significantly (128.4 mm Hg to 126.7 mm Hg, $P = .03$); blood pressure screening increased significantly (74.5% to 81.2%, $P = .03$), as did mean health-related self-efficacy (3.1 to 3.3, $P < .001$) (Table 2). Results varied by Asian American subgroup. Large, significant improvements were observed among Bangladeshi American participants for mean SBP (125.8 mm Hg to 119.5 mm Hg, $P = .007$) and mean DBP (79.0 mm Hg to 75.2 mm Hg, $P = .004$). Filipino American participants had a significant increase in doctor's visits in the last 6 months (46.8% to 67.4%, $P = .04$), and health-related self-efficacy significantly improved among Korean American participants (3.0 to 3.2, $P = .004$).

The REACH FAR KOT program appeared to be effective among participants with self-reported hypertension. Among these participants, mean SBP and DBP decreased significantly from baseline to 6 months among participants (−3.9 mm Hg, $P = .005$; −2.4 mm Hg, $P = .01$, respectively); and mean health-related self-efficacy increased significantly (3.1 to 3.2, $P = .04$). Participants without self-reported hypertension also had significant changes in health-related self-efficacy and blood pressure screening.

Finally, among 24 participants with elevated blood pressure at baseline (SBP ≥160 and/or DBP ≥100), mean SBP and DBP significantly decreased (−16.7 mm Hg, $P < .001$; −8.3 mm Hg, $P = .02$, respectively). No significant changes in blood pressure were observed over time when using longitudinal data collected from all program participants and across all screening events (results not shown).

Implications for Public Health

Our analysis demonstrates that faith-based programs may be an effective way to increase health-related self-efficacy among Asian Americans and improve blood pressure among certain Asian American subgroups or among those with self-reported hypertension. Blood pressure significantly improved for Bangladeshis after KOT program implementation. This result may be due to the high blood pressure at baseline for this group, but it may also result

from their unique sociodemographic profile in New York City. Bangladeshis have lower rates of English proficiency and income compared with other racial/ethnic subgroups in New York City, which may affect use of health care resources related to hypertension and CVD (16). Community-based programs such as KOT that provide free in-language screenings may be especially relevant and useful for Bangladeshis and groups with similar health disparities. Furthermore, these programs may help reduce SBP and DBP among those with uncontrolled blood pressure at baseline, even using a conservative elevated level (SBP/DBP, 160/100 mm Hg).

Our study has limitations. Caution should be used in interpreting the large changes in blood pressure that were observed, because regression to the mean may have occurred without a control group. The findings, however, provide a promising avenue for addressing undiagnosed elevated blood pressure, particularly for Asian American communities who may not have access to regular care and who may be more likely to be reached in trusted community settings such as FBOs. Additionally, because this evaluation used a pre–post design, our internal validity is limited.

However, our results indicate high program feasibility and sustainability, which is in large part due to the integration of sustainability planning throughout each KOT program site using a capacity-building approach. For example, training FBO volunteers who were known and trusted to deliver the blood pressure screening program built the FBO's capacity to engage in and sustain broader health promotion activities. Given the change in recent guidelines stating that high blood pressure should be treated earlier with lifestyle changes and/or medication at blood pressure readings of 130/80 mm Hg rather than 140/90 mm Hg, at-risk populations will increasingly need to be linked to blood pressure monitoring and health promotion resources at the community level. Programs such as KOT, which provide community-based health counseling and blood pressure screening, may offer easily replicable, low-cost, sustainable programs for underserved communities.

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This article has 13 authors because our program was a collaboration across multiple community-based organizations and an academic institution. S.Y., S.P., C.C., S.K., and N.I. conceptualized and wrote the article; R.D., J.Z., L.W., and H.C. contributed substantively to contents of the article; M.T., M.G., R.K., and S.K. were instrumental in community-facing activities, including implementation and evaluation. All authors reviewed and edited the manuscript.

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Tables

Table 1. Demographic Characteristics of Participants With Baseline and Follow-Up Data, REACH FAR Keep on Track, New York City/New Jersey, 2015–2016[a]

Characteristic	All (N = 348)	Asian Indian (n = 66)	Bangladeshi (n = 52)	Filipino (n = 47)	Korean (n = 168)	*P* Value[b]
	No. (%)					
Age, y						
18–34	23 (6.6)	5 (7.6)	6 (11.5)	8 (17.0)	3 (1.8)	
35–44	26 (7.5)	10 (15.2)	4 (7.7)	8 (17.0)	4 (2.4)	
45–54	66 (19.0)	17 (25.8)	9 (17.3)	13 (27.7)	26 (15.5)	<.001
55–64	94 (27.0)	19 (28.8)	21 (40.4)	14 (29.8)	34 (20.2)	
≥65	121 (34.8)	11 (16.7)	11 (21.2)	4 (8.5)	91 (54.2)	
Missing	18 (5.2)	4 (6.1)	1 (1.9)	0	10 (6.0)	
Sex						
Male	124 (35.8)	18 (27.7)	27 (51.9)	16 (34.0)	56 (33.3)	.04
Female	222 (64.2)	47 (72.3)	25 (48.1)	31 (66.0)	112 (66.7)	
Nativity						
Foreign-born	334 (96.5)	64 (97.0)	52 (100.0)	44 (93.6)	168 (100.0)	.006
US-born	12 (3.5)	2 (3.0)	0	3 (6.4)	0	
Baseline BMI[c]						
Underweight or normal weight[d]	109 (32.5)	10 (15.4)	8 (17.4)	17 (36.2)	71 (43.0)	
Overweight	149 (44.5)	29 (44.6)	21 (45.7)	23 (46.8)	71 (43.0)	<.001
Obese	77 (23.0)	26 (40.0)	17 (37.0)	8 (17.0)	23 (13.9)	
Blood pressure screening in last 6 months	257 (74.5)	54 (85.7)	46 (90.2)	30 (68.2)	115 (69.7)	.003
Doctor's visit in last 6 months	236 (68.0)	53 (81.5)	48 (92.3)	22 (46.8)	104 (63.0)	<.001
Ever been told had high blood pressure	146 (42.2)	20 (30.3)	32 (61.5)	19 (40.4)	68 (41.0)	.007
Has regular place of care	256 (81.0)	57 (96.6)	44 (91.7)	33 (76.7)	113 (72.9)	<.001

Abbreviations: BMI, body mass index; REACH FAR, Racial and Ethnic Approaches to Community Health for Asian Americans.
[a] Total sample for Asian subgroups does not sum to 348 because 15 participants reported they were another ethnicity or did not report ethnicity.
[b] χ^2 tests across the 4 Asian subgroups; does not include missing values.
[c] Classified based on World Health Organization BMI (kg/m^2) alternative cut-offs for Asian populations: underweight/normal weight, <23; overweight, 23.0 to <27.5; obese, ≥27.5. When using standard BMI definition: underweight/normal weight, <25.0 (53.4%); overweight, 25.0 to <30 (33.6%); obese, ≥30.0 (13.0%); 11.5% of Bangladeshi BMI measurements were missing.
[d] Four participants were classified as underweight (<18.5 kg/m^2).

Table 2. Baseline and Follow-Up BP Variables and Health-Related Self-Efficacy of Participants (N = 348), REACH FAR Keep on Track, New York City/New Jersey, 2015–2016[a]

Variable	Baseline	Follow-Up	*P* Value
All (N = 348)			
BP screening in last 6 months	257 (74.5)	281 (81.2)	.03
Doctor's visit in last 6 months	236 (68.0)	247 (71.2)	.36
Health-related self-efficacy, mean (SD)	3.1 (0.6)	3.3 (0.5)	<.001
SBP, mm Hg, mean (SD)	128.4 (18.2)	126.7 (17.2)	.03
DBP, mm Hg, mean (SD)	79.7 (10.6)	78.7 (9.4)	.05
Asian Indian (n = 66)			
BP screening in last 6 months	54 (84.4)	60 (90.9)	.26
Doctor's visit in last 6 months	53 (81.5)	58 (87.9)	.31
Health-related self-efficacy, mean (SD)	3.2 (0.5)	3.3 (0.6)	.20
SBP, mm Hg, mean (SD)	126.3 (16.9)	126.4 (15.4)	.95
DBP, mm Hg, mean (SD)	81.8 (10.1)	81.2 (8.7)	.51
Bangladeshi (n = 52)			
BP screening in last 6 months	46 (90.2)	45 (88.2)	.75
Doctor's visit in last 6 months	48 (92.3)	46 (88.5)	.51
Health-related self-efficacy, mean (SD)	3.1 (0.6)	3.3 (0.5)	.06
SBP, mm Hg, mean (SD)	125.8 (20.5)	119.5 (16.0)	.007
DBP, mm Hg, mean (SD)	79.0 (12.4)	75.2 (9.5)	.004
Filipino (n = 47)			
BP screening in last 6 months	115 (68.5)	39 (83.0)	.04
Doctor's visit in last 6 months	22 (46.8)	31 (67.4)	.04
Health-related self-efficacy, mean (SD)	3.4 (0.5)	3.4 (0.3)	.99
SBP, mm Hg, mean (SD)	118.7 (14.6)	116.0 (12.5)	.17
DBP, mm Hg, mean (SD)	77.4 (9.3)	77.2 (8.4)	.88
Korean (n = 168)			
BP screening in last 6 months	115 (68.5)	128 (76.6)	.09
Doctor's visit in last 6 months	104 (61.9)	103 (61.3)	.75
Health-related self-efficacy, mean (SD)	3.0 (0.5)	3.2 (0.4)	.004
SBP, mm Hg, mean (SD)	132.3 (17.9)	131.8 (17.7)	.66
DBP, mm Hg, mean (SD)	79.7 (10.5)	79.3 (9.4)	.64
Self-reported diagnosis of hypertension at baseline (n = 146)			
BP screening in last 6 months	125 (86.8)	131 (90.3)	.34
Doctor's visit in last 6 months	118 (80.8)	121 (83.4)	.56
Health-related self-efficacy, mean (SD)	3.1 (0.6)	3.2 (0.5)	.04
SBP, mm Hg, mean (SD)	135.3 (18.1)	131.4 (16.8)	.005
DBP, mm Hg, mean (SD)	81.9 (11.1)	79.5 (9.9)	.01

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation.
[a] Values expressed as number (%) unless otherwise indicated. Total sample for Asian subgroups does not total 348 because 15 participants reported they were another ethnicity or did not report ethnicity. Total sample for hypertension does not total 348 because 2 participants responded "don't know."

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Table 2. Baseline and Follow-Up BP Variables and Health-Related Self-Efficacy of Participants (N = 348), REACH FAR Keep on Track, New York City/New Jersey, 2015–2016[a]

Variable	Baseline	Follow-Up	*P* Value
Self-reported diagnosis of no hypertension at baseline (n = 200)			
BP screening in last 6 months	130 (65.3)	148 (74.4)	.049
Doctor's visit in last 6 months	116 (58.3)	124 (62.0)	.45
Health-related self-efficacy, mean (SD)	3.2 (0.5)	3.3 (0.4)	.005
SBP, mm Hg, mean (SD)	123.4 (16.5)	123.1 (16.8)	.81
DBP, mm Hg, mean (SD)	78.1 (10.0)	78.1 (9.0)	.93

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation.
[a] Values expressed as number (%) unless otherwise indicated. Total sample for Asian subgroups does not total 348 because 15 participants reported they were another ethnicity or did not report ethnicity. Total sample for hypertension does not total 348 because 2 participants responded "don't know."

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PROGRAM EVALUATION BRIEF

A Change-Management Approach to Closing Care Gaps in a Federally Qualified Health Center: A Rural Kentucky Case Study

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PEER REVIEWED

Summary

What is already known on this topic?

Delivery of quality adult preventive services, such as immunizations, cancer screening, tobacco use assessment, and cholesterol screening, is essential to improving population health. However, gaps often exist between recommended best practices in delivering preventive services and the care that is actually delivered.

What is added by this report?

Use of change-management approaches can help guide organizations through strategic implementation and sustainability of an evidence-based intervention, such as a Proactive Office Encounter model, to close the gap between recommendations and delivery.

What are the implications for public health practice?

The change-management approach not only serves to improve clinical workflows of an organization but also serves to improve patient outcomes and, subsequently, population health.

Abstract

Effective organizational change requires intentional planning. We applied Kotter's 8-Step Process for Leading Change model in understanding and evaluating how a federally qualified health center in rural Kentucky implemented a significant organizational change — a proactive office encounter (POE) model — to improve preventive care service delivery, close care gaps, and reduce health disparities among its patients. We completed qualitative interviews with 21 clinic personnel (eg, administrators, physicians, support staff, care coordinators) who were directly involved with POE implementation. We found evidence of steps 1 through 7 of Kotter's 8 steps of change in the POE implementation process. Step 8, anchoring new approaches in the organizational culture, was an area for improvement. Change-management models, such as Kotter's 8-Step Process for Leading Change, provide a systematic guide for health clinics to implement sustainable organizational change aimed at improving patient health outcomes.

Introduction

Delivery of quality adult preventive services, such as immunizations, cancer screening, tobacco use assessment, and cholesterol screening, is essential to improving population health (1). However, gaps often exist between recommended best practices in delivering preventive services and the care that is actually delivered (2). To effectively close care gaps in health care delivery environments, organizational changes may be needed to improve clinic culture, staff workflow efficiency, information technology supports (eg, electronic medical records), and mechanisms for continuous quality improvement. In particular, it is vital to assess *how* these changes are introduced and maintained within an organization. Research on organizational culture suggests organizations are "living, social organisms" and that change, without intentional planning and reinforcement, will not last (3). In addition, if change is not managed intentionally "over the intermediate and long terms, the old ways begin to creep back in" (3). Additional research suggests that change has both situational and psychological aspects, and ignoring either will result in a nonsustainable situation, wherein the organization is in a constant cycle of change implementation without achieving desired results (4,5).

Kotter's 8-Step Process for Leading Change, a well-known change-management model, posits that situational and psychological aspects of change are addressed through a series of dynamic, nonlinear steps (4,6) (Box). The 3 main tenets of Kotter's model are creating a climate for change, engaging and enabling the whole organization, and implementing and sustaining change (7). The theory helps to identify errors made by organizations as change is

introduced and counteract people who are ill-prepared and processes that are not designed to manage and sustain it (6). Kotter's model has been widely studied in business (8) and has also been applied in the health care environment. One health care application of Kotter's model was an assessment of organizational changes for improving patient safety, in which the model was deemed highly effective as a framework for guiding change (9). Other examples of using Kotter's model to implement new initiatives are an implementation of healthy workplace initiatives, an integration of electronic medical records into clinical practice, and an improvement of clinical and provider communication practices (8–11).

Box. The 3 Tenets and 8 Steps of Kotter's 8-Step Process for Leading Change (4,6)

Tenet 1: Creating a climate for change
Step 1: Establishing a sense of urgency
Step 2: Creating a guiding coalition
Step 3: Developing a vision and strategy
Tenet 2: Engaging and enabling the whole organization
Step 4: Communicating the change vision
Step 5: Empowering employees for broad-based action
Step 6: Generating short-term wins
Tenet 3: Implementing and sustaining change
Step 7: Consolidating gains and producing more change
Step 8: Anchoring new approaches in the culture

Purpose and Objectives

This case study focused on a retrospective application of the change-management model to understand how a federally qualified health center (FQHC) in rural Kentucky implemented a significant organizational change to improve its delivery of preventive care services, close care gaps, and reduce health disparities among its patient population. The White House Clinics, an 8-site FQHC in Appalachian Kentucky, implemented an evidence-based model, the proactive office encounter (POE) (12). POE was originally developed by Kaiser Permanente Southern California Region to systematically identify preventive care gaps through the strategic use of organizational workflow changes, refinements in information technology, and continuous quality improvement (13). The POE model requires that patients' medical records are assessed before all visits, so that the clinic is prepared for the original purpose of the visit and to ensure that patients adhere to preventive care (12). This case study evaluated the implementation of POE to determine whether the process aligned with Kotter's model, theorizing that use of these steps could increase the likelihood of POE sustainability in the FQHC.

Intervention Approach

Faculty and staff members of the University of Kentucky College of Public Health collaborated with White House Clinics to evaluate their implementation of POE and alignment with Kotter's model. The overall goal was to determine whether POE implementation at White House Clinics could be considered a successful organizational change. One of the primary evaluation activities was a series of qualitative interviews with clinic personnel directly involved with POE implementation. These personnel, or "key change agents," included clinic administrators (ie, chief executive officer, chief operating officer); physicians (eg, medical director, clinic leaders); paraprofessionals, nurses, and certified medical assistants providing direct patient care; and care coordinators charged with reviewing patients' medical records for preventive care gaps. We approached 22 key change agents for interviews and 22 agreed to participate; however, 1 person was unavailable to complete the interview because of a scheduling conflict. Therefore, 21 key change agents completed interviews. The semistructured interview guide was informed by organizational theory (14), Kotter's model (7), and the interdisciplinary expertise of the investigative staff (eg, implementation science, public health practice, health care administration).

Interview content

Kotter describes the first tenet, creating a culture of change within an organization, as 1) establishing a sense of urgency, 2) creating a guiding coalition, and 3) developing a vision and strategy (7). We asked participants to describe the extent to which implementing POE was an important priority at the White House Clinics, compared with other priorities, and how frequently POE implementation was discussed with staff members to determine a sense of urgency for the project. To determine whether the organization had used a guiding coalition structure to lead the project, we asked participants about whom they perceived to be POE implementation leaders.

The second tenet, engaging and enabling the whole organization, is described as 1) communicating the change vision, 2) empowering employees for broad-based action, and 3) generating short-term wins (7). We asked participants about resources used to implement POE, unanticipated challenges or barriers, and how the implementation could have been made easier.

Kotter describes the methods of the third tenet, implementing and sustaining change, as 1) consolidating gains and producing more change and 2) anchoring new approaches in the culture (7). We asked participants how implementation of POE affected workload and what steps were taken to make POE part of the daily routine.

We conducted interviews in July 2015 through September 2016. They lasted approximately 1 hour and were audio-recorded with the participant's permission. Participants were given a $75 gift card as a token of appreciation.

Evaluation Methods

We transcribed and analyzed interview recordings by using theoretical coding with constant comparative techniques (15) to align participants' thoughts and comments with Kotter's model. First, we ensured that team members understood the operational definitions of Kotter's model. We then categorized participant comments according to relevant steps of the Kotter framework, and we discussed findings until consensus was reached. We organized our findings according to Kotter's 3 major tenets and 8 steps. The University of Kentucky Institutional Review Board approved all study procedures.

Results

Most participants were non-Hispanic white (n = 19), female (n = 18), and aged 50 or younger (n = 18) (Table). They represented a range of positions within the organization and had been with White House Clinics for an average of 7 years.

Creating a climate for change

Overwhelmingly, participants described POE implementation as one of the organization's highest priorities. For example, a physician stated, "The push from administration to keep this project going was important. This was not something we could let fail."

In response to the question about a guiding coalition and POE implementation leadership, most participants stated that the chief executive officer was the primary leader; the enabling services service line manager and the medical director were also named. These leaders were confirmed by the chief executive officer to be the team members initially involved in POE implementation.

Engaging and enabling the whole organization

One physician described organizational communication by stating, "There were probably tons of meetings just to understand what it [POE] means, what it entails, what we have to do and how to do it." Some meetings were focused on building employee skills, such as new standing orders, workflow changes, motivational interviewing techniques, and protocols for "huddle meetings," where clinicians and support staff members review the day's medical records and patient list.

Interviews revealed examples of empowering employees for broad-based action. Standing orders, which identify clinical care processes that can be completed by clinical support staff members under stated conditions, were updated. One physician said, "This project told the nurses 'you can do this without asking the provider.' Certain immunizations, for example. This project empowers the nurse to do things. That's been a big change."

Short-term wins were seen as the organization reached milestones necessary for full implementation of POE. Examples of milestones included hiring new staff members (eg, care coordinators), development of health maintenance forms, and training providers and staff members who act on the information contained in the forms. In addition, White House Clinics leadership invited their academic partners to provide training on organizational communication strategies for the new processes. One of the most exciting wins, as described by the chief executive officer, was the increase in the number of patients receiving recommended preventive screenings such as mammograms, colonoscopies, and hepatitis C and HIV testing. In addition, the chief executive officer used the timing of these milestones as an opportunity to show gratitude to the staff who were instrumental in implementing POE: "We are glad you are here, your work is important. I know this is overwhelming right now, but we are really glad that you are doing it."

Implementing and sustaining change

The impact of POE on the clinic staff was evident in statements from care coordinators and nurses. One care coordinator said, "At first it [POE] greatly increased my workload, but now my workload has been reduced." A nurse said, "It helps provide better care because you're getting stuff done that you would otherwise forget to do." A pediatrician provided an example of how the organization built on the initial POE implementation with adult patients to produce additional change: "We are changing the [health maintenance forms] process for pediatric patients and it's going to be completely different." The changes included a greater focus on the scheduling frequency of well-child examinations and mapping screening tests such as hearing, vision, and dental examinations; human papillomavirus vaccination; and tobacco screening to children in the appropriate age group.

Interviews revealed instances where leadership worked to anchor the preventive focus that POE brings into the clinic culture. Through training and meetings with leadership, staff members indicated a common understanding that POE would be the vehicle to

ensure patients proactively receive preventive care and increase the likelihood of early detection of health issues. Standard use of health maintenance forms and morning huddle meetings were instituted. In addition, the chief executive officer said that after POE implementation, salary structure adjustments were made so that all staff positions were paid from the same wage scale. These adjustments broke down the informal hierarchy that previously placed care coordinators in a lower position than clinical support staff members. She stated emphatically, "You aren't going to tell me that what the scrubbers [care coordinators] do is not contributing to patients' health."

Implications for Public Health

This case study examined implementation of an intervention dedicated to closing preventive care gaps between recommended best practices and care actually delivered. Well-recognized change models, such as Kotter's 8-Step Process for Leading Change, provide a systematic approach to guide a health clinic through elements needed for sustainable change, from a focus solely on emergent or chronic care delivery to a prevention focus. Inclusion of all of Kotter's steps ensures that appropriate leaders in the organization guide such a change, that personnel involved in the change understand its purpose, and that the project is managed to the point of anchoring the change in the organization's culture.

Although our evaluation had strengths, it also had limitations. Kotter's model is most often used to guide large-scale change (6), and our project, although large for the White House Clinics, was small compared to other projects guided by the model. Leadership and staff members did not use the model proactively during the POE implementation planning process, and we did not assess validity and reliability of the model before using it in our case study. However, we found a strong connection between steps 1 through 7 of the change model and the implementation steps taken by White House Clinics. Step 8, anchoring new approaches in an organization's culture, was an area for improvement; this step is often problematic for organizations implementing new initiatives (6,9). In addition, the findings of the case study might not be generalizable to other FQHCs or similar clinical settings.

Despite these limitations, application of such organizational change frameworks could be particularly useful for clinical settings, such as FQHCs, that historically do not have the same resources as large health care organizations and that serve a substantial proportion of medically underserved patients. Use of change-management approaches can help guide these organizations through strategic implementation and sustainability of an evidence-based intervention such as POE. Thus, the change-management approach not only serves to improve clinical workflows of the organization but also serves to improve patient outcomes and subsequently population health.

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Table

Table. Characteristics of Interview Participants (N = 21) in a Qualitative Study of the Implementation of the Proactive Office Encounter[a] at an 8-Site Federally Qualified Health Center in Kentucky and Its Alignment With Kotter's 8-Step Process for Leading Change Model[b]

Variable	No. of Participants
Sex	
Male	3
Female	18
Age, y	
20–30	4
31–40	5
41–50	9
51–60	1
61–70	2
Race	
Non-Hispanic white	19
Asian	1
American Indian or Alaska Native	1
Length of time working at federally qualified health center, y	
≤2	2
3–5	7
6–10	5
≥11	4
Job responsibility	
Chief executive officer	1
Enabling services manager	1
Provider (family practice, pediatrics)	6
Nursing staff (registered nurse, registered medical assistant, certified medical assistant)	5
Team leader	3
Patient care coordinator	5

[a] An evidence-based model originally developed by Kaiser Permanente Southern California Region to systematically identify preventive care gaps through the strategic use of organizational workflow changes, refinements in information technology, and continuous quality improvement (13).
[b] A change-management model that posits that situational and psychological aspects of change are addressed through a series of dynamic, nonlinear steps (4,6).

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ORIGINAL RESEARCH

Putting the National Diabetes Prevention Program to Work: Predictors of Achieving Weight-Loss Goals in an Employee Population

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PEER REVIEWED

Summary

What is already known on this topic?

Worksites are valuable ancillary health care systems for population health promotion efforts, particularly the National Diabetes Prevention Program (DPP). Differences in key program characteristics have, however, limited the generalizability of findings from studies of worksite translations of the DPP.

What is added by this report?

We evaluated the effectiveness of the Vanderbilt University Medical Center Faculty and Staff Health and Wellness DPP, a worksite translation of the DPP that earned full recognition status from the Centers for Disease Control and Prevention in 2017.

What are the implications for public health practice?

Increased session attendance and increased physical activity among participants may increase success rates for employer-based DPPs.

Abstract

Introduction

Differences in eligibility criteria and intervention characteristics have limited the generalizability of findings from studies of worksite translations of the National Diabetes Prevention Program (DPP). The objective of our study was to identify factors associated with achievement of the DPP's 5% weight-loss goal in the Vanderbilt University Medical Center (VUMC) Faculty and Staff Health and Wellness DPP from 2014 to 2017.

Methods

We analyzed data from a DPP worksite translation that adhered to national standards for program quality and intervention fidelity. We compared baseline characteristics and program metrics for participants who did and did not achieve the program's 5% weight-loss goal, and we developed a multivariable logistic regression model to identify independent predictors of achieving this goal.

Results

Of the 165 employees enrolled in the DPP from 2014 to 2017, 43.6% (n = 72) met the 5% weight-loss goal. Mean (standard deviation) percentage weight loss for the program was 5.2% (6.0%), or 4.8 (6.0) kg. The median (interquartile range) body mass index at baseline was lower among participants who achieved the 5% weight-loss goal than among those who did not (31.6 [29.4–37.4] vs 34.7 [31.5–39.2], $P = .009$), and participants who achieved the goal reported more physical activity minutes per week (166.0 [135.2–223.0] min vs 128.5 [83.2–169.8] min, $P < .001$). Session attendance was greater for participants achieving the 5% weight-loss goal (23 [21–25]) sessions vs 18 [12–21] sessions, $P < .001$). In the adjusted analysis, physical activity and session attendance remained significant predictors of achieving the 5% weight-loss goal.

Conclusion

Session attendance and physical activity independently predicted achievement of the 5% weight-loss goal in this worksite translation of the DPP. Strategies designed to improve these metrics may increase DPP success rates.

Introduction

Worksites provide ideal settings to disseminate evidence-based health promotion programs. Sixty percent of US adults 16 years or older are employed (1), and worksites are a key source of information, communication, and support for employees (2). The substantial effect of obesity on health care costs, productivity, absenteeism, and disability, has created financial incentives to focus worksite wellness efforts on obesity (3). Employers spend 37% more on health care for obese adults than for normal-weight adults; most of this excess expenditure is attributable to type 2 diabetes, hyperlipidemia, and heart disease (4).

In 2010 the US Congress authorized the Centers for Disease Control and Prevention (CDC) to establish the National Diabetes Prevention Program (DPP). The DPP is based on data from several randomized controlled trials (5) demonstrating that type 2 diabetes can be prevented or delayed in adults at high risk through a structured lifestyle intervention (6). Targeted efforts by CDC, the American Diabetes Association, the American Medical Association, and the National Business Coalition on Health (7) have resulted in more than 60 employers and insurers now offering the DPP as an evidence-based weight-management program to employees (8).

Several studies evaluated DPP implementation efforts in community and clinical settings (9), but few focused on DPP implementation at worksites (7). Differences in program delivery limited the generalizability of findings from previous DPP worksite translation studies (7). The CDC Diabetes Prevention Recognition Program (DPRP) was established to minimize differences in program delivery by ensuring program quality and fidelity to scientific evidence (10–12). The objective of our study was to identify factors associated with achievement of the DPP's 5% weight-loss goal in the Vanderbilt University Medical Center (VUMC) Faculty and Staff Health and Wellness DPP, a worksite translation of the DPP that earned full recognition status from the CDC DPRP in 2017.

Methods

Health Plus, the workplace wellness division of Vanderbilt Health and Wellness, began offering the VUMC Faculty and Staff Health and Wellness DPP to the approximately 25,000 employees of Vanderbilt University (VU) and VUMC in 2014 (at no cost to employees). The eligibility criteria for the VUMC Faculty and Staff Health and Wellness DPP adhered to the 2015 DPRP standards for DPP participant eligibility (12). VU/VUMC employees had to be aged 18 or older and have a body mass index (BMI, in kg/m^2) of 24.0 or more (≥22.0, if Asian American). Additionally, employees had to meet at least 1 of the following criteria to qualify for the program: 1) a blood test result within the previous year consistent with a diagnosis of prediabetes (fasting glucose of 100–125 mg/dL, plasma glucose measured 2 hours after a 75g glucose load of 140–199 mg/dL, or hemoglobin A_{1C} of 5.7%–6.4%), 2) clinically diagnosed gestational diabetes mellitus during a previous pregnancy, or 3) a positive screening result on the American Diabetes Association or CDC questionnaires for prediabetes (10,13,14). People who were pregnant at the time of enrollment or had been diagnosed with type 1 or type 2 diabetes before enrollment were not eligible.

The VUMC Faculty and Staff Health and Wellness DPP

Consistent with the focus of the National DPP, the VUMC Faculty and Staff Health and Wellness DPP helps participants make moderate changes in diet and physical activity to achieve modest weight loss (5%–7% of baseline body weight) by presenting information, providing outside-of-class activities, and offering feedback to optimize behavior change (10,12). The program emphasizes self-monitoring of diet and physical activity, building self-efficacy and social support for maintaining behavior changes, and problem-solving strategies for overcoming common challenges to sustaining weight loss. The VUMC Faculty and Staff Health and Wellness DPP follows the 2012 National DPP curriculum (15), which was approved by CDC as meeting the requirements of the DPRP (10,12). Classes were delivered in person in a group setting and were organized into 16 core sessions during the first 6 months of the program, followed by 6 to 10 postcore sessions (per CDC guidance) during the second 6 months of the program.

Study design

We conducted an exploratory analysis of data from DPP participants enrolled in the first 5 cohorts (June 24, 2014, through August 28, 2017) of the VUMC Faculty and Staff Health and Wellness DPP. In accordance with the 2015 DPRP standards for evaluating DPP outcomes, we categorized people as DPP participants if they attended at least 4 sessions during the 12-month program (12). The primary analyses focused on the comparison of baseline characteristics and program metrics for DPP participants who achieved the minimum 5% weight-loss goal and those who did not. Through a Research Electronic Data Capture (REDCap) survey (16) at the time of enrollment, participants were asked to self-report their age, sex, and race/ethnicity, and indicate the method by which they qualified for the DPP (ie, blood test, questionnaire, or diagnosed gestational diabetes, or various combinations thereof). We calculated baseline BMI by using height and weight data collected from participants at the first DPP session. Program characteristics were physical activity minutes per week, the number of

sessions attended, and weight loss. Physical activity was self-reported by DPP participants at each DPP session. We assessed weekly physical activity minutes by asking participants to respond to the following question for each session via REDCap survey: "Please report your total physical activity minutes for the past week. The minutes you report should be moderate intensity, meaning you are going fast enough to breathe heavier than usual, but not so fast that you are unable to talk. An example of this is brisk walking. Report any activity that you have done for at least 10 minutes or longer." Participants were not required to complete the REDCap survey to report their weekly physical activity minutes if they instead verbally reported physical activity minutes to their coach or submitted this data via email as a free text report. We calculated an overall mean physical activity minutes per week for each participant. Health Plus staff members measured participants' weight at each DPP session. Health Plus staff members are trained by the Health Plus nurse case manager to follow a standardized protocol when measuring height and weight; protocol proficiency is re-assessed annually. Per the CDC DPRP protocol for calculating participants' percentage change in weight (10), we categorized participants as having achieved the 5% weight-loss goal (yes or no) after calculating each participant's percentage weight loss (difference in weight between the first and last session attended divided by baseline weight, then multiplied by 100).

The Vanderbilt Institutional Review Board recognized this evaluation as a quality improvement project for the purposes of evaluating program efficacy, quality improvement, and dissemination of program results.

Statistical analysis

We used Fisher exact tests for categorical variables and Wilcoxon rank-sum tests for continuous and ordinal variables to compare baseline characteristics and program metrics between DPP participants who achieved the 5% weight-loss goal and participants who did not. For categorical variables, we calculated the success rate by dividing the number of DPP participants who achieved the 5% weight-loss goal by the total number of participants in each category. We used LOWESS (locally weighted scatterplot smoothing) nonparametric regression trend lines with 95% confidence intervals to display percentage weight change during the program. These spline graphs provide a nonlinear smoothed curve based on a moving average to find a curve of best fit without assuming the data must fit some distribution shape. Baseline characteristics and program metrics that were significantly associated with achievement of the 5% weight-loss goal in bivariate analyses were included in a logistic regression model to determine which variables remained significant predictors of the 5% weight-loss goal. For ease of interpretation, we analyzed physical activity as 30-minute intervals per week in the logistic regression model. All analyses were performed using R version 3.4.3 (The R Foundation) (17).

Results

During the study period, 165 employees enrolled in the VUMC Faculty and Staff Health and Wellness DPP. The mean (standard deviation [SD]) age of DPP participants was 50.3 (8.6) years, and 85% were women. Most (77%) participants were obese, 64% of participants were non-Hispanic white, and 26% were non-Hispanic black. The general VU/VUMC employee population in 2017 was younger (mean 43.0 [SD, 12.8] y) than the DPP participant population, and a smaller percentage (27%) was obese. These differences reflect eligibility criteria for the DPP, because the likelihood that a person will have a positive screen for prediabetes on either the American Diabetes Association or CDC prediabetes questionnaires increases with increasing age and/or increasing BMI.

Of the 165 participants, 72 (43.6%) employees met the 5% weight-loss goal (Table 1). Mean (SD) percentage weight loss for the full cohort was 5.2% (6.0%), or 4.8 (6.0) kg. The trend line for participants who met the target weight-loss goal crossed the 5% weight-loss threshold at approximately session 9 (Figure 1). Participants achieving the 5% weight-loss goal lost a median (interquartile range [IQR]) 7.5 (5.3–13.3) kg, or 8.0% (6.2%–13.9%) of baseline weight; participants who did not achieve the goal lost a median (IQR) 1.4 (0–3.2) kg (Table 2).

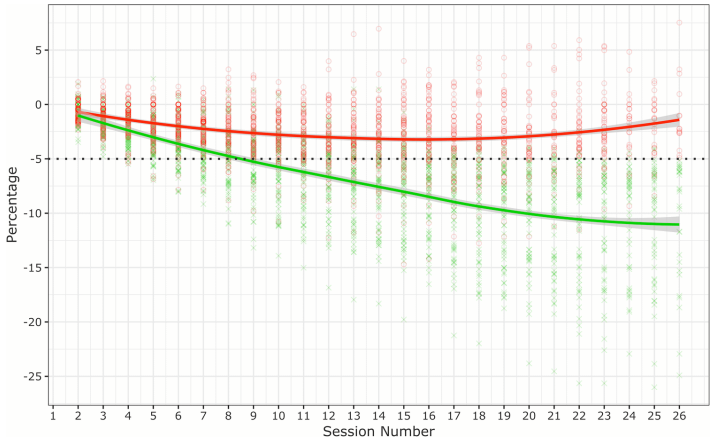

Figure 1. Percentage change in weight among 165 participants in the Vanderbilt University Medical Center (VUMC) Faculty and Staff Health and Wellness Diabetes Prevention Program, 2014–2017. The dotted line represents the 5% weight-loss goal. Each green cross represents a participant who achieved the 5% weight-loss goal. Each red circle represents a participant who did not achieve the 5% weight-loss goal. The solid red line and the solid green line are LOWESS (locally weighted scatterplot smoothing) nonparametric regression trend lines; shading indicates 95% confidence intervals.

Participants who achieved the 5% weight-loss goal were more likely than those who did not achieve the goal to have a lower baseline BMI (median [IQR] 31.6 [29.4–37.4] vs 34.7 [31.5–39.2]; $P = .009$). We found no significant differences in achievement of the 5% weight-loss goal by age, sex, race/ethnicity, or qualification method. The most common program qualification method was the combination of a positive screening questionnaire and a blood test in the prediabetes range in the previous year (73 of 165 participants, or 44.2%) (Table 1). Although qualification method was not significantly associated with achievement of the 5% weight-loss goal, success rates were lower for participants who qualified solely on the basis of a positive screening questionnaire (32.8% success rate) than for participants who qualified on the basis of the combination of a positive screening questionnaire and a blood test (52.1% success rate).

We observed significant differences in all program metrics when we compared participants who achieved the 5% weight-loss goal and those who did not (Table 2). Participants who achieved the 5% weight-loss goal reported a median [IQR] 166.0 [135.2–223.0] physical activity minutes per week, whereas participants who did not achieve goal reported 128.5 [83.2–169.8] physical activity minutes per week ($P < .001$). Similarly, participants who achieved the 5% weight-loss goal attended more program sessions than those who did not meet the weight-loss goal (23 [21–25] vs 18 [12–21] sessions; $P < .001$). These findings were consistent in both the core and postcore phases of the program. The median for the last DPP session attended was session 25 for participants who achieved the 5% weight-loss goal and session 23 for participants who did not achieve the goal ($P < .001$). Participants who reported an average of at least 150 minutes of physical activity per week or attended at least 21 DPP sessions had a 50% success rate in achieving the 5% weight loss goal (Figure 2). The steep slope of the line indicates that increasing physical activity above 150 minutes was associated with significantly higher success rates. Similarly, attending 21 sessions was associated with a 50% success rate, but the slope of the line indicates that increasing attendance to more than 21 sessions was associated with much higher success rates.

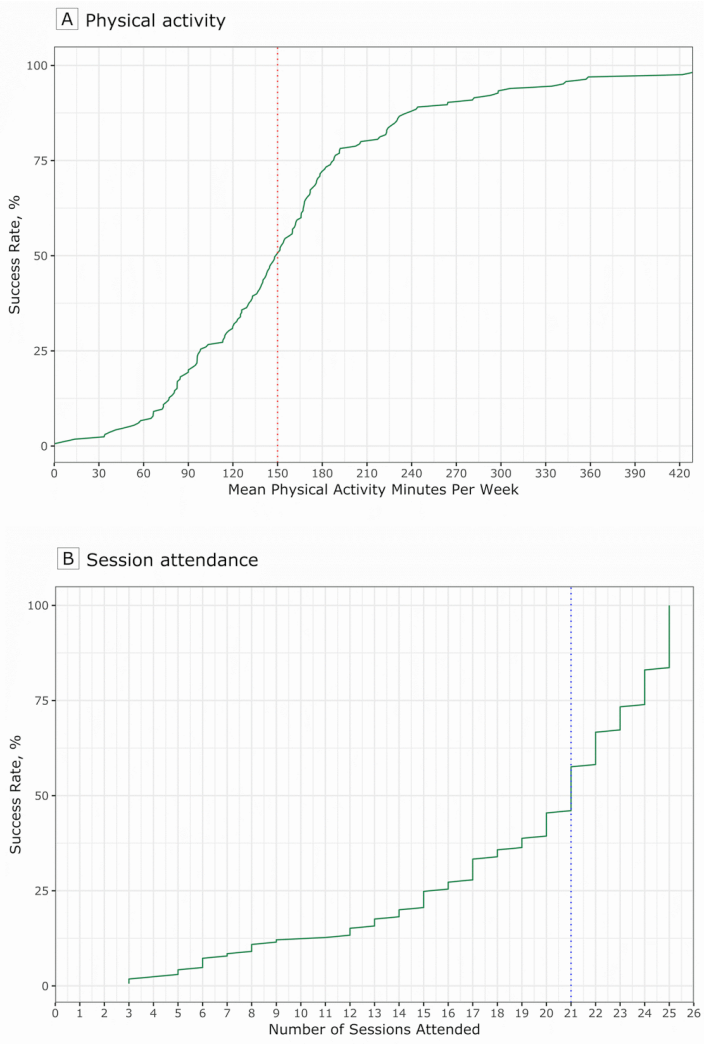

Figure 2. Success rates for achievement of 5% weight-loss goal among 165 participants in the Vanderbilt University Medical Center (VUMC) Faculty and Staff Health and Wellness Diabetes Prevention Program, 2014–2017. The red dotted line (A) indicates 150 minutes of physical activity and the blue dotted line (B) indicates 21 sessions. The points at which the red and blue dotted lines intersect with the solid green line indicate 50% success rates.

Baseline BMI, physical activity, and the number of sessions attended differed significantly between participants who achieved the 5% weight-loss goal and participants who did not, so we included these variables in the logistic regression model. In the adjusted analysis, only physical activity and number of sessions attended remained significant predictors of achieving the 5% weight-loss goal. The odds of achieving the 5% weight-loss goal were 20% greater for every additional 30-minute interval of physical activity per week (odds ratio [OR] = 1.20, 95% confidence interval [CI], 1.02–1.41; $P = .02$); the odds of achieving the 5% weight loss goal

were also 20% greater for every additional session attended (OR = 1.20; 95% CI, 1.10–1.32; $P < .001$). Baseline BMI was not a significant predictor of achieving the goal (OR = 0.97; 95% CI, 0.91–1.04; $P = .37$).

Discussion

We found that number of sessions attended and weekly minutes of physical activity were independently associated with achieving the 5% weight-loss goal in the VUMC Faculty and Staff Health and Wellness DPP. As a worksite translation of the National DPP with full recognition status from CDC, our program maintains rigorous standards for program quality and fidelity to scientific evidence. Previous studies of DPP worksite translations demonstrated substantial differences in fundamental elements of the DPP, including participant eligibility criteria and intervention characteristics (7). For example, a recent review of translational workplace DPP-based interventions showed that none of the 10 programs included in the review used DPRP's standard eligibility criteria (7). Only 2 programs offered both the 16-session core phase and the 6-month maintenance phase of the DPP, and 4 programs did not offer any maintenance sessions. The results of our study are more generalizable to other programs participating in the DPRP than findings from previous evaluations of employer-based DPPs because of our adherence to DPRP standards for implementation.

The weight-loss results we observed exceeded the weight-loss results reported in previous studies. Participants in our DPP lost, on average, 5.2% of their body weight at the time of program completion and 43.6% achieved the 5% weight-loss goal. A recent systematic review of real-world translations of the DPP reported a mean weight loss of 4% at 12-month follow-up across the 28 studies included in the analysis (18). A recent assessment of participant-level results from the National DPP found that average weight loss was 4.2% and that 35.5% of participants achieved the 5% weight-loss goal (11). Our results demonstrating the importance of the number of sessions attended in achieving weight loss is consistent with the results of these large multisite evaluations of the DPP (11,18). Ali et al found that for every additional lifestyle session attended, weight loss increased by 0.26% (18). Ely et al similarly found that for every additional DPP session attended, participants lost 0.31% of their body weight (11). Our finding that physical activity is a significant predictor of achieving the 5% weight-loss goal was also consistent with reports by Ely et al, who found that National DPP participants lost 0.3% of their body weight for every 30 additional minutes per week of physical activity reported (11). The consistent identification of the number of sessions attended and physical activity minutes as significant predictors of weight loss in the DPP provides strong evidence that strategies designed to increase session attendance and increase physical activity among DPP participants could increase success rates, particularly in employer-based programs.

Despite the program's effectiveness, participation rates for our employer-based DPP were low. The Diabetes Prevention Impact Toolkit recently developed by CDC in collaboration with RTI International (19,20) can be used to project the percentage of a population eligible to participate in a DPP based on the unique demographic characteristics of that population. Using this toolkit, we estimated 7,869 of the 25,444 benefits-eligible employees working at VU/VUMC in 2017 would be eligible for the VUMC Faculty and Staff Health and Wellness DPP. Yet only 229 employees completed the DPP in the 4 years it has been available as a benefit. Employer-based health promotion programs frequently report limited program participation (21,22) because of such barriers as geography, inconvenient locations, time limitations, insufficient incentives, and confidentiality concerns (23,24). Limited program participation is a problem within and beyond worksites. A systematic review of "real-world" translations of the DPP reported low participation rates (≤33%) in 25 of 35 studies (25). The rates were 10% or less in half of the studies (25). A recent analysis of National Health Interview Survey data also noted low DPP participation rates; only 2.4% of eligible adults in the sample had participated in the program (26). Feedback collected from our DPP participants during 2014–2017 suggested that the requirement to meet in person on the VU/VUMC main campus was a barrier to participation. We introduced an option to participate in a video-teleconference group (ie, telehealth) in 2018 to overcome this geographic barrier to program participation; future analyses will evaluate whether this option improves program participation rates.

Our study has several limitations. Like previous evaluations of the DPP, our study was limited to analyzing standard programmatic data available for the DPP and did not account for potential unmeasured confounders, including sleep, dietary intake, readiness for behavior change, and others. Physical activity minutes were self-reported and may have been prone to recall bias. Our calculation of weight loss as the difference between the first and last session attended is consistent with DPRP standards (10,12), but it does not account for the fact that the last session may have been earlier than 12 months after the participant enrolled in the DPP. Importantly, the median for the last session attended by participants in our program was 24, suggesting that the last weight recorded for most participants was close to the end of the 12-month program. Women were overrepresented in our sample; 67% of VU/VUMC employees are female but 85% of DPP participants were female. This selection bias is consistent with previous studies of workplace wellness programs, which observed higher participation rates among female employees (27,28).

Worksites are valuable ancillary health care systems for population health promotion efforts among US adults. Addressing weight management at a population level is challenging because a single intervention is unlikely to account for the diverse needs and preferences of so many people. VUMC Faculty and Staff Health and Wellness uses the AMSO framework (Awareness, Motivation, Skill-Building, Opportunity) for workplace health promotion to provide a variety of weight-management options to accommodate differences in readiness for behavior change, availability, goals, degree of support, and other factors among VU/VUMC employees (29). Within this framework, the DPP provides an excellent evidence-based skill-building program option for employees at high risk for developing diabetes. Strategies designed to improve program attendance and increase physical activity among DPP participants may increase success rates for employer-based DPPs adhering to DPRP standards.

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Tables

Table 1. Baseline Characteristics of DPP Participants (N = 165) by Achievement of 5% Weight-Loss Goal, Vanderbilt University Medical Center Faculty and Staff Health and Wellness DPP, 2014–2017

Characteristic	5% Weight-Loss Goal Not Met[a]	5% Weight-Loss Goal Met[a]	Success Rate, %[b]	*P* Value
No. of participants	93	72	43.6	—
Age, median (IQR), y	51.0 (44.0–56.0)	52.0 (47.0–57.0)	—	.23[c]
Sex				
Female	80 (86.0)	60 (83.3)	42.9	.67[d]
Male	13 (14.0)	12 (16.7)	48.0	
Race/ethnicity				
Non-Hispanic white	60 (64.5)	45 (62.5)	42.9	.74[d]
Non-Hispanic black	24 (25.8)	18 (25.0)	42.9	
Hispanic	4 (4.3)	3 (4.2)	42.9	
Non-Hispanic Asian	4 (4.3)	4 (5.6)	50.0	
Other or unknown	1 (1.1)	2 (2.8)	66.7	
BMI, median (IQR)	34.7 (31.5–39.2)	31.6 (29.4–37.4)	—	.009[c]
BMI category, kg/m^2				
Normal (18.5–24.9)	1 (1.1)	3 (4.2)	75.0	.04[d]
Overweight (25.0–29.9)	14 (15.1)	20 (27.8)	58.8	
Obese (≥30.0)	78 (83.9)	49 (68.1)	38.6	
DPP qualification method[e]				
Blood test	1 (1.1)	1 (1.4)	50.0	.40[d]
Questionnaire	41(44.1)	20 (27.8)	32.8	
Diagnosed gestational diabetes	1 (1.1)	1 (1.4)	50.0	
Blood test and questionnaire	35 (37.6)	38 (52.8)	52.1	
Blood test and diagnosed gestational diabetes	2 (2.2)	1 (1.4)	33.3	
Diagnosed gestational diabetes and questionnaire	10 (10.8)	8 (11.1)	44.4	
Blood test, diagnosed gestational diabetes, and questionnaire	3 (3.2)	3 (4.2)	50.0	

Abbreviation: BMI, body mass index; DPP, Diabetes Prevention Program; IQR, interquartile range.
[a] Values are number (percentage) unless otherwise indicated.
[b] Success rate calculated by dividing the number of DPP participants who achieved the 5% weight-loss goal by the total number of participants in each category.
[c] *P* value based on the nonparametric Wilcoxon rank-sum test.
[d] *P* value based on the Fisher exact test.
[e] To qualify to participate in the program, employees had to meet ≥1 of the following criteria: 1) a blood test result within the previous year consistent with a diagnosis of prediabetes (fasting glucose of 100–125 mg/dL, plasma glucose measured 2 hours after a 75-g glucose load of 140–199 mg/dL, or hemoglobin A_{1C} of 5.7%–6.4%), 2) clinically diagnosed gestational diabetes mellitus during a previous pregnancy, or 3) a positive screening result on a questionnaire for prediabetes (10,13,14). In addition, employees had to be aged ≥18 and have a BMI ≥24.0 (≥22.0, if Asian American).

Table 2. Program Metrics for DPP Participants (N = 165) by Achievement of 5% Weight-Loss Goal, Vanderbilt University Medical Center Faculty and Staff Health and Wellness DPP, 2014–2017[a]

Metric	5% Weight-Loss Goal Not Met[b]	5% Weight-Loss Goal Met[b]	*P* Value[c]
No. of participants	93	72	—
Physical activity, minutes per week			
Core phase	132.0 (91.5–164.0)	163.5 (132.8–220.5)	<.001
Postcore phase	120.0 (62.5–173.0)	165.0 (119.0–231.0)	<.001
Overall program	128.5 (83.2–169.8)	166.0 (135.2–223.0)	<.001
No. of sessions of attended			
Core phase	14 (12–15)	15 (14–15)	<.001
Postcore phase	4 (0–7)	8 (6–10)	<.001
Overall program	18 (12–21)	23 (21–25)	<.001
Last session attended[d]	23 (16–25)	25 (23–26)	<.001
Percentage of weight loss			
Core phase	2.5 (0.6–4.4)	7.2 (5.7–10.3)	<.001
Overall program	1.3 (0–3.3)	8.0 (6.2–13.9)	<.001
Absolute weight loss, kg			
Core phase	2.3 (0.9–4.1)	6.4 (5.0–8.7)	<.001
Overall program	1.4 (0–3.2)	7.5 (5.3–13.3)	<.001

Abbreviation: DPP, Diabetes Prevention Program.
[a] Classes were delivered in person in a group setting and were organized into 16 core sessions during the first 6 months of the program, followed by 6 to 10 post-core sessions during the second 6 months of the program.
[b] Values are median (interquartile range) unless otherwise indicated.
[c] *P* value for the nonparametric Wilcoxon rank-sum test.
[d] Of the sessions offered, numbered sequentially from 1 to 26, the last session attended.

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PROGRAM EVALUATION BRIEF

Implementation of Liver Cancer Education Among Health Care Providers and Community Coalitions in the Cherokee Nation

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PEER REVIEWED

Summary

What is already known on this topic?

Chronic infections with hepatitis C virus (HCV) are risk factors for primary liver cancer. Lack of knowledge and awareness among health care providers, populations at high risk, and the public are barriers to HCV prevention and control.

What is added by this report?

The Cherokee Nation Comprehensive Cancer Control program and the Cherokee Nation Health Services HCV Elimination Program implemented and evaluated activities to increase knowledge and awareness. Overall, awareness, knowledge, ability, and intention increased among participants in the 3 interventions.

What are the implications for public health practice?

Provider and community education interventions can improve knowledge and awareness of liver cancer and the ability and intention to talk about it among health care providers and community coalitions.

Abstract

Introduction

The Cherokee Nation Comprehensive Cancer Control Program collaborated with the Cherokee Nation Hepatitis C Virus (HCV) Elimination Program within Cherokee Nation's Health Services to plan and implement activities to increase knowledge and awareness of liver cancer prevention among health care providers and the Cherokee Nation community. From August 2017 to April 2018, the 2 programs implemented liver cancer prevention interventions that focused on education of health care providers and community members. We used descriptive statistics to analyze data collected from a brief, retrospective pre–post survey for each intervention. We assessed overall awareness and knowledge of liver cancer and ability and intention to address it on a scale of 1 to 5. Project Extension for Community Healthcare Outcomes didactic sessions resulted in a 1.1-point improvement, provider education workshops resulted in a 1.4-point improvement, and presentations at community coalition meetings resulted in a 1.7-point improvement. Our study shows that HCV interventions can be used by public health and medical professionals interested in controlling HCV and related diseases such as liver cancer.

Introduction

Hepatocellular carcinoma (HCC), or primary liver cancer, is the second leading cause of cancer death worldwide among cancers that affect both men and women (1). In the United States, chronic infections with hepatitis B virus (HBV) or hepatitis C virus (HCV) are strong risk factors for HCC (2). Primary liver cancer incidence is increasing worldwide, including in the United States (3). Liver cancer is more common in men than in women, and among Asian/Pacific Islander, Hispanic, and American Indian/Alaska Native populations than in other racial and ethnic groups (4).

An Institute of Medicine report in 2010 described several barriers to HBV and HCV prevention and control efforts, including a lack of knowledge and awareness among health care providers, populations at high risk, and the public (5). The report included recommendations in 4 areas: improve viral hepatitis surveillance, improve provider and community education to increase knowledge and awareness of HBV and HCV, increase support for vaccine-based strategies to eliminate HBV transmission, and integrate and enhance viral hepatitis services, including risk factor screening and serologic testing.

The National Comprehensive Cancer Control Program (NCCCP), funded by the Centers for Disease Control and Prevention (CDC), provides funding and technical support for the development and implementation of cancer control programs to create cancer control plans in all 50 states, the District of Columbia, 8 tribes and tribal organizations, and 7 US territories (6). These plans guide the work of cancer control coalitions formed by each awardee. Coalitions include health department staff members (at the state, tribal, territory, US Pacific Island jurisdiction, and local levels) with expertise in cancer and their key partners, such as nonprofit organizations and community health centers. Awardee cancer control coalitions focus on current and emerging cancer issues in their target population and implement strategies in prevention, early detection, treatment, and survivorship by using policies, systems, and environmental changes to reduce the burden of cancer.

Purpose and Objectives

In 2017, the Cherokee Nation Comprehensive Cancer Control (CNCCC) program initiated a partnership with the Cherokee Nation Health Services (CNHS) HCV Elimination Program. The goal of the HCV Elimination Program is to expand HCV testing and refer patients infected with HCV for treatment. The 2 groups collaborated to plan, implement, and evaluate activities to increase knowledge and awareness of HCC among health care providers and Cherokee Nation communities. Although lead staff members from the CNCCC program and HCV Elimination Program had collaborated on previous work, this partnership was their first official partnership. The objective of this study was to describe findings from the evaluation of 3 interventions implemented by the 2 programs.

Intervention Approach

The 2 programs implemented liver cancer prevention interventions from August 2017 through April 2018. Prevention strategies (Table 1) aligned with provider and community education recommendations in the 2010 Institute of Medicine report (5).

The HCV Elimination Program was responsible for conducting didactic sessions for CNHS health care providers on HCC epidemiology, diagnosis, and surveillance through the Project Extension for Community Healthcare Outcomes (ECHO) platform (The Echo Model). Launched in 2003 by a liver disease physician in Albuquerque, New Mexico, Project ECHO is a collaborative model of education and care management that brings together health care providers to increase access to specialty treatment in rural and underserved areas (7). The didactic sessions were delivered in a series of 15-minute presentations during regularly scheduled Project ECHO meetings that were hosted virtually using Microsoft Lync. The HCV Elimination Program was also responsible for conducting health care provider education workshops focused on liver cancer at 8 CNHS facilities. The same slide set used for Project ECHO didactic sessions was used for these workshops, but instead of delivering content in multiple sessions, the entire presentation was given in 1 workshop. The workshops were conducted in person at 7 of the 8 clinics and at the hospital in the Cherokee Nation in Oklahoma. Various health care providers, including nurses, case managers, physicians, nurse practitioners, and physician assistants, were invited to the workshops.

The CNCCC program was responsible for making liver cancer prevention presentations to community coalition members at cancer coalition meetings. Content for each meeting was identical; however, content delivery was tailored to each audience. Presentations focused on causes, prevention, symptoms, and diagnosis of liver cancer. Participants represented 26 coalitions in the Cherokee Nation and included workers from the public school system, local recreation centers, farmers markets, and other community organizations. The CNCCC program presented liver cancer information at 5 coalition meetings.

Evaluation Methods

For each of the 3 interventions, CNHS assessed changes among program participants in awareness, knowledge, ability, and intention by administering a brief, retrospective pre–post survey (8). Survey development was informed by materials developed by CNHS for provider and community presentations and outcomes of interest to CNHS. A paper-and-pencil survey was administered at the end of each session. For each intervention, we collected information on the number of participants and the number and types of medical professionals attending and organizations represented.

For didactic sessions and provider education workshops, *awareness* measured the provider's awareness of statistics and the role of the liver and liver cancer; *knowledge* measured the provider's knowledge of liver cancer risk factors, prevention, and signs and symptoms of the disease; *ability* measured the provider's ability to identify patients who are at high risk for liver cancer, and *intention* measured the provider's intent to speak with patients about HCC risk and recommend screening for patients at high risk. For the community coalition meetings, *awareness* measured the participant's awareness of the function of the liver and liver cancer statistics; *knowledge* measured the participant's knowledge of liver cancer risk factors, prevention, and signs and symptoms of the disease; *ability* measured the participant's ability to speak with a health care provider about liver cancer risk and prevention, and *in-*

tention measured the participant's intent to speak with a health care provider about screening for HCV infection. Survey participants marked their responses on a Likert-type scale (from 1 to 5, with 5 indicating the best outcome).

Our analyses focused on assessing whether the interventions had any effect on participants' awareness, knowledge, abilities, and intentions. Although pre-exposure and post-exposure data were reported in the same survey, surveys were completed anonymously; therefore, we were not able to match data for individual participants across didactic sessions. We combined items (awareness, knowledge, ability, and intention) to create a composite score for each intervention. We also developed an overall composite score, which used all survey questions pre-exposure and post-exposure to examine change overall. We calculated mean composite scores and standard deviations in Stata version 14 (StataCorp LLC). The range for the overall scores was calculated as an average of the ranges for all categories. The overall scores were calculated as an average of all of the scores that make up the score (awareness, knowledge, ability, intention). We used paired *t* tests to assess significance of overall change from pre-exposure to post-exposure (across awareness, knowledge, ability, intention) for each of the 3 interventions, but not for each variable of interest. We generated *P* values; however, not every individual attended all 8 didactic sessions. Therefore, differences between pre-exposure and post-exposure might not be large for the didactic sessions, which would cause the *P* values to be only slightly anticonservative. We excluded missing responses from analyses.

We collected contextual information about implementation challenges, facilitators, and lessons learned through ongoing communication between CNCCC and HCV Elimination Program staff members and NCCCP staff members. Lead CNCCC and HCV Elimination Program staff members took part in monthly technical assistance calls with NCCCP staff members throughout planning and implementation of the 3 interventions. At the close of the project, NCCCP staff members also met informally with lead staff members from each program to discuss final thoughts and experiences.

Results

Overall, awareness, knowledge, ability, and intention increased among participants in the 3 interventions. For overall awareness, knowledge, ability, and intention, Project ECHO didactic sessions resulted in a 1.1-point increase (2.9 pre-exposure vs 4.0 post-exposure, $t_{70} = 3.02$, $P < .001$), provider education workshops resulted in a 1.4-point increase (2.9 vs 4.3, $t_{101} = 4.91$, $P < .001$), and presentations at community coalition meetings resulted in a 1.7-point increase (2.5 vs 4.2, $t_{59} = 4.3$, $P < .001$). We found improvement in each variable of interest in each intervention (Table 2). The greatest improvement in knowledge and awareness (1.2-point increase for each) was in the Project ECHO didactic sessions. The provider education workshops had the greatest improvement in awareness (1.6-point increase), and the community coalition presentations had the greatest improvement in knowledge (2.1-point increase), closely followed by awareness (2.0-point increase).

Health care providers also improved their ability to identify patients at high risk for viral hepatitis and HCC and improved their intention to talk to patients about risk for the diseases. Among community coalition participants, we found an improvement in their ability and intention to talk to their health care provider about their risk for liver cancer and for getting tested for viral hepatitis.

Implications for Public Health

Our study has implications for the cancer control community, including cancer control coalitions and health care providers, because our findings address awareness and education of health care providers, populations at risk, and the public about health risks associated with liver cancer. The study shows how provider and community education interventions can improve knowledge and awareness of liver cancer and the ability and intention to talk about it among health care providers and community coalitions. The improvements in each variable of interest and overall improvements were greater among participants in community coalition meetings than among participants in didactic sessions and provider education workshops. Although greater improvements might be attributed to initially lower levels of knowledge among community coalition participants compared with health care providers, improvements demonstrate the commitment of community coalition members in obtaining vital information needed to best address the needs of their target population.

Several factors facilitated implementation of our intervention, and awareness of these factors can help others in implementing similar interventions. Regularly scheduled meeting times (ie, through Project ECHO) with providers interested in liver cancer and who care for relevant patient populations increased participation rates and resulted in a captive audience and a robust discussion. A collaborative approach across programs facilitated access to essential evaluation resources and expertise. An established relationship with clinic directors (ie, infectious disease specialists through Project ECHO) helped in scheduling the workshops and ensuring provider participation. Involving CNHS public health educators in the coordination of coalition meetings ensured that liver cancer

prevention presentations were included in meeting agendas and that space was secured for each meeting. Access to audiovisual equipment and printing resources and a meeting facilitator with a flexible schedule helped accommodate schedules of participants.

We found numerous challenges in planning and implementing these interventions. Developing the PowerPoint presentation for the Project ECHO didactic sessions and provider education workshops was challenging in scheduling, time consumption, and commitment. Finding convenient meeting times for the majority of health care providers was difficult. Also, competing responsibilities of CNHS public health educators made it difficult for them to dedicate a substantial amount of time to coordinating activities. For example, they traveled for 2 or 3 hours to reach community coalition meetings.

We learned several valuable lessons. The first is to start small. CNHS planned and implemented 3 unique liver cancer prevention interventions simultaneously. However, both NCCCP and HCV Elimination Program staff members found the workload demanding and in hindsight felt that focusing on just 1 or 2 activities at a time would have been better. Second is to be realistic about resources required, such as time and staffing. Planning and implementing the 3 interventions took a large amount of time. CNHS reported through interviews that it had to continuously shuffle priorities to conduct the provider education sessions and complete other time-intensive tasks. In addition, many administrative tasks (eg, monthly reporting requirements, scheduling workshops, completing data tracking sheets) were time consuming. The CNHS team provided an administrative staff member to complete these tasks. The third lesson is to identify and maximize resources. Both NCCCP and HCV Elimination Program staff members spent substantial time developing content for presentations. Greater collaboration among staff members in various programs and outreach to others who might have already developed high-quality resources that required only minor adjustments for the population of interest could have increased the efficiency of staff members and decreased the time required to implement the interventions.

Liver cancer rates are increasing in the United States and public health programs, including the NCCCP, should continue to build and diversify their work in addressing viral hepatitis for liver cancer prevention. The CNHS cancer control and HCV elimination programs have demonstrated a successful partnership model to address liver cancer that can be adapted by other programs. Increasing viral hepatitis and liver cancer prevention interventions among all public health programs is an important step in lowering liver cancer rates in the United States.

Acknowledgments

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or Cherokee Nation Health Services. We did not use any copyrighted materials in this article.

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Tables

Table 1. Liver Cancer Education Interventions for Cherokee Nation Health Care Providers and Community Coalitions, 2017–2018

Intervention	Strategy	Description of Activity	No. of Completed Surveys/No. of Attendees	Participant Characteristics	Time in Practice
HCV Elimination Program	Conduct monthly Project ECHO[a] didactic sessions	Conducted 15-minute didactic sessions during 8 Project ECHO clinics. Topics included incidence and prevalence of HCC, risk factors for and diagnosis of HCC, diagnosis of cirrhosis, and HCC surveillance.	72/83	All participants were health care professionals; 30.6% physicians; 20.8% nurses; 20.8% pharmacists; 8.3% psychologists; 6.9% nurse practitioners; 4.2% case managers; 8.3% described themselves as "other" health care professional	1 week to ≥40 years (median of 10 years in practice)
HCV Elimination Program	Conduct health care provider education workshops	Conducted 8 two-hour provider education workshops; one at a CNHS hospital, and 7 at CNHS outlying clinics. Topics included incidence and prevalence of HCC, risk factors for and diagnosis of HCC, diagnosis of cirrhosis, and HCC surveillance.	108/123	All participants were health care professionals: 35.2% nurses; 21.3% nurse practitioners; 17.6% physicians; 25.9% described themselves as "other" health care professional	0–50 years (median of 10 years in practice)
Cherokee Nation Comprehensive Cancer Control Program	Conduct presentations at community coalition meetings	Conducted 5 presentations at community coalition meetings, held in different venues in different geographic locations. Each presentation was approximately 30 minutes and was intended to reach the general community.	62/78	Participants represented 26 organizations	NA

Abbreviations: CNHS, Cherokee Nation Health Services; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; NA, not applicable; Project ECHO, Project Extension for Community Healthcare Outcomes.

[a] Project ECHO is a collaborative model of education and care management that brings together health care providers to increase access to specialty treatment in rural and underserved areas (https://echo.unm.edu).

Table 2. Pre-Exposure and Post-Exposure Composite Scores for Project ECHO[a] Didactic Sessions, Health Care Provider Education Workshops, and Presentations at Community Coalition Meetings

Intervention/Variable of Interest	No. of Surveys Included in Analysis/No. of Completed Surveys	Composite Scores[b]	
		Pre-Exposure, Mean (SD) [Range]	Post-Exposure, Mean (SD) [Range]
Project ECHO didactic sessions			
Awareness of the role of the liver, liver cancer, and statistics	71/72	2.98 (1.02) [1–5]	4.14 (0.73) [1–5]
Knowledge of liver cancer risk factors, prevention, and signs and symptoms of the disease		2.72 (1.14) [1–5]	3.91 (0.80) [1–5]
Ability to identify at-risk patients		2.58 (1.05) [1–5]	3.70 (0.80) [1–5]
Intention to speak with patients about HCC risk and recommend screening for at-risk patients		3.05 (1.13) [1–5]	4.03 (0.88) [1–5]
Overall[c]		2.92 (1.03) [1–5]	4.03 (0.73) [1–5]
Provider education workshops			
Awareness of the role of the liver, liver cancer, and statistics	102/108	2.81 (0.81) [1–5]	4.39 (0.52) [1–5]
Knowledge of liver cancer risk factors, prevention, and signs and symptoms of the disease		2.96 (0.80) [1–5]	4.25 (0.65) [1–5]
Ability to identify at-risk patients		2.58 (1.05) [1–5]	3.70 (0.80) [1–5]
Intention to speak with patients about HCC risk and recommend screening for at-risk patients		3.05 (1.13) [1–5]	4.03 (0.88) [1–5]
Overall[c]		2.88 (0.81) [1–5]	4.25 (0.67) [1–5]
Community coalition meetings			
Awareness of the role of the liver and liver cancer statistics	60/62	2.23 (0.83) [1–4]	4.25 (0.54) [3–5]
Knowledge of liver cancer risk factors, prevention, and signs and symptoms of the disease		2.09 (0.98) [1–5]	4.20 (0.51) [3–5]
Ability to speak with a health care provider about liver cancer risk and prevention		2.23 (1.09) [1–5]	4.14 (0.66) [1–5]
Intention to speak with a health care provider about screening for hepatitis C virus infection		3.23 (0.99) [1–5]	4.23 (0.72) [1–5]
Overall[c]		2.49 (0.85) [1–5]	4.23 (0.59) [1–5]

Abbreviations: ECHO, Extension for Community Healthcare Outcomes; HCC, hepatocellular carcinoma; SD, standard deviation.

[a] Project ECHO is a collaborative model of education and care management that brings together health care providers to increase access to specialty treatment in rural and underserved areas (https://echo.unm.edu).

[b] Participants scored their awareness, knowledge, ability, and intention by using a Likert-type scale from 1–5, with 5 being the highest score for each variable measured.

[c] Paired *t* tests used to assess significance of overall change from pre-exposure to post-exposure (across awareness, knowledge, ability, intention) for each of the 3 interventions; $P < .001$ for each intervention overall.

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PROGRAM EVALUATION BRIEF

A Media Campaign to Increase Health Care Provider Assistance for Patients Who Smoke Cigarettes

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PEER REVIEWED

Summary

What is already known on this topic?

Although most smokers visit a health care provider annually, only about half are offered evidence-based assistance in quitting. Counseling by a health care professional can at least double a smoker's odds of successful quitting.

What is added by this report?

The New York State Department of Health designed a provider-targeted media campaign to increase provider-assisted quitting. Forty-three percent of providers were aware of at least 1 advertisement, and providers who had seen an advertisement were more likely to provide evidence-based assistance.

What are the implications for public health?

Reaching health care providers through targeted media can encourage evidence-based smoking cessation treatment.

Abstract

Although most smokers visit a health care provider annually, only half report being provided evidence-based assistance with quitting, defined as brief counseling and an offer of medication. The New York State Department of Health designed a provider-targeted media campaign to increase provider-assisted quitting, which was implemented in 2016. Messaging focused on the addictive nature of tobacco products and evidence-based interventions. Online surveys of 400 New York State health care providers measured advertising awareness, associations between awareness and assistance with quit attempts, and perceptions that patients expect providers to assist with quitting. Forty-three percent of providers were aware of at least 1 advertisement, and providers who had seen an advertisement were more likely to provide evidence-based assistance (AOR = 2.55, $P = .01$), which includes recommending or prescribing cessation medications. Provider-targeted media is a promising approach to reach health care providers and encourage evidence-based smoking cessation treatment.

Introduction

Quitting nicotine addiction associated with cigarette smoking can be difficult (1,2). Clinical guidelines call for providers to ask about smoking status, advise smokers to quit, assess quit readiness, assist patients with brief counseling and medications, and arrange for follow-up care, referred to as the 5 A's (Ask, Advise, Assess, Assist, and Arrange) (3). The New York State Department of Health (NYSDOH) has focused its tobacco control efforts on increasing cessation assistance by health care providers in the form of counseling (eg, education about the risks of smoking and the rewards of quitting) and the delivery of 1 or more US Food and Drug Administration (FDA)-approved smoking cessation medications. Delivery of counseling plus cessation medication can at least double the odds of successful cessation, and certain medication combinations further improve outcomes (3).

About 80% of cigarette smokers see a health care provider annually, making the potential reach of provider-based assistance greater than other recommended public health interventions (eg, telephone quitlines reach about 1% of smokers annually) (4). Although 90% of smokers report that their provider asked about tobacco use at their last visit (5), only 45% to 72% of patients who used tobacco were advised to quit, depending on patient demographics (6). Less than half of patients reported that their provider counseled them on cessation issues or recommended or wrote a prescription for medications (3,6). This is a missed opportunity to provide patients with treatment options that can ease withdrawal

symptoms from nicotine and provide coping mechanisms to improve cessation outcomes. Providers cite as barriers to providing effective cessation treatments a lack of training, patients' rejection or disinterest in quitting, and an assessment that other medical issues are more urgent than smoking (7), though effective counseling, such as motivational interviewing, can overcome patient barriers (2,8).

Purpose and Objectives

NYSDOH developed, implemented, and evaluated a pilot project to determine the impact of a paid media campaign directly targeting providers with information about guideline-concordant, evidence-based smoking cessation strategies (3), including the most effective cessation methods, expected outcomes, and key prescribing information (Figure). This campaign complemented a broad public health strategy that included local NYSDOH contractors directed to engage with health system administrators in their catchment area to encourage adoption of system strategies from clinical guidelines (3) (eg, tobacco use screening in the electronic health record), and paid media directed at smokers to encourage quit attempts by engaging with providers. This broad set of strategies has the potential for reaching a large proportion of smokers with an evidence-based intervention, because 70% of smokers express a desire to quit (6) and 80% see a provider annually (4).

Figure. Three advertisements used in New York State Department of Health promotion of tobacco cessation patient interventions among health care providers. The 3 photographs provide links to a website: https://talktoyourpatients.health.ny.gov/.

The goals of this campaign were to determine whether a media strategy could reach primary care providers with messages they would find meaningful and would promote their use of evidence-based smoking cessation treatments. We hypothesized that campaign awareness would be positively associated with increased provision of cessation assistance. Evaluation measures reflected

the core components of the campaign advertisements, including treatment-related beliefs and behaviors.

Intervention Approach

Formative research was conducted in 3 phases, beginning with a review of evaluation studies conducted on behalf of NYSDOH to inform development of key campaign messages. Previous projects informed our ideas about provider attitudes toward patients who smoke, perceived barriers to treating smokers, and provider expectations about helping smokers quit. We examined patients' awareness of available cessation insurance benefits (especially Medicaid) because lack of awareness can be a barrier to getting treatment.

Following this review, focus groups were conducted with physicians, nurse practitioners, and physician assistants. Participants were asked to discuss 4 message concepts: 1) addressing smoking as a critical part of care, 2) smoking cessation treatment does not take that much time, 3) if you don't bring it up, patients might not think it's important, and 4) quitting takes time and likely needs to be repeated to achieve success.

A recurring theme of the focus groups was the addictive nature of smoking, which providers believed warranted their intervention. The theme of addiction implied that quitting is difficult, that relapse is common, and that repeated treatment would likely be necessary. Addiction messaging was augmented with messaging regarding the need for evidence-based treatments, including specific actions providers should take: treat smoking and nicotine addiction with counseling and FDA-approved medication per clinical guidelines (3). As a result of the formative work, the concept of smoking as nicotine addiction was adopted as the central theme of the campaign (1).

In the third phase of the formative process, 3 advertisements were developed for testing among an online panel of providers. Testing assessed perceived effectiveness of advertisements, the extent to which advertisements educated providers about nicotine addiction and its treatment, the extent to which advertisements motivated them to help patients quit, and identification of advertisements most aligned with the intent of the provider-targeted media campaign. Advertisement placement was also guided by the results of the formative work, which indicated that providers primarily refer to social media and professional journals, both print and online, to access professional information. This was augmented with strategic out-of-home and hospital-based placement. Social media and online advertisements linked providers to a website developed by NYSDOH providing specific information about smoking cessation, counseling, and medications (https://talktoyourpatients.health.ny.gov/).

Campaign Evaluation Methods

The media campaign ran from March through July 2016. In July, we surveyed 400 New York State health care providers recruited from Lightspeed Research's online panel of providers. Lightspeed used email to recruit panel members who were physicians, nurse practitioners, or physician assistants in New York State, aiming for an even distribution across provider types. Providers were excluded if they did not provide patient care in the past 12 months or reported that 20% or fewer of their patients were adults. This was a convenience sample, and the online panel vendor did not report the number of providers invited to participate or share identifiable data on providers; the number of providers excluded is unavailable.

Evaluation measures reflected the core components of the campaign advertisements, including treatment-related beliefs and behaviors. The survey assessed advertisement awareness, provider use of evidence-based treatments for smoking cessation, provider perceptions of patient expectations, and provider demographics. For advertisement awareness, we showed providers each of the 3 advertisements and asked if they had seen the advertisements in the past 3 months. For provider perceptions of patient expectations, we instructed providers to indicate the extent to which they agreed or disagreed with the statement, "Patients expect that I should discuss tobacco use and quitting."

We used previously established definitions for measures of ask, advise, and assist (9). Providers were asked how often in the past month they asked new or returning patients if they use tobacco. We categorized "always" or "often" as an affirmative response. We asked providers how often in the past month they advised patients who use tobacco to quit. For assistance, we asked how often in the past month providers did the following for patients who use tobacco: suggest that they set a specific date to stop using tobacco; suggest that they use a tobacco use cessation class, program, or counseling; suggest that they call a telephone quitline; provide them with booklets, videos, or other materials to help them quit on their own; and recommend or prescribe nicotine replacement or other stop-smoking medications when appropriate. We categorized assistance with a quit attempt as an "always" or "often" response to any of these 5 items.

We assessed provider characteristics of age, race/ethnicity, provider type, sex, cigarette smoking status, and cessation training in the past 5 years. We used 2 survey questions to classify smoking status as current smokers (smoked 100 cigarettes in their lifetime and currently smoke every day or some days), former smokers (smoked 100 cigarettes in their lifetime but currently do not

smoke), and never smokers (have not smoked 100 cigarettes in their lifetime). For provider training, we asked whether providers participated in formal training or education on tobacco treatment and cessation counseling methods during the past 5 years.

We calculated post-stratification calibration weights using SUDAAN software's PROC WTADJUST (10), based on the number of providers in New York State. We estimated descriptive statistics using Stata 14 (StataCorp LLC). We used adjusted Wald tests to assess the association between campaign awareness and provider beliefs about patients' expectations about discussing tobacco use and quitting and between advertisement awareness and provider assistance. Logistic regression models were conducted to estimate adjusted odds ratios (AORs) with 95% confidence intervals (CIs) of the relationship between awareness of the campaign and key outcomes, controlling for covariates (age, race/ethnicity, provider type, sex, and training). The reference group for all logistic models were those providers not aware of the campaign. All study protocols were approved by RTI International's institutional review board.

Results

Respondents were physicians (33.5%), physician assistants (33.5%), and nurse practitioners (33.0%). Most respondents were female (59.5%) and white (81.0%). Overall, 20.8% had received tobacco-related training in the past 5 years. Most respondents were never cigarette smokers (74.8%); 22.5% were former smokers, and 2.8% were current smokers. The mean age of respondents was 47.6 (standard deviation, 12.0).

Forty-three percent of providers were aware of at least 1 of the advertisements. Campaign awareness did not differ by provider type. Advertisement awareness was associated with providers strongly agreeing that patients expected them to discuss smoking and quitting in bivariate analyses ($P = .03$), but not after controlling for other factors. The rate at which providers asked patients about tobacco use and advised them to quit did not differ by campaign awareness (Table). Providers aware of the campaign had greater odds of assisting tobacco users with a quit attempt than providers not aware of the campaign (AOR, 2.55; CI, 1.29–5.07; $P = .01$). Independent of other covariates, nurse practitioners had greater odds of assisting their patients than physicians (AOR, 4.05; CI, 1.45–11.3; $P = .01$).

Implications for Public Health

Increasing smoking cessation rates is a public health priority (2). Although current population tobacco control interventions have produced lower cigarette smoking prevalence, declines have been slow (2,6). Opportunities exist to accelerate that decline if health care providers increase delivery of evidence-based cessation methods to their patients who smoke (6). As part of a comprehensive strategy to increase provider delivery of effective treatment in New York State (11), NYSDOH developed a media campaign targeting health care providers with messaging focused on the addictive nature of tobacco products and guideline-concordant treatment.

Evaluation of this campaign showed that providers can be reached by using print and digital media channels, with advertisements placed in medical journals and in and around hospitals. Moreover, messaging developed for this campaign was deemed meaningful by providers. Awareness of messages was associated with higher levels of evidence-based treatment delivery. Nurse practitioners showed the highest likelihood of providing cessation assistance, which may be related to their prominent role in current medical practice. This may suggest that future campaigns leverage messaging specific to nurse practitioners to enhance impact.

One limitation of our study is the cross-sectional nature of the survey; as a result, we are unable to causally attribute the outcomes of the study to the media campaign. Although the association of advertisement awareness with outcomes was possibly a function of the advertisements themselves, it is equally likely that provider differences in receptivity to the content increased the likelihood that providers would differentially attend to the advertisements. Providers already concerned about delivering effective cessation treatment might be more likely to notice the advertisements than providers who might not believe that providing cessation services is one of their primary responsibilities. Additionally, it is likely that these results are not necessarily representative of all health care providers in New York State because the sample came from a predetermined panel list and not a random sample. Reliance on self-reported data rather than objective behavioral measures is an additional limitation necessitated by the scope of the project.

This initial effort to reach health care providers with cessation-related messaging is encouraging. In response to this project's limitations, we have identified a cohort of providers to follow longitudinally for the next campaign. Under these conditions, pre–post changes may be more indicative of exposure to campaign materials. Campaign messaging is also being modified on the basis of provider responses in the first phase and will focus more on directing providers to adopt specific treatment regimens shown to be most effective, especially combination medication therapies. Messaging is further being developed for a campaign focused on providers of behavioral health care. The results of this study are promising and suggest that a media campaign directed at health care providers with key messages focusing on a clear set of recommended treatment procedures could benefit the nearly 80% of

smokers who see a provider annually. This approach for reaching a large proportion of smokers with effective provider interventions has far more potential than current public health standards (4).

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Table

Table. Provider (N = 400) Awareness of Provider-Targeted Media Campaign to Increase Patient Assistance With Tobacco Cessation, New York State Department of Health, 2016

Outcome	Aware of Campaign, % (95% CI) (n = 172)	Unaware of Campaign, % (95% CI) (n = 228)	*P* Value for the Difference	AOR (95% CI) [*P* Value][a]
Strongly agree that patients expect providers to discuss tobacco use and quitting	25.4 (17.9–34.6)	14.1 (9.1–21.2)	.03	1.86 (0.95–3.65) [.07]
Ask patients about tobacco use	95.1 (88.4–98.0)	90.6 (84.0–94.6)	.19	1.81 (0.55–5.96) [.33]
Ask new patients about tobacco use	93.8 (86.6–97.2)	89.4 (82.6–93.7)	.24	1.80 (0.63–5.10) [.27]
Ask returning patients about tobacco use	80.1 (70.8–87.0)	73.1 (64.7–80.1)	.22	1.34 (0.67–2.68) [.41]
Advise patients to quit	92.1 (84.7–96.1)	84.4 (76.7–89.8)	.07	1.87 (0.74–4.72) [.19]
Assist patients with quitting	83.2 (74.2–89.5)	65.6 (55.8–72.6)	.001	2.55 (1.29–5.07) [.01]
Suggest setting a quit date	50.6 (41.0–60.1)	38.7 (30.7–47.3)	.07	1.45 (0.84–1.51) [.18]
Suggest a cessation class or program	63.3 (53.3–72.2)	45.6 (37.3–54.2)	.01	2.01 (1.15–3.53) [.02]
Suggest calling a quitline	43.5 (34.3–53.1)	16.9 (11.8–23.8)	<.001	3.84 (2.08–7.09) [<.001]
Provide self-help materials	37.1 (28.4–46.7)	16.4 (11.1–23.4)	<.01	2.80 (1.51–5.17) [<.001]
Prescribe or recommend nicotine replacement therapy or stop-smoking medications	55.3 (45.6–64.7)	41.5 (33.5–50.1)	.03	1.59 (0.92–2.75) [.10]

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval.
[a] Providers aware of campaign versus providers not aware, estimated using logistic regression controlling for age, race/ethnicity, provider type, sex, and training. Reference group for all logistic regressions was providers not aware of the campaign.

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PROGRAM EVALUATION BRIEF

Single Cigar Price and Availability in Communities With and Without a Cigar Packaging and Pricing Regulation

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PEER REVIEWED

Summary

What is already known about this topic?

Single cigars, little cigars, and cigarillos are considered starter tobacco products for youth and are available in flavors and for low prices. Localities in Massachusetts and Minnesota demonstrated that a regulation requiring a minimum price for cigars led to a short-term decrease in availability and an increase in the price of single cigars.

What is added by this report?

Annual pricing survey data collected from tobacco retailers in Massachusetts from 2014 through 2018 demonstrated that as more communities adopted a cigar packaging and pricing regulation, the price of single cigars increased and the availability of single cigars decreased, even in communities that had not implemented the policy. During the same time period, current youth use of cigars also decreased substantially.

What are the implications for public health practice?

Local municipalities who adopt similar point-of-sale tobacco regulations may contribute to a long-term increase in price and decrease in availability of single cigars among youth-accessible retailers.

Abstract

Single cigars are available for sale throughout the tobacco retail environment, are often sold for prices as low as 49 cents, and are available in flavors that appeal to youth. Since 2012, 151 municipalities in Massachusetts have enacted a minimum cigar packaging and pricing regulation that increases the price of a single cigar to a minimum of $2.50 and the price of multi-packs of 2 cigars to a minimum of $5.00. We used pricing data collected from retailers across the state to measure the effect of the regulation on price and availability of single cigars over the long term. From 2014 through 2018, the statewide average price of single cigars increased from $1.35 to $1.64, concurrent with a decrease in statewide availability. Prices of single cigars were higher in communities with the regulation but also rose over time in communities without the regulation. The increased price and decreased availability of single cigars may reduce youth exposure and access to these products.

Introduction

Following the 2009 Family Smoking Prevention and Tobacco Control Act, which banned the sale of candy-flavored, fruit-flavored, and other flavored cigarettes, the largest cigarette manufacturers purchased existing cigar brands and produced cigars that were available in a variety of youth-attractive flavors, individually packaged in bright colors, and sold for as low as 49 cents each (1). From 2006 through 2010, revenue from flavored cigar sales nearly doubled among retailers in the greater Boston area, and by 2010, more than 100 different flavors of cigars were on the market (2). Data for this same period show a rise in use of cigars and cigarillos by Massachusetts youth. The retail environment is a major source of exposure and access to tobacco for youth, and policies that increase price and reduce availability of tobacco products in the retail environment are effective in curbing youth use (3).

In 2012, Boston became the first municipality in Massachusetts to implement a cigar packaging and pricing regulation (CPPR) that raises the minimum price at which single cigars or cigarillos could be sold. Studies conducted in Minneapolis and Boston demonstrated high retailer compliance with similar regulations (4,5). Ours is the first study to examine statewide single cigar price and availability of 3 cigar brands over a 5-year period.

Each year, the Massachusetts Tobacco Cessation and Prevention Program (MTCP) engages with local enforcement agents and a contracted data collection vendor to visit a large representative sample of tobacco retailers in Massachusetts and administer a survey that obtains the price and availability of different tobacco products. In odd-numbered years, the Massachusetts Youth Risk

Behavior Survey (MYRBS) is administered to a representative sample of high schools in Massachusetts to collect data on youth tobacco use, including cigars. We used data from both surveys to examine single-cigar availability and price over a 5-year period in Massachusetts and statewide trends in youth cigar use during the same period.

Purpose and Objectives

Marketing of cigars, cigarillos, and little cigars closely follows the historic pattern of tobacco industry marketing practices: use of social media, celebrity endorsements, targeted advertisements to youth and African-American populations, and increased availability in communities of color (6,7). Cigars and cigarillos are often cheaper than cigarettes, which may make them more accessible to youth, low-socioeconomic populations, and communities of color, populations all demonstrated to be price-sensitive to tobacco (8).

MYRBS surveillance data show that in 2011, high school youth's use of cigars (14.3%) surpassed their use of cigarettes (14%) for the first time (9). Later surveys indicated that approximately 15% of youth reported that they obtained their tobacco directly or indirectly at a retail store (9).

In Massachusetts, each municipality (of 351 total) has the authority to pass health regulations, including point-of-sale tobacco control policies. CPPR requires tobacco retailers to price single cigars for a minimum of $2.50 and multi-packs of 2 or more cigars for a minimum of $5.00, although each municipality has the option to amend policy language. Violations result in tiered fines, with multiple violations resulting in permit suspension. MTCP-funded Massachusetts Board of Health programs and trade associations — Massachusetts Municipal Association, Massachusetts Association of Health Boards, and Massachusetts Health Officers Association — provide technical assistance for municipalities that consider passing tobacco control policies, including model regulation language and community mobilization at local hearings. Funded Massachusetts Board of Health programs provide retailer education and enforcement, allowing for a stable infrastructure that ensures high retailer compliance. Although some municipalities do not directly receive MTCP funds, enforcement is promoted and conducted in these municipalities, with MTCP-funded technical assistance provided by the Massachusetts Health Officers Association.

Intervention Approach

Since Boston's CPPR took effect in 2012, 151 municipalities in Massachusetts implemented a CPPR by the end of the study period (June 30, 2018), making up 46% of the state's tobacco retailers and covering 47% of the state's population. Policy passage in municipalities was as follows: 2012, n = 3; 2013, n = 30; 2014, n = 39; 2015, n = 32; 2016, n = 32; 2017, n = 12; and 2018, the end of the study period, n = 3.

State and federal policies that raise the price of cigarettes have been successful in reducing youth use of cigarettes through minimum price laws, excise taxes, minimum packaging, and the prohibition of certain flavors (10). However, lowering prices is one tactic historically used by the tobacco industry to increase demand among price-sensitive populations, including youth (11). Research has demonstrated that increases in cigarette prices have been associated with a reduction in youth use (12,13).

Like flavored cigarettes, flavored cigars have been promoted by the industry as starter products among youth, using flavors to mask the harsh tobacco taste (14). National data indicate that flavored cigars and cigarillos account for more than a third of cigar sales and half of cigarillo sales (15). A reduction in availability of single cigars may also address youth access, exposure, and use of flavored tobacco products.

Evaluation Methods

Pricing survey. The pricing survey collects retailer data such as establishment name, address, store type (eg, gas station, convenience store), and whether the retailer is part of a chain or independently owned. The survey measures price and availability of 3 major cigarillo brands: Dutch Master, Black and Mild, and Garcia y Vega Game, chosen because of their prevalence in Massachusetts (2). All prices presented in this article are pre-tax prices to allow for comparison across brands.

Pricing survey sampling. MTCP engages with 2 groups of data collectors to conduct the pricing survey. Local enforcement agents conduct the surveys in 100% of retailers in 186 municipalities (with and without CPPR) where enforcement work is funded. In the remaining unfunded communities with at least 1 retailer present, MTCP contracts with JSI Research and Training Institute, Inc. (JSI) to perform data collection. MTCP maintains a database of all active tobacco retailers in the state from which a simple random sample of retailers in both funded and unfunded regions is drawn each quarter of the year (3-month periods). Because randomization occurs on the retailer level and not the municipal level, a representative sample of retailer data is available for each quarter throughout the year.

The study period was 5 years and collected 4 full years of data: 2014 (calendar year), and fiscal year (FY) 2016 (July 2015–June 2016), fiscal year 2017 (July 2016–June 2017), and fiscal year 2018 (July 2017–June 2018). In all years, 100% of retailers in fun-

ded municipalities were selected for surveys. For unfunded municipalities, 38% of active retailers were sampled in 2014,100% in FY 2016, 40% in FY 2017, and 100% in FY 2018, resulting in the following samples: 2014 (n = 5,471), FY 2016 (n = 6,843), FY 2017 (n = 5927), and FY 2018 (n = 4,481). Decreased sampling in 2014 and FY 2017 in unfunded communities was a result of limited funding in those years.

Massachusetts Youth Risk Behavior Survey. Every odd year, the Massachusetts Department of Elementary and Secondary Education and the Massachusetts Department of Public Health conduct the MYRBS to monitor trends of health risk behaviors among high school students (9). Through a random selection process, a representative sample of schools across the state is chosen to participate; within each school, classes from grades 9 to 12 are randomly selected to be surveyed. Student participation is voluntary. Surveys are administered by the Center for Survey Research at the University of Massachusetts Boston, which also prepares data for analysis, including weighting the data according to Centers for Disease Control and Prevention (CDC) protocol. Respondents are asked about their cigar use: "During the past 30 days, on how many days did you smoke cigars, cigarillos, or little cigars?" with response options that ranged from "0 days" to "all 30 days." Respondents were considered current users if they indicated use in the past 30 days.

Data analysis. For each year, mean price of each brand and an aggregate mean price for all 3 cigar brands combined were calculated overall for the state and for communities with and without the CPPR. Single-cigar availability was also calculated overall for the state by individual cigar brand and aggregated for communities with and without the CPPR. Data were weighted by region and store type to account for the variation in completion rates (retailers successfully surveyed) in funded and unfunded regions, because data collectors in MTCP-funded communities are likely to have established relationships with retailers. Because of the nature of policy implementation, the CPPR within individual municipalities passed and took effect at different points over the 5 years. Individual municipalities typically provided an adequate amount of time for retailers to comply, ranging from 3 months to 1 year, so the policy effective date was used to classify whether or not a community had the regulation at the time of data collection. Communities were classified by either having a CPPR or not, despite individual variations in policy that may be present in a small subset of municipalities. At the time of this study, only aggregated numbers were available, so statistical testing or modeling could not be completed.

Results

The average price of single cigars in Massachusetts increased steadily each year from 2014 through 2018, from $1.35 to $1.64 (Table), and availability of single cigars decreased statewide. In 2014, single cigars were available in 49% of retailers across the state. By FY 2018, single cigars were available in only 21% of retailers.

The price of single cigars was higher in communities with the regulation than in communities without it (Table). In communities with the CPPR, the price increase of single cigars (aggregated) ranged from $2.24 to $2.41. Over time, prices of single cigars increased in communities without the regulation. The price of Garcia y Vega Game single cigars has increased from under a dollar ($0.89) to $1.22 by FY 2018 in communities without the CPPR.

Over time, availability of single cigars decreased in communities with a CPPR. From 2014 to FY 2018, availability of single cigars (aggregated) decreased from 28% to 14% in communities with the regulation. Trends over time suggest that availability of single cigars also decreased in communities without the regulation. Although availability overall for Black and Mild cigars remained steady, availability for both Dutch Master and Garcia y Vega Game single cigars dropped substantially across the state (Dutch Master, from 50% to 12%; Garcia y Vega, from 42% to 6%).

MYRBS data indicated that from 2011 through 2017, current use of cigars decreased from 14.3% to 6.7% (Figure).

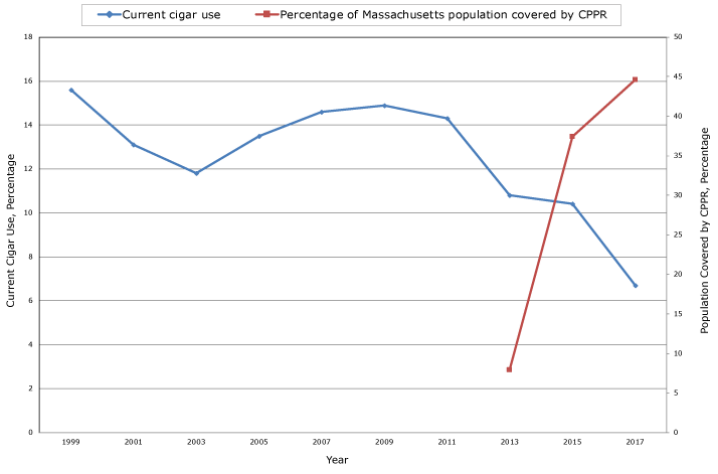

Figure. Cigar use among high school youth and percentage of population covered by cigar packaging and pricing regulation (CPPR), Massachusetts, 1999–2017. Abbreviation: NA, not applicable.

Implications for Public Health

Data for Massachusetts show an increase in the price of single cigars in several municipalities over the 5-year period. This study is the first to show that over time, with increasing policy coverage across the state, the price of single cigars increased and the availability of single cigars also decreased in communities that had not implemented the policy. The substantial statewide coverage of the CPPR may reduce youth access and youth use of cigars or cigarillos. However, other factors may affect cigar use, because youth may be switching instead to other popular nicotine products, such as e-cigarettes. Other tobacco policies passed on a municipal level, such as age restrictions, restrictions of sales of flavored tobacco products, and banning the sale of tobacco in pharmacies may also affect youth access and use.

This study has several limitations. We presented aggregated pricing and availability data, which do not allow for statistical testing; thus, we cannot directly attribute the observed outcomes to the policy. Data were unavailable before 2012, when the first CPPR was passed in Massachusetts, so we did not have a true baseline period. We used pre-tax prices for comparison purposes, and the final price may be different because of coupons or taxes. Data collection was switched from calendar year to fiscal year, leaving a gap in 2015 data. Future analysis should use individual-level retailer data to ascertain the effect of the CPPR, controlling for other tobacco control policies, community demographics, variation in policy language, and funding status.

Tobacco industry influence remains pervasive in the point-of-sale retail environment, in which youth are exposed to a variety of flavored tobacco products, advertisements, and cheap prices. A comprehensive approach to addressing tobacco industry tactics by adopting policies like the CPPR, alongside other point-of-sale policies, such as restrictions on the sale of flavored tobacco products, may increase price and reduce exposure, access, and ultimately youth use.

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Table

Table. Retailers Selling Single Cigars and Price of Cigars, Massachusetts,2014, FY2016–FY2018[a]

Variable	No. of Retailers (Average Price of Single Cigar, $)				No. of Retailers (% of Stores Selling Single Cigars)[b]			
	2014	FY 2016	FY 2017	FY 2018	2014	FY 2016	FY 2017	FY 2018
Aggregate average[c,d,e]	7,513 (1.35)	5,842 (1.51)	3,922 (1.56)	3,794 (1.64)	7,513 (49)	5,842 (32)	3,922 (24)	3,794 (21)
Communities with no regulation	6,333 (1.17)	4,740 (1.29)	3,181 (1.35)	2,455 (1.21)	6,333 (56)	4,740 (38)	3,181 (29)	2,455 (27)
Communities with regulation	1,180 (2.24)	1,102 (2.48)	1,194 (2.50)	1,399 (2.41)	1,180 (28)	1,102 (20)	1,194 (14)	1,399 (14)
Dutch Master	2,583 (1.49)	1,665 (1.77)	895 (1.84)	742 (2.03)	2,583 (50)	1,665 (27)	895 (16)	742 (12)
Communities with no regulation	2,083 (1.32)	1,252 (1.53)	714 (1.68)	435 (1.70)	2,083 (55)	1,252 (30)	714 (19)	435 (14)
Communities with regulation	500 (2.50)	413 (2.50)	259 (2.50)	307 (2.45)	500 (35)	413 (22)	259 (10)	307 (10)
Black and Mild	2,836 (1.39)	2,812 (1.45)	2,352 (1.49)	2,716 (1.54)	2,836 (56)	2,812 (46)	2,352 (44)	2716 (44)
Communities with no regulation	2,362 (1.23)	2,308 (1.23)	1,907 (1.29)	1,788 (1.12)	2,362 (63)	2,308 (55)	1,907 (53)	1,788 (60)
Communities with regulation	474 (2.43)	504 (2.48)	707 (2.49)	928 (2.39)	474 (33)	504 (27)	707 (24)	928 (23)
Garcia y Vega Game	2,094 (1.00)	1,365 (1.27)	675 (1.39)	336 (1.57)	2,094 (42)	1,365 (22)	675 (13)	336 (6)
Communities with no regulation	1,888 (0.89)	1,180 (1.08)	560 (1.17)	232 (1.22)	1,888 (50)	1,180 (28)	560 (15)	232 (8)
Communities with regulation	206 (2.35)	185 (2.47)	228 (2.52)	104 (2.37)	206 (15)	185 (10)	228 (7)	104 (3)

Abbreviation: FY, fiscal year.

[a] 2014, calendar year; FY 2016, July 2015–June 2016; FY 2017, July 2016–June 2017; FY 2018, July 2017–June 2018. N values for each individual cigar brand (excluding the n value for the aggregate average) represent the number of retailers in the sample carrying that brand of cigars. The reduction in the N value over time is due to the reduction in the number of stores carrying single cigars as more communities across Massachusetts adopt CPPR, not a reduction in the number of retailers surveyed in the overall sample. The total number of unique retailers sampled each year is as follows: 2014 sample, n = 5,471 retailers; FY 2016 sample, n = 6,843 retailers; FY 2017 sample, n = 5,927 retailers; FY 2018 sample, n = 4,481 retailers.

[b] All percentages are weighted by region and store type to account for the variation in survey completion rates in funded and unfunded regions.

[c] The N values used for the aggregate average represent the total number of data points collected. They do not represent the number of unique stores sampled or the number of unique stores with any single cigars for sale. If a retailer carries Dutch Master, Black and Mild, and Garcia y Vega Game, it is counted 3 times.

[d] The aggregate average price represents the average price across all 3 cigar brands; it is calculated as: (price of all Dutch Master + price of all Black and Mild + price of all Garcia y Vega)/(total number of data points collected).

[e] The aggregate average percentage of retailers selling single cigars for a given year is calculated as (number of retailers that sell Dutch Master + number of retailers that sell Black and Mild + number of retailers that sell Garcia y Vega)/(total number of unique retailers sampled that year × 3).

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ORIGINAL RESEARCH

Estimating the Relative Impact of Clinical and Preventive Community-Based Interventions: An Example Based on the Community Transformation Grant Program

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PEER REVIEWED

Summary

What is already known on this topic?

Previous work demonstrated the potential long-term impact of clinical and community interventions to prevent chronic disease. However, that work considered only hypothetical interventions that may not accurately reflect the feasibility of implementation in a real-world setting.

What is added by this report?

We examined the potential 10- and 25-year impact of clinical and community interventions to prevent chronic disease as they were implemented under the Community Transformation Grant program.

What are the implications for public health practice?

Results support public health practitioners in strategic planning for chronic disease prevention.

Abstract

Introduction

Public health focuses on a range of evidence-based approaches for addressing chronic conditions, from individual-level clinical interventions to broader changes in policies and environments that protect people's health and make healthy living easier. This study examined the potential long-term impact of clinical and community interventions as they were implemented by Community Transformation Grant (CTG) program awardees.

Methods

We used the Prevention Impacts Simulation Model, a system dynamics model of cardiovascular disease prevention, to simulate the potential 10-year and 25-year impact of clinical and community interventions implemented by 32 communities receiving a CTG program award, assuming that program interventions were sustained during these periods.

Results

Sustained clinical interventions implemented by CTG awardees could potentially avert more than 36,000 premature deaths and $3.2 billion in discounted direct medical costs (2017 US dollars) over 10 years and 109,000 premature deaths and $8.1 billion in discounted medical costs over 25 years. Sustained community interventions could avert more than 24,000 premature deaths and $3.4 billion in discounted direct medical costs over 10 years and 88,000 premature deaths and $9.1 billion in discounted direct medical costs over 25 years. CTG clinical activities had cost-effectiveness of $302,000 per death averted at the 10-year mark and $188,000 per death averted at the 25-year mark. Community interventions had cost-effectiveness of $169,000 and $57,000 per death averted at the 10- and 25-year marks, respectively.

Conclusion

Clinical interventions have the potential to avert more premature deaths than community interventions. However, community interventions, if sustained over the long term, have better cost-effectiveness.

Introduction

Public and private sector stakeholders have worked together for decades to prevent chronic disease, improve quality of life, and reduce medical costs and death associated with chronic disease. Evidence-based approaches for addressing chronic conditions range from individual-level clinical interventions addressing better identification and control of chronic diseases to broader changes in policies and environments around diet, physical activity, and smoking that make healthy living easier in a community. Public health now focuses on all these areas but recognizes that different interventions may have different potential impacts (1). Assessing the potential impact of interventions is challenging, because interventions take time to affect health and economic outcomes. As a result, only a small part of the impact of these interventions can be quantified in the first few years through observing program reach and initial impact on behaviors. Simulation modeling is a useful tool to extend the time horizon for assessing the potential long-term impact of clinical and community interventions.

Previous comparisons of clinical and community interventions generally considered policy change scenarios that may not have accurately reflected the real-world applications of these interventions (2). In this study, we simulated the potential 10- and 25-year impacts of 2 types of interventions as they were implemented as part of the Community Transformation Grant (CTG) program, a large multicommunity public health program funded by the Centers for Disease Control and Prevention (CDC) from 2011 through 2014.

Methods

The CTG program is a large-scale example of a program that supported the implementation of both clinical and community approaches to address chronic disease (3). CTG awardees were required to address at least one of the following focus areas: 1) increase options for tobacco-free living (eg, smoke-free policies for workplaces or multiunit housing), 2) promote and improve access to opportunities for active living and healthy eating (eg, working with partners to build bike paths and increase the availability of fruits and vegetables at corner stores), 3) increase use of clinical and community preventive services (eg, community health worker initiatives), and/or 4) expand access to healthy and safe physical environments (eg, Safe Streets initiatives) (4). After a competitive application process, CDC allocated $103 million to 61 state and local government agencies, tribes and territories, and nonprofit organizations in 36 states, covering 130 million people (3,5).

We used the CTG program as an example of a chronic disease prevention program to estimate the long-term potential health and economic outcomes of clinical and community interventions if they were sustained at the same level over time. We used information on the classifications of interventions that were conducted as part of the CTG program and their reach as inputs to the Prevention Impacts Simulation Model (PRISM) to estimate the potential long-term impact of clinical and community interventions. In the CTG program, reach was operationalized as the estimated number of people in the target population who had increased access to (eg, those living within 1 mile of a park), are protected by (eg, a workplace smoke-free policy), or are otherwise affected by (eg, patients covered by a community health worker program) an intervention (6).

PRISM is a computer simulation model containing mathematical equations that describe how risk factors interact to produce chronic disease and poor health outcomes and the impacts of various community and clinical interventions. PRISM calculates outcomes annually and cumulatively from 1990 through 2040 (7–10). PRISM was validated in several ways during its development and has been used to estimate the long-term impact of other community health programs, such as the Communities Putting Prevention to Work program (11) and public health prevention activities of the Los Angeles County Public Health Department (12).

PRISM includes a wide range of chronic disease–related intermediate outcomes that can be influenced by clinical and community intervention strategies. These strategies are represented in the model as "levers," which reflect changes in the numbers of people reached by the strategy. Lever movement provides an estimate of the intent-to-treat population and not the population that changed their health behaviors as a result of lever movement. PRISM simulates the impact of lever movement on cardiovascular disease (CVD) risk behaviors, like smoking and physical activity in the reached population, by applying published estimates of the effect of increased access on health behavior. For example, building a park would increase the lever for access to physical activity spaces; PRISM then simulates the impact on physical activity for the portion of the reached population that used the park and increased their physical activity. These impacts on risk factors, in turn, reduce the prevalence of cardiovascular disease, pulmonary disease, lung cancer, and resulting deaths and costs. PRISM includes levers that address tobacco use; nutrition; physical activity; clinical care for preventing or mitigating hypertension, diabetes, and high cholesterol; and aspirin use. Most PRISM levers are represented by an index ranging from 0 (no implementation of the strategy) to 1 (optimal implementation of the strategy across the entire population). Because PRISM levers represent broad strategies to improve access, each PRISM lever can be moved by one or more evidence-based interventions. For example, the lever "Increasing access to physical activity spaces" can be moved by

each of 10 interventions that are expected to produce a positive health outcome, including bike shares (13–17), safe-streets initiatives (18,19), parks (19-21), and joint-use agreements (22–24). Each evidence-based intervention was assigned to an intensity category (minimal, low, medium, and high) that represented its ability to move the lever for those reached by the intervention. The intensity category was assigned primarily on the basis of the impact of the intervention estimated in the literature. A list of all evidence-based interventions that can move each lever and details on the process of generating the list and assigning intensity categories are available in an online supplement (https://forio.com/app/cdc/prism/#/resources).

PRISM simulation outcomes reflect the impact of changes in lever settings compared with baseline trends (ie, no change from the status quo). Baseline PRISM levers were set to reflect a community's public health environment pre-intervention (ie, before the CTG program began, in 2011). For example, when analyzing the impact of increasing access to physical activity spaces, we did not simply assume that a community started from a baseline access level of zero, but instead we used publicly available information about each community's policies and environment to estimate the baseline level for each lever. Baseline lever settings were determined by reviewing data and literature on the existing environment for physical activity, nutrition, tobacco, and clinical services policies, such as city, county, and state information from the literature, and secondary data sources, such as the US Census Bureau and the National Health and Nutrition Examination Survey.

Translating CTG activities into PRISM inputs

Building on previous work (11), we used the RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework to translate CTG activities into PRISM lever inputs for simulation modeling (25–27). The evaluation focused on reach and effectiveness. To assess reach, we used awardee-submitted estimates of the number of people reached by their activities. CDC provided awardees with written guidance on estimating reach, including metrics, definitions, and potential data sources. Awardees were also encouraged to obtain technical assistance from CDC project officers when estimating intervention reach. Reach was operationalized as the estimated number of people in the target population who had increased access to (eg, those living within 1 mile of a park), are protected by (eg, a workplace smoke-free policy), or affected by (eg, patients covered by a community health worker program) an intervention (6). Determining reach included 1) documenting the setting where the intervention was implemented during the funding period, 2) using census data or setting-specific data (eg, school enrollment) to identify the population count for the setting where the intervention was implemented, and 3) aggregating data. If interventions were implemented in settings or populations that potentially overlapped, the overlap was estimated and accounted for in the aggregation process. Submitted reach estimates were reviewed and validated by trained CDC program officers, subject matter experts, and contractors by using census, school enrollment, and other local data sources.

Because reach was an intent-to-treat metric, not all people reached by the intervention will use the intervention or change their behavior as a result of access. The model incorporates effect-size estimates for the proportion reached whose use and behavior changes (ie, the estimated proportion of people in the target population who have increased access to or are protected by an intervention). Because PRISM is a population model representing the entire community, the denominator for proportional reach was the entire adult population, child population, or the total population of the targeted community as indicated by the US Census Bureau.

To assess effectiveness, we used information on the interventions completed by each awardee as reported in the annual reports submitted to CDC. A team of coders reviewed each awardee's progress reports and determined which evidence-based interventions (https://forio.com/app/cdc/prism/#/resources) were conducted as part of each awardee activity. Each evidence-based intervention was assigned a categorical intensity that was used to determine the PRISM lever movement. For 20% of the awardee activities, a second coder performed a secondary review for quality control, and the 2 coders reconciled differences.

We computed the lever movement for each activity by taking the intensity of the interventions conducted as part of that awardee's activity and multiplying by proportional reach. We then computed the total lever movement for each awardee by aggregating the lever movements for all of that awardee's activities that affected each lever.

We estimated the impact of a subset of CTG activities that met our criteria for being evidence-based on premature deaths averted and medical costs saved after 10 and 25 years. The goal of the CTG program was to implement clinical and community interventions that could be sustained into the future with minimal further input, so we assumed that all interventions would be sustained at a constant level and that maintenance costs would be incurred for at least 10 and 25 years. We also examined the projected program implementation costs of awardee activities (including program maintenance costs) and the projected impact on risk factor management costs to calculate the total cost and cost-effectiveness of the CTG program. We constructed cost-effectiveness ratios as the sum of implementation costs and net medical costs (ie, risk factor management costs minus medical cost savings) divided by the incremental health gains of the program (ie, premature deaths prevented). We estimated the impact of each awardee's activities

overall and separately for clinical and community levers. We examined the median and range of the estimated impact across awardees and the aggregate for all CTG awardees. Medical costs were inflated to 2017 dollars by using the medical cost component of the Consumer Price Index (28). Future cost savings were discounted by 3% per year (29).

We conducted a probabilistic sensitivity analysis in which model parameters were varied across a distribution assumed on the basis of the literature (29) to estimate the lower and upper bounds of a 95% confidence interval for premature deaths averted, risk factor management costs, medical costs saved, and cost per premature death averted.

Results

Of the 61 CTG program awardees, 29 worked to build capacity for public health interventions and did not implement any interventions. The remaining 32 awardees implemented interventions that could be translated into PRISM levers and were included in this analysis. These awardees covered a population of 87 million people. They implemented clinical interventions reaching 19 million people, community tobacco interventions reaching 20 million people, community nutrition interventions reaching 37 million people, and community physical activity interventions reaching 26 million people.

CTG awardees worked on interventions that affected 21 different PRISM levers (Table 1). Thirty awardees worked on interventions targeting community PRISM levers (including nutrition, physical activity, and tobacco) and 12 awardees worked on interventions targeting clinical PRISM levers. Physical activity access was the lever addressed by the largest number of CTG awardees (20 awardees) and was increased an average of 20 percentage points across all awardees (ie, a 20 percentage-point increase in the number of people with access to places where they can engage in physical activity). Smoke-free multiunit housing was implemented by 18 awardees, with an average movement of 10 percentage points (ie, a 10 percentage-point decrease in multiunit housing complexes that permit smoking). Other levers moved in our analysis were fruit and vegetable access (12 awardees, average movement = 12 percentage points), physical activity promotion (15 awardees, average movement = 7 percentage points), physical activity requirements in schools (13 awardees, average movement = 11 percentage points), and workplace smoke-free policy (12 awardees, average movement = 23 percentage points). The most frequently implemented clinical interventions were related to improving quality care for people with diabetes (8 awardees, average movement = 12 percentage points), hypertension (7 awardees, average movement = 8 percentage points), and high cholesterol (11 awardees, average movement = 7 percentage points).

Results from PRISM simulations indicate that the projected 10-year impact (from 2015 through 2024) of clinical levers moved by CTG awardee activities would be more than 36,000 premature deaths averted, $3.2 billion in discounted medical cost savings, and $14.2 billion in risk factor management costs incurred (Table 2). The projected 10-year impact of community levers moved by CTG awardee activities would be nearly 25,000 premature deaths averted, $3.4 billion in discounted medical cost savings, and $3.0 billion in risk factor management costs incurred. The 10-year cost-effectiveness of CTG clinical activities was $302,000 per premature death prevented. The estimated cost-effectiveness of CTG community activities was $169,000 per premature death prevented.

The projected 25-year impact (from 2015 through 2039) of clinical levers moved by CTG awardee activities would be more than 109,000 premature deaths averted, $8.1 billion in discounted medical cost savings, and $28.4 billion in risk factor management costs incurred (Table 2). The projected 25-year impact of community levers moved by CTG awardee activities would be more than 88,000 premature deaths averted, $9.1 billion in discounted medical cost savings, and $6.5 billion in risk factor management costs incurred. The 25-year effectiveness of CTG clinical activities was $188,000 per premature death averted, and the 25-year effectiveness of CTG community activities was $57,000 per premature death averted.

Discussion

This analysis provides estimates of the effects of large-scale clinical and community interventions as they were implemented during the CTG program, complementing previous work estimating the impact of hypothetical interventions (2). Results show that CTG clinical activities were projected to avert more premature deaths after 10 years and 25 years than CTG community interventions, but that the gap between the intervention categories shrank from the 10-year mark to the 25-year mark. However, CTG community interventions were projected to save more medical costs after 10 years and 25 years than CTG clinical interventions; this gap increased from the 10-year mark to the 25-year mark. Community interventions in the CTG program had much higher projected program implementation costs than clinical interventions, but led to a much smaller increase in risk factor management costs at the 10-year and 25-year marks. No standard benchmark exists to assess the cost-effectiveness in relation to premature deaths. However, Neumann and colleagues recommended using $100,000 or $150,000 as acceptable amounts to pay per quality-adjusted life

year (QALY) gained (30). A cost-effectiveness threshold for premature deaths prevented would be expected to be greater than that for QALYs gained because, on average, preventing a premature death is expected to have a higher value than 1 QALY. Based on this cost-effectiveness threshold, sustained community interventions would likely be considered cost-effective, especially when considered over a period of 10 years or longer.

A previous study using similar methods evaluated another CDC-funded program, Communities Putting Prevention to Work (CPPW), and projected that the program would prevent 14,000 premature deaths in 51 communities during a 10-year period (11). The larger number of premature deaths prevented by the CTG program versus CPPW is likely attributable to the CTG program's use of clinical interventions, our additional analytic efforts to code evidence-based interventions into PRISM, and the use of existing infrastructure by high-capacity awardees to implement community health interventions.

Our analysis is subject to several limitations. First, all simulation models are approximations to reality and are limited by the evidence of effect sizes that is available. Second, we derived model inputs from awardee progress reports, which may overstate accomplishments. Third, although PRISM is a broad cardiovascular disease model, it accounts for most, but not all, strategies implemented in the CTG program (eg, it does not account for outdoor smoke-free air regulations). Fourth, the analysis assumes that all activities would be sustained for 10 years and 25 years, which is the most optimistic scenario possible. In reality, interventions often lose strength once they are no longer actively promoted. This assumption may be more reasonable for interventions that change policies or the community environment, but may be less realistic for interventions that require regular ongoing support. Fifth, translating programmatic information into any simulation model is challenging, and quantifying community policy and environmental changes introduces aspects of subjectivity. The process used in this analysis was refined from CPPW to reduce subjectivity by focusing on evidence-based interventions from the literature, all of which were assigned to a given category of impact. This approach is consistent with approaches used by others to estimate the "dose" for community health interventions (25–27). Finally, this analysis focused on the aggregate impact of the CTG program and did not address variability in reach and potential health and economic outcomes for specific awardees or target populations.

Study findings suggest that clinical and community interventions, like those implemented in the CTG program, may be expected to have substantial benefits. Clinical interventions have the potential to prevent more premature deaths than community-based interventions in both the intermediate (10 years) and long term (25 years). However, sustaining community-based interventions over the long term may save more in medical costs and have greater cost-effectiveness than investing in only clinical interventions.

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Tables

Table 1. Summary of PRISM Levers Moved as a Result of the Community Transformation Grant Program, Number of Communities that Moved Each Lever, and Average Movement of Levers[a]

PRISM Lever	Description of Lever	No. of Communities Moving the Lever	Average Lever Movement, Percentage Points[b]
Community lever			
Fruit and vegetable access	The percentage of the population having convenient, affordable access to fresh fruits and vegetables.	12	12
Fruit and vegetable promotion	The extent of promotion for fruit and vegetable consumption through local communication and food placement in the locations in which people typically buy or consume food, as well as through mass media.	4	2
Physical activity access	The percentage of adults with access to safe and affordable walking, biking, social, and green space opportunities for physical activity in worksites and community locations.	20	20
Physical activity promotion	The extent of local communication, placement, and pricing of physical activity options at worksites and in the community, as well as use of mass media and social marketing.	15	7
Physical activity requirements in childcare	The percentage of children aged 2 to 5 in daily childcare that is required to meet recommended physical activity levels and not to exceed screen time limits.	4	3
Physical activity requirements in schools	The percentage of children aged 6 to 17 that is required to meet recommended physical activity levels during school or in after-school programs.	13	11
Smoke-free multiunit housing	The percentage of multiunit housing residents that live in housing that allows smoking.	18	10
Smoke quit services	The use of smoking quit services as affected by affordability, availability, and outreach.	9	24
Smoking counter marketing	Local communication about tobacco products in locations where people shop, work, and live, as well as a mass media social marketing campaign.	5	4
Workplace smoke-free policies	The percentage of indoor workplaces, including restaurants and bars, that allow smoking.	12	23
Clinical lever			
Use of quality CVD care after a CVD event	The percentage of the post-CVD population receiving cardiovascular care according to current clinical practice guidelines.	1	4
Use of quality diabetes care non-CVD	The percentage of the non-CVD/post-CVD population with diagnosed diabetes that is receiving diabetes care according to current clinical practice guidelines.	8	12
Use of quality diabetes care after a CVD event		7	12
Use of quality high cholesterol care non-CVD	The percentage of the non-CVD/post-CVD population with diagnosed high cholesterol that is receiving cholesterol care according to current clinical practice guidelines.	11	7
Use of quality high cholesterol care after a CVD event		10	7
Use of quality hypertension care non-CVD	The percentage of the non-CVD/post-CVD population with diagnosed hypertension that is receiving hypertension care according to current clinical	7	8

Abbreviation: CVD, cardiovascular disease; PRISM, Prevention Impacts Simulation Model.

[a] PRISM is a computer simulation model containing mathematical equations that describe how risk factors interact to produce chronic disease and poor health outcomes and the impacts of various community and clinical interventions (7–10). Clinical and community intervention strategies are represented in the model as "levers," which reflect changes in the numbers of people reached by the strategy.

[b] Movement is defined as an improvement from the baseline lever level (ie, percentage-point change from baseline). Movement reflects only changes in the fraction of the targeted population that had increased access and does not reflect the percentage of people that changed behavior as a result of increases in the levers.

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Table 1. Summary of PRISM Levers Moved as a Result of the Community Transformation Grant Program, Number of Communities that Moved Each Lever, and Average Movement of Levers[a]

PRISM Lever	Description of Lever	No. of Communities Moving the Lever	Average Lever Movement, Percentage Points[b]
Use of quality hypertension care after a CVD event	practice guidelines.	7	8
Aspirin use compliance female, aged <65	The percentage of prophylactic (daily or every other day) aspirin use among the target population for whom such use is recommended by the US Preventive Services Task Force.	1	1
Aspirin use compliance, female, aged ≥65		1	1
Aspirin use compliance, male, aged <65		1	1
Aspirin use compliance, male, aged ≥65		1	1

Abbreviation: CVD, cardiovascular disease; PRISM, Prevention Impacts Simulation Model.

[a] PRISM is a computer simulation model containing mathematical equations that describe how risk factors interact to produce chronic disease and poor health outcomes and the impacts of various community and clinical interventions (7–10). Clinical and community intervention strategies are represented in the model as "levers," which reflect changes in the numbers of people reached by the strategy.

[b] Movement is defined as an improvement from the baseline lever level (ie, percentage-point change from baseline). Movement reflects only changes in the fraction of the targeted population that had increased access and does not reflect the percentage of people that changed behavior as a result of increases in the levers.

Table 2. Projected 10-Year and 25-Year Cost-Effectiveness of Community Transformation Grant (CTG) Activities for Clinical and Community Levers[a]

Outcome	Clinical Levers (N= 12)	Community Levers (N= 30)
Projected 10-year cost-effectiveness		
Premature deaths averted	36,530 (35,169–37,730)	24,486 (13,942–41,164)
CTG program implementation costs, $, billion	0.1 (0.1–0.1)	4.6 (3.9–5.3)
Discounted medical cost savings, $, billion	3.2 (3.0–3.4)	3.4 (2.2–5.5)
Risk factor management costs incurred, $, billion	14.2 (11.6–16.1)	3.0 (3.0–3.0)
Total costs,[b] $, billion	11.0 (8.3–13.2)	4.1 (2.8–4.8)
Cost per premature death averted,[c] $	302,000 (220,000–374,000)	169,000 (68,000–342,000)
Projected 25-year cost-effectiveness		
Premature deaths averted	109,130 (104,850–113,180)	88,374 (51,315–140,496)
CTG program implementation costs, $, billion	0.2 (0.2–0.2)	7.6 (6.4–8.8)
Discounted medical cost savings, $, billion	8.1 (7.6–8.5)	9.1 (5.7–14.3)
Risk factor management costs incurred, $, billion	28.4 (23.2-32.2)	6.5 (5.9–7.5)
Total costs,[b] $, billion	20.5 (15.0–24.8)	5.0 (2.0–6.7)
Cost per premature death averted,[c] $	188,000 (132,000–236,000)	57,000 (14,000–130,000)

Abbreviation: CTG, Community Transformation Grant.
[a] All values are point estimate (lower bound–upper bound).
[b] Total costs = Program Implementation Costs – Medical Costs Averted + Risk Factor Management Costs Incurred.
[c] Cost per Death Averted = Total Costs/Deaths Averted.

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PROGRAM EVALUATION BRIEF

A Cohort Review Approach Evaluating Community Health Worker Programs in New York City, 2015–2017

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PEER REVIEWED

Summary

What is already known about this topic?

Findings from community health worker (CHW) interventions targeting chronic disease prevention and management demonstrate inconsistent results, which may be attributable to funding mechanisms. Monitoring tools developed to address resource constraints, such as the cohort review, have not been used previously to evaluate CHW programs.

What is added by this report?

We applied a cohort review approach as an evaluation framework for a community-focused CHW intervention in New York City. We assessed program implementation and outcomes during the first 2 years of the program. The cohort approach highlighted 6-month outcome successes related to hypertension and diabetes control and identified workload challenges affecting recruitment and retention.

What are the implications for public health practice?

Adapting a cohort monitoring approach can be useful for evaluating the implementation of CHW programs. Such an approach also addresses issues associated with resource constraints and limited program duration.

Abstract

The objective of this study was to describe how a cohort review approach was applied as an evaluation framework for a community health worker intervention among adult residents in 5 public housing developments in New York City in 2015–2017. The cohort review approach involved systematically monitoring participants engaged in the Harlem Health Advocacy Partners program during a given time period ("cohort") to assess individual outcomes and program performance. We monitored participation status (completed, still active, disengaged, on leave, or died) and health outcomes. In this example of a cohort review, levels of enrollment and program disengagement were higher in cohort 1 than in cohort 2. For 6-month health outcomes, the percentage of participants with hypertension who had controlled blood pressure was static in cohort 1 and improved significantly in cohort 2. The percentage of participants with diabetes who self-reported controlled hemoglobin A_{1c} increased significantly in cohort 1 at 6-month follow-up. The cohort approach highlighted important outcome successes and identified workload challenges affecting recruitment and retention.

Introduction

Although evidence for the effectiveness of community health workers (CHWs) is mounting, reviews of interventions related to chronic disease prevention and management demonstrate inconsistent results (1–3). One key issue is that many CHW programs are funded through grants or operating budgets that are often unpredictable, unstable, and time limited (4). Such funding mechanisms pose unique challenges: with short-term funding, some health outcomes may not emerge within funded evaluation time frames, and positive benefits of programs, including the adoption and maintenance of behavior change, may not have the opportunity to accrue or be sustained. Another problem is inconsistency in how results are reported.

These challenges have affected other public health interventions focused on sustained patient interactions, and monitoring tools developed in response to these challenges can be adapted for CHW program evaluation. For example, the introduction of an annual review process known as a "cohort review" was an important innovation in the monitoring and evaluation of tuberculosis control efforts (5); it involved systematic monitoring of groups of patients beginning treatment within a given period ("cohort"). Structured

indicators allowed local and national comparisons, as well as measurement against previous cohorts, to assess improvements in program recruitment, retention, and outcomes.

We adapted cohort review methods to the evaluation of a CHW program. By standardizing participant status definitions and tracking outcome milestones, CHWs and evaluators can develop an analytic framework to better monitor participation status, participant characteristics, and health outcomes. The cohort process also allows for the assessment of trends of program performance indicators that are actionable for decision makers, particularly when comparison groups are unavailable or are no longer supported by funding sources.

Purpose and Objective

The objective of this study was to describe how the cohort review approach was applied as an evaluation framework for a community-focused CHW intervention, the Harlem Health Advocacy Partners (HHAP) program, in New York City. HHAP is an ongoing municipal project that aims to improve the health of adults residing in 5 public housing developments in East/Central Harlem. Despite rich histories of community organizing, East/Central Harlem has been subject to policies and processes such as redlining, broken windows policing, and "benign neglect" that have contributed to high levels of poverty and poor health outcomes. HHAP was launched to address health and social conditions in the neighborhood, with the aim of closing racial/ethnic gaps in health and social outcomes between public housing residents in East/Central Harlem and other New Yorkers (6,7). We developed and applied the cohort review approach to the health coaching component of HHAP to assess program implementation and outcomes during the first 2 years of the program.

Intervention Approach

During the first year of HHAP, 224 participants were enrolled from February through August 2015 (cohort 1), and subsequent cohorts followed an annual enrollment cycle. Cohort 2 enrolled 348 participants from September 2015 through August 2016. Concurrent to cohort 1 enrollment, we recruited a 1-year comparison sample of 176 residents from 5 nearby developments, selected on the basis of frequency-matched sociodemographic characteristics and proximity to the intervention developments (8). After cohort 1, comparison groups were not available.

In addition to a residence requirement, eligibility criteria for health coaching and the comparison group included being aged ≥18 and having at least one of 3 self-reported chronic conditions (asthma, diabetes, or hypertension). Participants who reported ever having received a physician diagnosis of asthma, hypertension, or diabetes were defined as adults with these conditions, on the basis of the following question: "Have you ever been told by a doctor, nurse, or other health professional that you have . . . ?" Both cohort 1 and cohort 2 participants were recruited primarily via community outreach conducted by CHWs, who canvassed the grounds of the selected public housing developments and collaborated with community and senior centers in each development to promote the program. The comparison group was recruited from a random sample telephone survey (9). CHWs attempted to deliver core intervention components within 6 to 12 months of enrollment.

The HHAP intervention includes 4 components: 1) health coaching, 2) navigation of the health care system, 3) wellness activities, including peer support and walking groups, and 4) advocacy to build leadership among residents to address community health needs and improve systems and conditions that influence neighborhood health. The health coaching provided by CHWs also included referrals, emergency interventions during acute-risk situations (eg, morbidly high blood pressure readings, mental health crises), and the setting of one or more SMART (specific, measurable, achievable, results-focused, and time-bound) goals. Additional health care navigation support was available through referrals to a partner organization that assists residents in obtaining medical services and ensures they receive the care to which they are entitled. A full description of the HHAP model is available elsewhere (8).

Evaluation Methods

For cohort 1, CHWs conducted intake assessments as part of participant enrollment (baseline), and an academic research team from the NYU–CUNY Prevention Research Center (PRC) conducted follow-up assessments. The academic research team conducted all comparison group assessments. Cohort 1 and comparison participants received a $20 cash incentive for completing surveys. For cohort 2, CHWs conducted baseline and follow-up assessments. Surveys were conducted at 3 months, 6 months, 9 months, or 12 months after enrollment. Among participants enrolled in cohort 1 and cohort 2, 209 of 224 (93.3%) in cohort 1 and 233 of 348 (67.0%) in cohort 2 completed any follow-up assessment survey. For this analysis, we tabulated data on 6-month follow-up from both years; the response rate was 85.7% (192 of 224) for cohort 1, 92.6% (163 of 176) for the comparison group, and 41.7% (145 of 348) for cohort 2.

We categorized all HHAP participants into mutually exclusive and exhaustive categories of participation in health coaching: completed, enrolled active, disengaged, on leave, or died (Box). CHWs assigned and updated participant status. The NYU-CUNY PRC collected data on health outcomes in the baseline surveys and

follow-up surveys. These outcomes were blood pressure control, blood pressure control among participants with hypertension, and self-reported hemoglobin A_{1c} (HbA_{1c}) control among participants with diabetes. Blood pressure was the average of 3 measurements taken at each survey point, and we defined control as systolic blood pressure under 140 mm Hg or diastolic blood pressure under 90 mm Hg (10). We dichotomized self-reported status of glycemic control as controlled if a health professional told a participant their diabetes was within goal and as "uncontrolled or don't know" if they were told it was not within goal or if they were unaware of their status.

Box. Definition of Each Category of Participation in the Health Coaching Component of the Harlem Health Advocacy Partners Program, New York City, 2015–2017

Status	Definition of Status
Enrolled	Completed intake
Completed	Health coaching completed
Enrolled active	Still active in health coaching and have not yet completed
Disengaged	No longer participating in health coaching. Includes people referred out, people lost to follow-up, people unable to fit health coaching into their schedule, and people who request to stop participating
On leave	Temporarily on leave from the program
Died	Died while enrolled active

Using SAS version 9.4 for all analyses (SAS Institute Inc), we compared the baseline characteristics of cohort 1 with the baseline characteristics of cohort 2 and the comparison group with *t* test for continuous variables and χ^2 test for categorical variables. For health outcome variables, we tested significance by cohort between enrollment and 6-month post-enrollment by using the McNemar χ^2 test. We chose this test because it is widely used and easy to interpret.

Results

A greater percentage of residents participating in HHAP health coaching than in the comparison group were aged 65 or older and self-reported hypertension (Table 1). Most participants were female and either Hispanic or non-Hispanic black, reflecting the population of the public housing developments (9). Participants were demographically similar to one another across cohorts, except that a greater proportion of cohort 2 participants than cohort 1 or comparison group participants were Hispanic.

Enrollment increased 55.4% from cohort 1 to cohort 2, from 224 to 348 participants. Of the 224 cohort 1 participants, 216 (96.4%) participants were still active in the program after 6 months, 5 (2.2%) had disengaged, 1 (0.4%) was on leave, and 2 (0.9%) had died. Of the 348 participants enrolled in cohort 2, 303 (87.1%) were still active after 6 months, 39 (11.2%) had disengaged, 2 (0.6%) were on leave, and 2 (0.6%) had died.

The percentage of participants with self-reported hypertension in cohort 1 and controlled blood pressure did not change from baseline to 6-month follow-up (58.8% to 60.1%, $P = .79$) (Table 2). Blood pressure control among residents with hypertension in the comparison group may have worsened from baseline to 6-month follow-up (61.0% to 53.3%, $P = .16$). In cohort 2, the percentage of participants with diagnosed hypertension and controlled blood pressure increased significantly, from 57.7% to 73.9% ($P = .002$). The percentage of participants with self-reported diabetes who reported their HbA_{1c} as controlled increased significantly in cohort 1 (50.0% to 64.3%, $P = .02$), whereas self-reported HbA_{1c} control did not improve among comparison group participants (65.7% to 64.2%, $P = .74$). Although the change was not significant, we found improvements in HbA_{1c} control among cohort 2 participants (72.3% to 83.0%, $P = .20$).

Implications for Public Health

Our findings from the first 2 years of HHAP's health coaching component demonstrate the utility of the cohort review approach in providing a structure for evaluating a multiyear program, particularly when an ongoing comparison group is not available. The approach highlighted successes in health outcomes among participants retained in the program and challenges in program retention.

The assessment showed that more participants in cohort 2 than in cohort 1 disengaged from the program after 6 months. One reason for the higher level of disengagement in cohort 2 could be the challenge of maintaining health-coaching participants carried over from cohort 1 while recruiting for cohort 2, since CHWs in cohort 2 were also responsible for managing participants from the previous year. In addition, in the beginning of cohort 2, programmatic operations were transferred from an external organization to the New York City Department of Health and Mental Hygiene, which may have resulted in a disruption for some participants. Finally, the incentive offered in cohort 1 may have positively influenced program retention and the number of follow-up interviews. Because the cohort process cycle emphasizes continuous monitoring and improvement, the HHAP program addressed retention and workload issues in cohort 3.

Our cohort assessment quantified improvements in key health outcomes shown in previous studies, namely in blood pressure (11) and glycemic control (2,12). The increase from cohort 1 to cohort 2 in the number of participants with controlled blood pressure suggests that the ability of CHWs to enhance care increases over time. This care includes efforts to keep participants connected with their primary care physician and to motivate participants to take all routine tests and medications for their conditions.

In planning for evaluating CHW programs using a cohort approach, metrics for the implementation process should be developed a priori and aligned with program objectives. Our analysis underscored the challenge of defining the participation status of a participant as complete. The definition was challenging because the criteria for program completion changed over 2 cohort years; awareness of this challenge helped formalize the definition of completion. Moreover, the program further disaggregated the disengaged group into 4 new categories: withdrew, lost to follow-up, transferred out of health coaching, and unavailable (ie, unable to fit health coaching into their schedule). It will be important to monitor these categories to assess whether participants are not interested or able to participate in the program, which would reflect a poor fit between the program and a participant's needs (withdrew), or the program is unable to maintain contact with participants because of other factors (lost to follow-up).

We found the cohort review approach adaptable to new program goals. For example, to better HHAP's efforts to address the social determinants of health in addition to disease management, we developed outcome metrics for social determinants of health for cohort 3, and the program will continue to monitor other variables that may contribute to health outcomes.

Our study has several limitations. Our findings in part reflect differences in HHAP programmatic operations between cohort 1 and 2. Cohort 1 data were collected by both CHWs and an academic research team and participants in cohort 1 received a cash incentive for completing surveys, whereas cohort 2 data were collected by CHWs only, often with fewer follow-up assessments, and cohort 2 participants did not receive an incentive. Differences in data collection may have biased comparisons between cohort 1 and cohort 2. Some health outcome data were self-reported; however, any bias introduced by self-report is unlikely to be differential across cohorts, except if selection bias was introduced because of higher loss to follow-up in cohort 2. Finally, given the large number of disengaged participants in cohort 2, we are not fully confident that improved outcomes were solely a function of programmatic improvements. Improved outcomes may reflect differential disengagement of participants who would have been less likely to improve.

Although previous CHW evaluations focused on individual-level outcomes, we found the cohort monitoring approach to be an effective method for evaluating the implementation process of CHW programs while also addressing issues associated with resource constraints and limited program duration (13). Adapting a cohort approach can begin to fill this gap (4,14).

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Tables

Table 1. Baseline Characteristics of Study Population, Health Coaching Component of the Harlem Health Advocacy Partners Program, 2015–2017[a]

Characteristic	Cohort 1[b], No. (%) (n = 224)	Comparison Group[c], No. (%) (n = 176)	Cohort 2[d], No. (%) (n = 348)	*P* Value[e]
Age group, y				
18-44	21 (9.4)	20 (11.4)	41 (11.8)	.04
45-64	104 (46.6)	102 (58.3)	161 (46.4)	
≥65	98 (44.0)	53 (30.3)	145 (41.8)	
Sex				
Male	42 (18.8)	35 (19.9)	78 (21.4)	.55
Female	182 (81.3)	141 (80.1)	270 (77.6)	
Race/ethnicity				
Hispanic	111 (50.0)	101 (57.4)	170 (60.1)	.02
Non-Hispanic black	105 (47.3)	71 (40.3)	113 (39.9)	
Other	6 (2.7)	4 (2.3)	0 (0.0)	
Education				
≤8th grade	49 (22.2)	23 (13.1)	50 (18.9)	.35
Some high school	51 (23.1)	43 (24.6)	72 (27.2)	
High school diploma or GED	72 (32.6)	50 (28.6)	79 (29.8)	
Some college	33 (14.9)	38 (21.7)	50 (18.9)	
College degree or more	16 (7.2)	21 (12.0)	14 (5.3)	
Disease prevalence[f]				
Hypertension	197 (88.0)	127 (72.2)	289 (83.1)	<.001
Diabetes	116 (51.8)	74 (42.1)	172 (49.4)	.13
Asthma	88 (39.3)	87 (49.4)	139 (39.9)	.07
Asthma attack in past year	41 (18.5)	36 (20.7)	56 (16.1)	.55
All 3 conditions (hypertension, diabetes, and asthma)	41 (18.3)	19 (10.8)	57 (16.4)	.12
Smoking[g]	50 (22.4)	58 (33.0)	66 (19.9)	.006

[a] The Harlem Health Advocacy Partners program is an ongoing municipal project that aims to improve the health of adults residing in 5 public housing developments in East/Central Harlem, New York City (8).
[b] Recruited from February through August 2015.
[c] Concurrent to cohort 1 enrollment, a 1-year comparison sample of 176 residents was recruited from 5 nearby developments, selected on the basis of frequency-matched sociodemographic characteristics and proximity to the intervention developments.
[d] Recruited from September 2015 through August 2016.
[e] *P* value determined by *t* test for continuous variables and χ^2 test for categorical variables and compares cohort 1 characteristics with characteristics of cohort 2 and comparison group.
[f] Eligibility criteria for health coaching and the comparison group included being aged ≥18 and having at least 1 of 3 self-reported chronic conditions (asthma, diabetes, or hypertension). Participants who reported ever having received a physician diagnosis of asthma, hypertension, or diabetes were defined as adults with these conditions, on the basis of the following question: "Have you ever been told by a doctor, nurse, or other health professional that you have . . . ?"
[g] Smoking was dichotomized into an indicator for smoking every day or some days by using the following question: "Do you now smoke cigarettes every day, some days, or not at all?"

Table 2. Health Outcome Measures at Enrollment (Baseline) and 6 Months After Baseline Among Participants Who Completed a 6-Month Follow-Up Assessment, Harlem Health Advocacy Partners, 2015–2017[a]

Health Outcome	Cohort 1[b] (n = 192)		Comparison Group[c] (n = 163)		Cohort 2[d] (n = 146)	
	No. (%)	*P* Value[e]	No. (%)	*P* Value[e]	No. (%)	*P* Value[e]
No. of participants whose blood pressure was monitored[f]	174	—	143	—	132	—
Blood pressure was controlled[g]						
At baseline	108 (62.1)	.89	92 (64.3)	.45	83 (62.9)	.003
At 6-month follow-up	107 (61.5)		87 (60.8)		101 (76.5)	
Maintained control	79 (45.4)	—	68 (47.6)	—	74 (56.1)	—
Control improved	28 (16.1)		19 (13.3)		27 (20.5)	
Control declined	29 (16.7)		24 (16.8)		9 (6.8)	
Maintained uncontrolled	38 (21.8)		32 (22.4)		22 (16.7)	
No. of participants with self-reported hypertension[h]	169	—	117	—	124	—
No. of participants whose blood pressure was monitored[f]	153	—	105	—	111	—
Blood pressure was controlled						
At baseline	90 (58.8)	.79	64 (61.0)	.16	64 (57.7)	.002
At 6-month follow-up	92 (60.1)		56 (53.3)		82 (73.9)	
Maintained control	64 (41.8)	—	44 (41.9)	—	56 (50.5)	—
Control improved	28 (18.3)		12 (11.4)		26 (23.4)	
Control declined	26 (17.0)		20 (19.1)		8 (7.2)	
Maintained uncontrolled	35 (22.9)		29 (27.6)		21 (18.9)	
No. of participants with self-reported diabetes[h]	101	—	70	—	73	—
Self-reported HbA_{1c} levels among diagnosed diabetes	98	—	67	—	47	—
HbA_{1c} was controlled						
At baseline	49 (50.0)	.02	44 (65.7)	.74	34 (72.3)	.20
At 6-month follow-up	63 (64.3)		43 (64.2)		39 (83.0)	
Maintained control	37 (37.8)	—	39 (58.2)	—	29 (61.7)	—
Control improved	26 (26.5)		4 (6.0)		10 (21.3)	
Control declined	12 (12.2)		5 (7.5)		5 (10.6)	
Maintained uncontrolled or "don't know"	23 (23.5)		19 (28.4)		3 (6.4)	

Abbreviations: —, does not apply; HbA_{1c}, hemoglobin A_{1c}.

[a] The Harlem Health Advocacy Partners program is an ongoing municipal project that aims to improve the health of adults residing in 5 public housing developments in East/Central Harlem, New York City (8).

[b] Recruited from February through August 2015.

[c] Concurrent to cohort 1 enrollment, a 1-year comparison sample of 176 residents was recruited from 5 nearby developments, selected on the basis of frequency-matched sociodemographic characteristics and proximity to the intervention developments.

[d] Recruited from September 2015 through August 2016.

[e] Difference between values at intake and 6-month follow-up examined by using McNemar χ^2 test.

[f] Blood pressure measurements were not obtained for every participant because of equipment malfunction, technical errors, or participant refusal.

[g] Defined as systolic blood pressure <140 mm Hg or diastolic blood pressure <90 mm Hg.

[h] Participants who reported ever having received a physician diagnosis of hypertension or diabetes were defined as adults with these conditions, on the basis of the following question: "Have you ever been told by a doctor, nurse or other health professional that you have . . . ?"

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PROGRAM EVALUATION BRIEF

Advancing Tobacco Control Through Point of Sale Policies, Providence, Rhode Island

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PEER REVIEWED

Summary

What is already known about this topic?

Evaluation of point of sale (POS) policies that restrict the sale of flavored tobacco products is a new area of research and evidence of its effectiveness is limited.

What is added by this report?

Rigorous enforcement of Providence, Rhode Island's flavored tobacco restrictions and price discounting resulted in increased citations of policy violations over 2 years. High school students' current e-cigarette use decreased by 7 percentage points from preenforcement to postenforcement.

What are the implications for public health practice?

Findings from this study highlight the need for new approaches to POS tobacco policy evaluations. Such policies might be undermined by the tobacco industry's increased marketing of products with ambiguous flavor descriptions.

Abstract

Local point of sale (POS) policies are key strategies for preventing and decreasing tobacco use among youth. In January 2013, Providence, Rhode Island implemented a comprehensive POS tobacco policy restricting the sale of flavored tobacco products and discounts of tobacco product prices. Lack of sustained funding for enforcement has been challenging. Our research focuses on the policy evaluation after enforcement began. We observed a decrease in availability of flavored tobacco products as citations for violations increased. However, we observed little change in the availability of flavored tobacco products with ambiguous descriptors that connote a flavor. Current use (within 30 days before survey) of tobacco products among high school students declined after the policy was enforced. Collectively, these findings demonstrate that POS tobacco policies are effective. The tobacco industry's marketing of products that do not explicitly reference flavors might undermine enforcement of POS tobacco restrictions in Providence and elsewhere in the United States.

Introduction

The retail environment or point(s) of sale (POS) is currently the primary venue where tobacco companies market their products in the United States. In 2016, the US market had 565 unique e-cigarette brands (1), many marketed in distinct flavors (2), and more than 250 unique cigar flavors (3). Flavored tobacco products are heavily marketed in convenience stores, places that adolescents visit at least once per week (4). E-cigarettes are the most commonly used tobacco product among adolescents (20.8%), followed by cigarettes (8.1%) and cigars (7.6%) (5). The popularity of e-cigarettes is attributed, in part, to the sale of these products in flavors that appeal to youth (1). Of equal concern is the proliferation of tobacco products with text or images that indicate a flavor without specifically naming the flavor (6), hereafter referred to as "not clearly labeled." Studies provide evidence that frequent exposure to retail tobacco marketing encourages youth smoking (7–9). Evaluations of local POS tobacco control policies to prevent and reduce youth smoking are still at early stages.

Purpose and Objectives

In January 2012, the city of Providence passed a local POS tobacco policy to restrict the sale of flavored tobacco products and limit price promotions that make tobacco products cheaper and more accessible. In doing so, Providence, Rhode Island, became the first city in the United States to restrict tobacco price discounting and multipack offers and the second city to limit the sale of flavored tobacco products (excluding menthol), except in legally permitted tobacco bars. Providence requires city tobacco retailers to apply annually for a license, with escalating penalties for policy violations up to license revocation. Penalties assessed for violations provide a funding stream for enforcement. Originally slated to take effect on March 1, 2012, the policy was challenged in the courts by the tobacco industry, but the court ruled in favor of the

city (10). The 3 policy strategies were implemented in January 2013 and became the Rhode Island Model Tobacco Policy. By 2017, Providence had a comprehensive retail POS tobacco policy for 5 years. Enforcement of the policy by Providence police was complex and challenging. First, local resources were not enough to sustain compliance check inspections of tobacco retailers. Second, enforcement officers did not have compliance check inspection forms tailored to the city's ordinances, which were needed to improve data collection.

We evaluated the effects of Providence's POS tobacco policy after the Rhode Island Department of Health (RIDOH) Tobacco Control Program was awarded a 2-year Centers for Disease Control and Prevention (CDC) grant in 2017, which supported rigorous enforcement of the policy. Our aims were to

1. Determine whether both flavored and nonflavored tobacco products and tobacco price promotions are readily available at retail POS.
2. Determine whether citations for illegal sale of flavored tobacco products and tobacco price promotions increased with enforcement and then declined, as retailers were educated about the model policy.
3. Examine whether enforcement of the POS tobacco policy decreased youth smoking.

Intervention Approach

In 2015, the RIDOH Tobacco Control Program was one of 5 states to be awarded a 2-year CDC competitive grant. The grant supported the community infrastructure needed to advance the adoption of the Rhode Island Model Tobacco Policy in 6 cities statewide, as was successfully done in the city of Providence. The Providence Healthy Communities Office authored a Tobacco Point of Sale Enforcement Toolkit. The city's enforcement unit provided technical assistance to other grantees on enforcement of local POS tobacco policies. The 2-year grant provided a strong foundation for an additional 2 years of CDC funding to support the implementation and evaluation of the Rhode Island Model Tobacco Policy in the towns of Barrington, Johnston, and West Warwick and the cities of Central Falls, Providence, and Woonsocket. Although not funded, the RIDOH Tobacco Control Program partnered with the town of Middletown to support implementation of the Rhode Island Model Tobacco Policy.

With new grant funding, the Providence Healthy Communities Office conducted observational retail store assessments using the national Standardized Tobacco Assessment for Retail Settings (STARS) (11) adapted for Rhode Island (RI-STARS). RI-STARS is a paper-and-pencil form designed to assess the availability, placement, and pricing of flavored tobacco products that are clearly labeled and those not clearly labeled at retail POS. Retailer education was included at the end of each visit to ensure vendors complied with Providence's tobacco ordinances. Providence law enforcement officers were responsible for conducting compliance checks with forms tailored to the city's policy and penalty structure. Actions requiring enforcement were from 3 separate RIDOH compliance check forms: 1) sales of tobacco products to minors, 2) sales of flavored tobacco products to underaged youth and adults, and 3) price discounting and multipack offers. A tobacco retail violation form documents violations and adjudication actions through Providence's Board of Licensing and District Court. RI-STARS and RIDOH compliance checks use Garcia y Vega Game Blue cigarillos (Game Blue) as a measure of the availability of a known flavored product that is not clearly labeled as such. Game Blue is a product used specifically for comparison on enforcement and RI-STARS forms.

Evaluation Methods

Two rounds of store observation audits with retailer education and 5 rounds of RIDOH retail compliance checks were conducted during the study period. Stores for on-site observations and the first round of compliance checks were randomly selected from the Rhode Island Taxation List of Providence tobacco retailers (n = 445). In the 4 subsequent rounds of compliance checks, stores found to be in violation of the Rhode Island Model Tobacco Policy were kept in the sampling frame. Additional stores were then randomly selected from the taxation list so that each round of compliance checks had between 65 and 200 stores for enforcement, depending on the availability of funding. US Food and Drug Administration (FDA) compliance inspections were collected every 6 months to identify stores cited for violations. Stores found to be in violation of federal tobacco laws were cross-checked with RIDOH compliance check forms to identify repeat offenders who were illegally selling tobacco products to minors.

Data on adolescents' current use of tobacco products were obtained from the 2012, 2016, and 2018 Annie E. Casey Evidence2Success Providence Youth Experience Survey (YES) (12). In 2012, Providence, Rhode Island, became the first site to adopt the Annie E. Casey Foundation's Evidence2Success framework and implement the YES. YES is a cross-sectional, self-administered, anonymous, school-based survey that tracks trends in child well-being. The Providence high school YES was implemented as a census survey to collect information in classrooms from all 10th and 12th grade students at the time of administration. Current use (within 30 days before survey) of cigarettes was measured in all 3 survey years. Questions about other tobacco use were

asked in 2016 and 2018. All tobacco questions were coded as binary (0 or 1) variables. Students who said they did not answer the surveys honestly were excluded from analyses. The final analytic samples in the 2012, 2016, and 2018 YES were 2,150, 2,062, and 2,223, respectively.

Overall differences across years were assessed by using 1-way analysis of variance (ANOVA), by α of 0.05, and by overlapping 95% confidence intervals (CIs). Data were analyzed by using SAS 9.4 (SAS Institute, Inc).

Results

Aim 1 was to determine whether both flavored and nonflavored tobacco products and tobacco price promotions were readily available at retail POS. RI-STARS store audits were completed in 90 stores in October 2017 and 82 stores in January 2018 (Table 1). Analysis of observational data showed that the availability of flavored products decreased from 37 of 90 stores in Round 1 (41%) to 14 of 82 stores in Round 2 (17%), a decrease of 24 percentage points. The availability of clearly labeled cigarillos and cigars also decreased at retail POS. Game Blue cigarillos remained accessible in 76% of store audits in Round 1 and 73% of store audits in Round 2. Approximately half of the stores visited sold discounted cigarettes. None of the 55 stores visited in December 2018 were observed to have Game Blue cigarillos (the 4th and final round of store audits). Clearly labeled flavored cigarillos, premium large cigars, and e-juices were observed in 2% of stores. Coupon cigarette price promotions were observed in 11% of stores visited.

Aim 2 was to determine whether citations for the sale of flavored tobacco products and tobacco price promotions increased with enforcement and then declined as retailers were educated about the model policy. During 9 months, there were 110 RIDOH compliance check inspections of tobacco retailers for sales of tobacco to a minor, 378 RIDOH compliance checks for sales of flavored tobacco products, and 15 RIDOH compliance checks for price discounting of cigarettes. Most stores were found to be compliant with Providence's POS tobacco policies (n = 413; 82%). The 91 stores cited for a violation had repeated (up to 4) compliance checks. Between the first and last rounds of compliance checks, violations for sale of tobacco to a minor decreased by 12 percentage points to 2%; flavored tobacco adult sale violations (clearly and not clearly labeled products) increased by 20 percentage points to 22%; and violations for price discounting increased by 10 percentage points to 70% (Table 2). Compliance check inspections continued through the end of the 24-month grant. This resulted in an additional 55 compliance checks for tobacco sales involving minors, 127 compliance checks for sales of flavored tobacco, such as, e-cigarettes, cigars, and hookah tobacco, and 32 compliance checks for cigarette price discounting.

By the end of the 2-year grant, 9 stores were cited for youth violations. Seven stores received a warning, 1 store received a fine of $250. At the time of this report, the case against 1 store was pending. Of the 85 stores cited for flavor sale violations, 72 cases were adjudicated. Two stores were given warnings, 1 store received a fine of $100, 52 stores received fines of $250, 11 stores were fined $350, 1 store was fined $400, and 5 stores received fines of $500. Cases brought against 9 of the remaining 13 cases were dismissed. Three stores closed before their cases were heard in Providence's Board of Licensing and District Court. Thirteen stores were cited for price discounting violations. Five stores received a fine of $250 and 1 store was fined $600. Seven stores had their cases dismissed. The city of Providence imposes a fine of $250 for the first policy offense, $350 for the second policy offense, and $500 for any subsequent policy offenses. Tobacco retailers with more than 3 offenses are subject to license revocation.

FDA inspectors conducted 496 undercover inspections of Providence tobacco retailers during the 2-year grant period (Table 3). The FDA cited 46 stores for tobacco sales to minors; 20 stores received warning letters and 26 received civil money penalties. Three tobacco retailers were cited for violating Providence's POS tobacco policy and FDA restrictions.

Aim 3 was to examine whether enforcement of the POS tobacco policy decreased youth smoking. The percentage of high school students who reported currently smoking cigarettes was significantly higher in 2016 (7.6%) than in 2012 (3.2%; Table 4). Current cigarette smoking declined by 4.6% after enforcement began in 2016 and was 3.0% in 2018. By contrast, the Rhode Island Youth Risk Behavior Survey (YRBS), which is a representative sample of Rhode Island public high school students, found that the prevalence of current cigarette smoking was 11.4% (95% CI, 9.0%–14.4%) in 2011 and 6.1% (95% CI, 4.3%–8.7%) in 2017.

Between 2016 and 2018, current use of any tobacco product declined significantly, from 22.2% to 12.1%. E-cigarettes declined from 13.3% (95% CI, 11.4%–15.1%) to 6.6% (95% CI, 5.3%–7.8%) during 2 years (Table 4). By contrast, the YRBS reported the prevalence of current e-cigarette use among Rhode Island high school students was 19.3% (95% CI, 16.1%–22.8%) in 2015 and 20.1% (95% CI, 16.9%–23.7%) in 2017.

Implications for Public Health

Providence's POS tobacco policy represents an important public health achievement. For the first time, the city of Providence had the ability to compare the availability of clearly and not clearly labeled flavored tobacco products at retail POS. The findings from store observations have policy implications. Game Blue cigarillos, a flavored product that is not explicitly labeled as flavored, remained accessible in most stores surveyed through July 2018. By fall 2018, Game Blue was no longer available in stores surveyed (data not shown). On-site retailer education likely contributed to the observed decrease, as did enforcement of Providence's POS tobacco policy.

Law enforcement officers demonstrated that the newly designed compliance check forms were suitable for monitoring tobacco sales to minors, flavored tobacco sales, and discount restrictions. Rigorous enforcement during 2 years resulted in 107 individual store violations; 79% were for sale of flavored tobacco products. A study of flavored e-cigarette sales as a percentage of all e-cigarette sales in the United States from 2012 to 2016 found that Rhode Island was the only state with a significant decline in flavored e-cigarette sales from 2015 through 2016 (1). Although we cannot attribute these findings solely to Providence's POS policy, the city's restriction on the sale of flavored tobacco products might have contributed to this decline. Evaluations of POS tobacco policies that restricted the sale of flavored tobacco products have been conducted in New York City (13,14), Minneapolis and Saint Paul, Minnesota (15), and Massachusetts (16). These policies take different approaches, but the evaluations show that the availability and sale of these products declined significantly after policy enforcement. Minneapolis also saw a significant reduction in the availability of tobacco products with ambiguous flavor names after the flavor restriction was implemented (15). The short-term benefits (within 1 or 2 years after policy implementation) of local-level policy restrictions are promising. Still, enforcement of flavored tobacco bans is difficult. Providence has no mechanism for testing ambiguously labeled flavored tobacco products at a retail POS or when a case is challenged in court. The tobacco industry's increased marketing of products by concept ("Jazz") or by characterizing flavors (fruit), rather than using clearly descriptive names, might undermine enforcement of POS tobacco policies in Providence and elsewhere in the United States (6,17).

Providence's law enforcement officers showed that enforcement of a ban on price discounting, which no other city or town in the United States had yet tried, was possible. Enforcement of this ban is complex. Tobacco products scanned with a price promotion set by the tobacco industry show the reduced price directly on the register without the deduction taken. This presents major challenges to preventing this type of price marketing by the tobacco industry.

One strength of the policy evaluation is that it expanded monitoring of the tobacco landscape in Providence to include FDA compliance inspection data. During the study period, the city of Providence and the FDA conducted separate undercover youth buying inspections to stop illegal tobacco sales to minors. Three stores were cited by FDA and RIDOH for selling tobacco products to an underaged youth. Penalties increased significantly for repeat offenders. FDA and RIDOH enforcement activities likely contributed to the decline in teen use of cigars and cigarillos, e-cigarettes, and hookah tobacco, which are marketed with flavors that appeal to youth. The findings from our analysis of school survey data demonstrate the importance of ongoing enforcement of local ordinances and federal laws to prevent flavored tobacco product sales to underaged youth.

The tobacco research field has an unprecedented opportunity to evaluate POS tobacco policies. Findings from this study are promising. More research is needed to build a strong empirical evidence base that regulating POS tobacco access, availability, and marketing decreases early initiation and continued use of heavily marketed flavored tobacco products among children and youth. Additional research is needed to evaluate POS tobacco policies in the context of other population-based tobacco prevention and control efforts.

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Tables

Table 1. RI-STARS Tobacco Product Observed Availability, Providence, Rhode Island, 2017 and 2018

RI-STARS Observed Availability	Round 1: October 2017 (N = 90 Stores)	Round 2: January 2018 (N = 82 Stores)
Stores with clearly labeled flavored products	37 (41%)	14 (17%)
Products observed		
Cigarillos	30 (33%)	5 (6%)
Cigars	21 (23%)	2 (2%)
Smokeless tobacco[a]	8 (9%)	1 (1%)
E-cigarettes	2 (2%)	1 (1%)
E-liquids	19 (21%)	12 (15%)
Stores with not clearly labeled flavored products	68 (76%)	60 (73%)
Stores with price promotions	40 (44%)	40 (49%)
Buy-one-get-one	13 (14%)	5 (6%)
Coupons	40 (44%)	37 (45%)

Abbreviation: RI-STARS, Rhode Island State Tobacco Assessment for Retail Settings.
[a] Smokeless tobacco included chew, snuff, dip, and snus.

Table 2. Compliance Checks for Tobacco Points of Sale, Providence, Rhode Island, 2017 and 2018[a]

Compliance	RIDOH Compliance Checks	
	Round 1: November 2017 (N = 99 Checks)	Rounds 2–5: February–July 2018 (N = 408 Checks)
Youth tobacco compliance checks	50 (56%)	61 (15%)
Youth tobacco sale violations	7 (14%)	1 (2%)
Clearly labeled flavored products	2 (29%)	0
Not clearly labeled flavored products[b]	4 (57%)	1 (100%)
Not flavored cigarillos	1 (14%)	0
Flavored tobacco product compliance checks	44 (49%)	334 (82%)
Flavored tobacco adult sale violations	1 (2%)	72 (22%)
Clearly labeled flavored products	0	37 (51%)
Not clearly labeled flavored products[b]	1 (100%)	35 (49%)
Price discounting compliance checks	5 (6%)	10 (2%)
Price discounting adult sale violations[c]	3 (60%)	7 (70%)

Abbreviation: RIDOH, Rhode Island Department of Health.
[a] Providence, Rhode Island, compliance check inspections of tobacco retailers during 9 months (November 2017–July 2018).
[b] Garcia y Vega Game Blue Cigarillos, a product used specifically for comparison in this survey.
[c] Price discounting violations were for non-flavored conventional cigarettes.

Table 3. Youth Tobacco Compliance Checks, US Food and Drug Administration, Providence, Rhode Island, March 2017–March 2019

Violation	Inspections (N = 496)
Youth tobacco sale violations	46 (9.3%)
Warning letter	20 (43.5%)
Civil money penalty	26 (56.5%)

Table 4. Tenth- and Twelfth-Grade Student Use of Tobacco Products, Providence, Rhode Island, 2017 and 2018[a]

Survey Year	Sample Size	% Yes (95% Confidence Interval)				
		Cigarettes	Cigars and Cigarillos	E-cigarettes	Hookahs	Any Tobacco Product[b]
2012 (POS policy passed January 2012; implemented January 2013)	2,150	3.2 (2.4–4.0)	NA	NA	NA	NA
2016 (3 years post implementation of policy)	2,062	7.6 (6.3–9.0)	7.1 (5.7–8.5)	13.3 (11.4–15.1)	13.5 (11.6–15.3)	22.2 (20.0–24.3)
2018 (5 years post implementation of policy)	2,223	3.0 (2.1–3.8)	1.9 (1.2–2.6)	6.6 (5.3–7.8)	7.7 (6.4–9.2)	12.1 (10.5–13.7)

Abbreviations: POS, point of sale; NA, not asked.
[a] Students were asked, "Which of the following tobacco products have you tried in the past 30 days?" From the Annie E. Casey Foundation Evidence2Success Youth Experience Survey (YES), Providence, Rhode Island.
[b] Smoked cigarettes, cigars, cigarillos, electronic vapor products, hookah, or used smokeless tobacco or other unspecified tobacco product.