

A Multilevel Health Promotion Intervention in Minority-Owned Workplaces

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Abstract

Introduction Changing health behaviors and health-related environments is important in reducing chronic disease. Minority workplaces are potential venues to provide regular, effective health promotion opportunities to underserved individuals. The purpose of this study was to test the feasibility of changing workplace policy, programs, and practices in minority-owned workplaces.

Methods Four minority Native American-owned businesses were recruited to participate in this study. The intervention was a set of recommended standards and guidelines gleaned from the US Preventive Task Force and The Community Guide relevant to workplaces. Each workplace selected between 4 and 6 target areas to improve over the year-long intervention period. The evaluation tool was a semi-structured survey conducted at baseline and at 1-year follow-up, with workplace staff responsible for benefits and services to employees. Feasibility was evaluated by assessing the likelihood that the workplaces implemented health promotion activities in the year-long intervention.

Results Several practices and policies changed significantly during the intervention in the four workplaces, including coverage for nicotine replacement therapy (NRT), elimination of out-of-pocket costs for screening and tobacco cessation, accountability systems for providers, posted stair use, cessation line availability that included NRT, offering weight loss programs, offering physical activity programs, and conducting targeted communication programs about health promotion. Other practices and policies changed in the expected direction but were not significant.

Conclusion Changing workplace programs, practices, and policies is feasible in minority workplaces, with support and tools provided by outside organizations. These findings could drive a full-scale test of the intervention in minority businesses in order to improve the health of disadvantaged workers.

Keywords Workplace health promotion · Minority business · Native American · Policy change

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Introduction

American Indian/Alaska Native (AI/AN) populations are generally considered to suffer from the most dramatic disease and behavior health disparities of any non-White racial/ethnic group in the USA. AI/AN people report higher rates of diabetes, cardiovascular disease, and certain cancers (i.e., colorectal and breast) REF. All of these chronic diseases have preventable components that likely begin or develop in middle age. Therefore, providing AI/AN adults across the lifespan with health promotion opportunities and support might reduce these disparities.

One potential point of intervention in AI/AN communities is through the workplace because workplaces provide access

to AI/AN people, supported by communications and financial infrastructures. The workplace offers an appealing and appropriate setting to influence individual health behaviors [1]. About 72 % of the adult population in the USA was employed between 2005 and 2009, and employees spend up to 30 % of their waking hours at work [2–4]. Workplaces are also small communities where social environments can be changed to promote health, and a peer community of co-employees influences behavior and provides social support [5, 6]. Employers control a number of organizational practices that can influence employee health behaviors, and consequently, human resource managers, health insurance providers, and sponsor of employee programs are an important target for health-related interventions [7, 8].

Minority-owned businesses or minority business enterprises (MBEs) are different from workplaces in the general population, as they are at least 51 % owned and controlled by one or more American citizens classified as an ethnic minority [9]. Making up between 2 and 7 % of all businesses depending on the state, minority-owned firms employed 4.7 million people nationally with an annual payroll totaling \$115 billion [10]. Minority-owned business size runs from a single employee to thousands in a multisite workplace, similarly to a general population workplace. Technically, MBEs have access to the same supports as dominant culture businesses when dealing with complex regulations and financial strains, but in reality, due to racial discrimination and biased practices by banks and other financial systems, MBEs have less actual access to these capital and human resources and are less able to provide appropriate and supportive services to their employees [11]. Therefore, providing resources to specifically support MBEs has the potential to make a large impact on health outcomes.

We relied on two evidence-based sets of recommendations to guide our choice of chronic disease programs—those of the US Preventive Services Task Force (USPSTF) and those of the Task Force on Community Preventive Services. The USPSTF focuses on individual behaviors, including lifestyles and clinical preventive services [12]. The USPSTF recommends eight clinical preventive services relevant to preventing chronic diseases among average-risk adults of working age (18–64 years of age). [12]. The Task Force on Community Preventive Services focuses on community-based prevention, including organizational practices applicable to employers and the workplace [13]. Several of the recommendations are applicable to the design of health insurance benefits, workplace policies, and workplace programs.

We based our program elements on previous research for workplaces in the general population [14]. The literature did not contain any examples of research projects targeting minority-owned businesses for health promotion. We did not know if the minority-owned businesses would be interested in adding health promotion activities for their employees or

whether they would have the resources to implement activities at the level of general population businesses. Nor did we see in the literature any evidence documenting the ability of MBEs to implement workplace health promotion activities. Therefore, using principles of feasibility research [15], we designed this study to help us understand the possibility of working with minority-owned businesses to implement health promotion activities. Feasibility was defined as workplaces reporting interest in participating in health promotion activities and workplaces implementing a fair amount of activities during the course of intervention. The aim of this study was to evaluate the feasibility of implementing a program designed to increase the existence and frequency of changes in the policies and programs of minority-owned businesses regarding their employees' health.

Methods

Eligibility, Recruitment, and Enrollment of Minority Workplaces

We recruited four Native American workplaces to participate in this study, following the successful recruitment procedures used in other health promotion programs for workplaces and religious and community organizations. We identified a list of workplaces that fit our eligibility criteria. These criteria were size (100–1000 employees), location within 100 mi of the research institution, and meeting the Federal definition of minority workplace, where minority was Native American. We selected the size criterion to identify workplaces based on manageable size and structure but also wanted at least 100 employees in each workplace for sampling.

To recruit, we contacted six randomly selected Native American workplaces selecting eligible workplaces from the list of partners maintained by the National Cancer Institute's Cancer Information Service (CIS) of the Northwest region, serving Washington, Alaska, Idaho, Oregon, and Nevada. The CIS maintained a list of diverse partners that could be contacted for research or health promotion purposes but otherwise had no specific commitment or involvement with CIS. We scanned the list of approximately 100 minority-owned businesses and organizations to identify the initial eligible six for approach. The initial approach included information about the study, first, by mail and then in person. The initial contact letter was signed by the principal investigator (PI) of the study and mentioned the name of the CIS Partnership Coordinator who would be the interventionist for the site. The Partnership Coordinator was a staff person engaged in maintaining relationships with all partners affiliated with the CIS; she had the requisite skills and connections to engage in intervention activities, helping local Native American employers feel comfortable with the approach. We followed the

initial mailed contact letter with a telephone call from the CIS interventionist. The telephone contact served to introduce the project, invite discussion by the employer, collect baseline contact information, and serve as a scheduling call for an in-person recruitment meeting to present the project and discuss participation. The recruitment meeting took place at each workplace and was attended by the PI, the CIS interventionist, and representatives from the workplace. For some workplaces, the representatives included just Human Resource staff; for other workplaces, it comprised a team of employees. The project presentation consisted of an overview of the proposed intervention using a standard set of slides containing the mission of the project, the requirements of the project for workplaces, and the potential benefits of the projects for workplaces and employees. The materials were based on previous research that recruited organizations to health promotion projects [16, 14]. We provided workplace staff with samples of intervention materials to show the employers how the project would work. It took between one and two in-person contacts to recruit and enroll one workplace.

Of the six workplaces that we approached, four agreed to participate in this project. One workplace said that it was in the middle of a complicated leadership change, and the other did not feel that it was ready for an outside project. Each of the four participating workplaces received a \$1000 stipend to help with implementing the intervention activities.

Participants

We initially made contact with the chief executive officer of each workplace, as listed in the WA state contact information for each workplace. In each case, we spoke with this designated leader, and then, for data collection, we spoke with another person at the workplace, the head of Human Resources, or the assistant to the CEO. This person served as the point person for data collection but in each case brought in others at the workplace to provide specific answers to questions. Therefore, the data collection was conducted with multiple employees at each workplace. All of the employees that we spoke with were invited to the intervention meetings as described below.

Evaluation

The workplace-level quantitative evaluation consisted of two measures of the workplace-level activities, one collected before the intervention began and one collected approximately 1 year after the baseline collection. Our main outcome evaluation instrument implemented at both time points was the 104-item Working Well employer practices survey originally developed by Golaszewski for New York State's Heart Check program and used in our previous workplace evaluations [17, 14]. In adapting the survey, we shortened it and added targeted

questions that detected the presence or absence of our 15 evidence-based practices listed in Table 1.

The evaluator (a non-intervention staff person) called worksite personnel familiar with the employer's health plans and employee programs (often the benefits manager) to conduct the survey. To ensure comparability of the measurement, the same non-intervention staff person administered both surveys to all four workplaces. The survey collected information related to employee chronic disease prevention across four areas: (1) health benefits, (2) workplace policies, (3) employee programs, and (4) communication and tracking. The Working Well survey contained 104 items asking about the extent of employers' adoption of our 15 recommended practices. For example, the survey asked about the existence of tobacco use policies at the workplace. If the person answered that there were tobacco policies, further questions clarified the type of policies, the focus on the policies, the stringency of the policies, and the penalties for the policies. This allowed us to construct the specific policy adherence for each workplace and match it to the specific recommendation as stated in the Task Force materials. The scoring of each item was calculated so that practices with greater health impact have higher maximum scores. For example, the best score that can be obtained for implementation of stair-use reminders is three, but the best score that can be obtained for implementation of a tobacco cessation telephone counseling service is 14. Interviewers rated each of the targeted health promotion activities for a specific workplace by coding answers to questions about each activity. Workplaces received no points for a given activity if they reported no action for that activity, partial points if they reported some of the activity, or full points if they reported the activity exactly in line with the protocol. The maximum overall score that could be achieved is 204.5 if all recommendations were performed fully. To standardize the scoring across workplaces, we reported here a percent of maximum achievable score on a scale from 0 to 100 %.

We collected semi-structured qualitative interviews with key informants at each workplace at baseline, during the intervention calls and contacts, and after the follow-up survey was administered. During the baseline interview, we asked the informants what they expected their workplace to score well in, where they felt that they most needed help, and where they felt that challenges and problems would occur in implementing this intervention package. At each of the intervention calls study, staff asked how the program was going, what was easy to change, where there were barriers, and how they generally were approaching the implementation. At the final interview, after the follow-up measure but before providing a final score to each workplace, we asked the informants how the implementation process went and what the difficulties were during the implementation phase of the program. All interview results were written down by the evaluation staff and served to aid in interpreting the quantitative data. The

Table 1 Chronic disease prevention practices disseminated to employers

Recommended employer practice	Chronic disease prevention practices to be marketed to employers	Source	Implementation materials to support the recommendations
Benefits	1. Provide an insurance benefit for over-the-counter nicotine replacement therapy	USPSTF, TF	Case examples
	2. Provide an insurance benefit for annual flu vaccines	USPSTF	Contract language
	3. Eliminate out-of-pocket costs for cancer screening, flu shots, and smoking cessation	USPSTF, TF	Costs for first year
	4. Mandate accountability systems that measure, and provide feedback on, providers' delivery of high-value preventive services	TF	Cost/return calculator (tobacco cessation treatments)
	5. Mandate reminder systems for providers and employees to ensure that employees receive high-value preventive services	TF	Evidence base
Policies	6. Implement smoking bans or restrictions at worksites	TF	Evidence base
	7. Post-stair-use reminder signage to encourage physical activity at the worksite	TF	How-to guides (tobacco ban/restriction)
	8. Provide on-site facilities for physical activity	TF	Point-of-decision prompts
	9. Require a sun protection policy for worksites	TF	Policy language
	10. Improve the availability of healthy food choices on-site and install point-of-decision reminders	TF, 5-A-Day	5-a-Day materials
Programs	11. Sponsor a tobacco cessation quit line, including nicotine replacement therapy	TF	Costs for first year
	12. Offer weight loss programs at workplace	TF, 5-A-Day	Program examples, contact info
	13. Sponsor an incentive-based group physical activity program	TF	Physical activity program, on-line Vendor list
Communication	14. Conduct targeted communication, focusing on key health behaviors and use of preventive benefits	TF	Guidelines
Tracking	15. Anonymously survey employees' health behaviors to track effectiveness of health promotion efforts	TF	Survey questions, modified from BRFSS

USPSTF US Preventive Services Task Force, *TF* Task Force on Community Preventive Services, *5-a-Day* 5-a-Day project

qualitative data were not coded for underlying themes but were simply reviewed by the study investigators, and specific responses were noted where relevant to the quantitative data.

Intervention Design and Implementation

We used a comprehensive package that relies on two evidence-based sets of recommendations to guide chronic disease programs, those of the US Preventive Services Task Force (USPSTF), which focuses on individual behaviors, including lifestyles and clinical preventive services, and the Task Force on Community Preventive Services, which focuses on community-based prevention, including organizational practices applicable to employers and the workplace [12, 13]. These recommendations are applicable to the design of health insurance benefits, workplace policies, and workplace programs. Based on the literature from other workplace intervention projects [14], our project assembled the evidence for available workplace intervention strategies and tailored this package to be culturally appropriate for implementation in four Native American workplaces, evaluating the effects of this intervention on workplace-level changes in policies and programs 1 year after the initial assessment. The targeting to

Native American workplaces was accomplished through both simple and deeper changes in content from previous research. Simple changes focused on changing pictures to include Native workers, including symbols of Native culture in the materials (e.g., an eagle feather included in the margins) and inclusion of examples of occupations that would be found on reservations (e.g., fishing). Deeper changes included inclusion of family, specific components to deal with lower SES families, and an increased focus on the idea of overall wellness defined as a multicomponent state. These changes came about because of consultations with project consultants from each workplace who indicated that these things were important to employees in their current materials and programs.

Table 1 displays the 15 recommended practices that we used in our intervention package. All of these practices aimed to control the impact of chronic diseases by increasing individual behaviors: (1) colon cancer screening, (2) healthy eating, (3) mammography use, (4) Pap smear use, (5) physical activity, and (6) tobacco cessation treatment. All of the 15 practices were evidence-based, and all but the policy recommendation around healthy food choices come from the Guide to Community Preventive Service [13]. Because, at the time of study implementation, there were no guide chapters on

nutrition, we based the healthy food choice recommendation on local successful Seattle 5-a-Day workplace project recommendations [18]. This project was successful in improving fruit and vegetable consumption in worksites in the same region as our pilot. For health insurance, there were three groups of benefit design recommendations: (1) reducing out-of-pocket costs, (2) reminders, and (3) measurement systems within health care organizations. Recommended policies applicable to the workplace include smoking bans or restrictions, on-site flu shots, sun protection policies, stair-use reminders, and on-site facilities to increase physical activity. Recommended programs include telephone counseling for tobacco cessation, group physical activity programs that are individually adapted and offer social support, and availability of immunizations at the workplace.

The first step of the two- to four-visit implementation process was the development and delivery of a State of the Workplace report that provided a report card for each workplace. The purpose of the report card was to let each workplace know how it was doing in health promotion relative to what is currently recommended. This report provided feedback and scores based on the baseline assessment, focusing on the list of 15 evidence-based chronic disease prevention opportunities for the employer (see Table 1). We worked with workplace decision makers to determine which recommendations best met the employer's priorities. We reviewed all options for improvement with the decision makers and asked them to choose which three to five activities they would like to focus on for the next year. This was often done by balancing the potential health effects with the perceived difficulty in focusing on each target. The second step was the development and delivery of the tailored intervention report, the Workplace Solutions report. The Solutions report focused on the five to six areas chosen by the workplace team for change, providing examples of programs and policies, strategies for implementation, and references for additional materials. In many ways, the Solutions report was a collaborative strategic plan for each workplace to implement during the year of intervention. After delivering the Solutions report, we conducted a meeting with company decision makers and logistics staff to consult about the findings, recommendations, and solutions in the report. Every other month after the implementation meeting, the study staff scheduled a follow-up contact to conduct a brief status check, discuss progress on the employer's health promotion efforts, present new or emerging opportunities, and to help solve problems that had occurred when choosing and implementing the intervention package. CIS interventionists initiated these calls, receiving responses from workplace staff with either positive comments (e.g., things are going fine) or questions about possible program direction (e.g., we need help with the wording of our tobacco

policy). During these calls, we discussed any difficulties experienced by the workplaces and tried to help with resources and ideas for ways to deal with the difficulties. The CIS interventionist recorded the questions and responses for each call, and these field notes became part of the qualitative data that were collected during the process. Copies of intervention reports are available as Online Resources 1 and 2.

Analyses

Scores were tallied for each workplace at baseline and follow-up assessment and then combined across workplaces to form overall scores for baseline and follow-up in each of the 15 behavioral areas and in each category. We performed a Wilcoxon paired signed-rank test to determine if the workplaces changed significantly from baseline to follow-up assessment. The Wilcoxon signed-rank test is a non-parametric statistical hypothesis test used when comparing repeated measurements on a single sample to assess whether their population mean ranks differ, when normal distributions cannot be assumed [19]. We then interspersed quantitative findings with results of the interviews to aid in understanding the workplace's perspective of the intervention.

Results

Table 2 contains information describing each workplace in this study. As seen from this table, the workplaces ranged in size from 120 to 520 employees, with high proportions of Native American employees in all workplaces. The workplaces had a variety of structures and locations, and all were geographically isolated from each other and from the research institution. Staff at all four workplaces expressed consideration of responsibility toward improving the health of Native people through work and through benefits offered at the workplace. The workplace staff at all four workplaces indicated that they thought they were doing "a good job, the best job possible" but were also very open to suggestions for improvement in their practice. Staff at all four workplaces reported that they did not routinely use evidence as a base for their practices. Only rarely did an outside group, like an insurance company or broker, offer information on evidence-based practices at workplaces. Thus, the selection of policies and practices came as a result of trying to do what the decision makers thought was proper, along with employee request and expressed need.

Data on the implementation of the intervention activities are presented in Table 3. As seen in this table, each of the four workplaces chose between three to five targets for change at the beginning of the intervention. Generally, we attempted two to three face-to-face meetings on the intervention activities between study staff and workplace teams and an

Table 2 Description of workplaces enrolled in the multilevel health promotion intervention

Workplace	No. of employees	Types of work	Workplace structure	% Native American employees	Insurance status
A	350	Health care facility, federally qualified health center, wellness center	Both the health center and the wellness center are housed in same new facility, with central administration	90	Self-insured privately, with IHS insurance to supplement
B	120	Tribal headquarters	One central location (60 %) with three satellite offices	63	Preferred provider organization
C	290	Health care facility	Four nearby facilities with central administration	60	Private insurance, with IHS coverage for most Native employee
D	520	Casino	One central facility, near tribal center with IHS health facility	65	Private self-insured

IHS Indian Health Service

additional three to four telephone or email contacts across the intervention year.

The interview data indicated some of the reasons for these intervention activity choices. Workplaces chose targets based on realizing that with little expense or work, they could codify an existing informal policy or program and meet the standards for evidence-based delivery. Once the evidence was presented and discussed during the initial intervention selection meetings, the workplace staff people were usually receptive to understanding what the improvements would be and how they could make the improvements work. Most expressed concern over interactions with the health insurance company that provided private insurance held by the workplace, but all four were receptive to initiating these interactions. Workplace staff also targeted topics for change because they reported that the employees had previously expressed interest in a specific area of improvement. This often occurred in the case of exercise or healthy eating groups/activities at the workplace. Cost was often cited as a factor in the decision to target a specific program, but all workplaces had some resources to use in improving offerings for employees and were glad to have input from the study team and materials. All of the four workplaces accepted the \$1000 to assist with the implementation, but all four workplaces indicated that they likely spent more than this amount on the implementation process.

Results of the Intervention on Workplace Practices, Programs, and Policies

Table 4 presents the baseline and follow-up data from the Working Well survey for the four workplaces in this study. As previously stated, we collected data using the Working Well survey at baseline (before the intervention activities began) and follow-up (12 months after the baseline survey was implemented). Overall scores were calculated as the average of all the elements of a category (e.g., benefits). As seen in Table 4, workplaces were able to implement improvements in most of the areas identified on the survey. Significant changes from baseline to follow-up were identified for the following areas: coverage for nicotine replacement therapy (NRT), elimination of out-of-pocket costs for screening and tobacco cessation, accountability systems for providers, posted stair use, cessation line availability that included NRT, offering weight loss programs, offering physical activity programs, and conducting targeted communication programs about health promotion. Most of the other changes were in the appropriate and predicted direction but were not significant.

The final discussions with the workplace teams were generally positive and reflected that workplace teams were pleased with their progress and with the study interactions. Workplace staff felt like they were “on the right track” and

Table 3 Implementation of the intervention in four Native workplaces

Workplace	No. of targets chosen	Areas chosen	No. total intervention meetings	No. total intervention contacts
A	6	Cancer screening, health reminders, tobacco cessation, flu vaccines, use the stairs, tobacco ban	2	4
B	3	Implement tobacco ban, implement flu vaccines on site, implement physical activity program	3	4
C	3	Use the stairs, physical activity, cancer screening	3	4
D	4	Use the stairs, tobacco cessation, flu vaccines on site, physical activity program	3	4

Table 4 Changes from pre- to post-intervention in activities using the Working Well survey: minority workplace intervention

Chronic disease prevention practices	Baseline score	Follow-up score
Benefits		
1. Provide an insurance benefit for over-the-counter nicotine replacement therapy	35	55 ^a
2. Provide an insurance benefit for annual flu vaccines	40	60
3. Eliminate out-of-pocket costs for cancer screening, flu shots, and smoking cessation	25	85 ^a
4. Mandate accountability systems that measure, and provide feedback on, providers' delivery of high-value preventive services	5	50 ^a
5. Mandate reminder systems for providers and employees to ensure that employees receive high-value preventive services	0	25
Policies		
6. Implement smoking bans or restrictions at worksites	35	62
7. Post-stair-use reminder signage to encourage physical activity at the worksite	0	100 ^a
8. Provide on-site facilities for physical activity	35	45
9. Require a sun protection policy for worksites	Not applicable	Not applicable
10. Improve the availability of healthy food choices on-site and install point-of-decision reminders	62	75
Programs		
11. Sponsor a tobacco cessation quit line, including nicotine replacement therapy	21	45 ^a
12. Offer weight loss programs at workplace	50	85 ^a
13. Sponsor an incentive-based group physical activity program	33	56 ^a
Communication		
14. Conduct targeted communication, focusing on key health behaviors and use of preventive benefits	35	65 ^a
Tracking		
15. Anonymously survey employees' health behaviors to track effectiveness of health promotion efforts	0	20

^a All overall score differences from baseline to follow-up significantly different ($p < 0.05$) using Wilcoxon paired signed-rank test

that they would make progress on some of the trickier areas in the future because a year “was too short to make all the changes that they wanted to.” Difficult areas for change included negotiating changes in benefits with the insurance companies and balancing out the needs of the employees to reduce smoking with tribal policies about tobacco use and tobacco regulations. No one expressed concern that the problems would be insurmountable, but all four workplaces indicated that more time would have been helpful.

Discussion

MBEs of this type were a feasible place to test this model of disseminating evidence-based programs and policies to a wide audience. Data indicate that in 1 year, workplace staff could make changes in key targeted variables to improve the health-promoting opportunities of their employees. We believe that these workplace-level changes were likely to actually support changes in the employees' choices and behaviors, although we were not able to evaluate employee-level changes in this study. A full-scale test of this intervention dissemination model would include pre- and post-surveys of employee

perspectives and behaviors. This would connect workplace-level changes with individual changes, resulting in improvements in health outcomes.

Workplace suggestions for improvement were welcomed by workplace staff and decision makers. The positive relationship between the workplace staff, mostly human resource coordinators and the insurance providers, was encouraging and surprising in this study. Many of the changes identified as possible targets in the intervention protocol required insurance companies to make changes in their policy offerings and activity support. We had anticipated that, as did the workplace staff, this would be potentially difficult or unsuccessful. However, the workplace staff was able to negotiate some of the changes that they wanted and indicated that, given another year or two, they might be able to do more. This supports the idea that the 1-year intervention period was too short to make all the possible changes to the insurance-related policies and coverage. In future work, a longer timeline would be more desirable and potentially more efficacious.

There are several limitations to the present study and its data that shape the interpretation. The largest is the uncontrolled design that prohibits comparison to a usual care or control group. An additional design limitation is the relatively

small sample size, which does not permit any significance testing. We also did not measure employee behaviors relevant to chronic disease prevention, such as smoking, physical activity, or screening. This means that we have no way of identifying direct effects on behaviors relevant to changes in chronic disease rates. Cost was a very informal although important part of this project. Each of the workplaces discussed cost in choosing the areas to target and in implementing the program, but formal cost analyses were not a part of the data collection. In future projects, we intend to make cost a formal part of both assessment and intervention, to provide estimates of program costs and to assist workplaces with anticipating costs to program implementation. Finally, there was no long-term follow-up of the findings in this year-long intervention. In order to change chronic disease rates, these types of changes must be implemented and maintained over years, and this is certainly an important design feature for future research. All of these limitations mean that the present study must be interpreted cautiously, and the findings must be replicated in a randomized trial or otherwise well-designed full-scale study before adopting any program.

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Conflict of Interest Authors Bowen, Briant, Harris, Hannon, and Buchwald have no conflicts of interest to report.

Ethical Standards All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all patients for being included in the study.

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