DOI: 10.1377/hlthaff.2015.0641 HEALTH AFFAIRS 34, NO. 11 (2015): 1956-1963 ©2015 Project HOPE— The People-to-People Health Foundation, Inc. By Hilary K. Seligman, Courtney Lyles, Michelle B. Marshall, Kimberly Prendergast, Morgan C. Smith, Amy Headings, Georgiana Bradshaw, Sophie Rosenmoss, and Elaine Waxman

A Pilot Food Bank Intervention Featuring Diabetes-Appropriate Food Improved Glycemic Control Among Clients In Three States

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ABSTRACT Food insecurity—defined as not having adequate quantity and quality of food at all times for all household members to have an active, healthy life—is a risk factor for poor diabetes control, yet few diabetes interventions address this important factor. Food pantries, which receive food from food banks and distribute it to clients in need, may be ideal sites for diabetes self-management support because they can provide free diabetes-appropriate food to people in low-income communities. Between February 2012 and March 2014, we enrolled 687 food pantry clients with diabetes in three states in a six-month pilot intervention that provided them with diabetes-appropriate food, blood sugar monitoring, primary care referral, and self-management support. Improvements were seen in pre-post analyses of glycemic control (hemoglobin A1c decreased from 8.11 percent to 7.96 percent), fruit and vegetable intake (which increased from 2.8 to 3.1 servings per day), self-efficacy, and medication adherence. Among participants with elevated HbA1c (at least 7.5 percent) at baseline, HbA1c improved from 9.52 percent to 9.04 percent. Although food pantries are nontraditional settings for diabetes support, this pilot study suggests a promising health promotion model for vulnerable populations. Policies supporting such interventions may be particularly effective because of food pantries' food access and distribution capacity.

ne in six Americans is food insecure—that is, they do not have "access at all times to enough food for an active, healthy life for all household members." Many food-insecure people adopt coping strategies to fill the resulting gap, often by purchasing foods perceived to be the least expensive. However, these foods tend to be carbohydrate rich, calorically dense, and nutritionally poor. 3,4

About twenty-nine million US adults are estimated to have diabetes. For people with diabetes who are also struggling with food insecurity, a tension exists between their need to stretch their

food budgets and their need to purchase diabetes-appropriate food, such as vegetables, lean proteins, and whole grains. Inadequate and inconsistent access to diabetes-appropriate food is likely an important factor in the association between food insecurity and poor glycemic control among adults with diabetes. ⁶⁻⁹ In addition, the need to purchase food may conflict with the need to purchase medication and monitoring supplies. ¹⁰

As a result, the food-insecure patient with diabetes is significantly disadvantaged across multiple dimensions of self-management. If such a patient's health care provider is unaware of the food insecurity, the patient's inability to carry

out diabetes self-management activities successfully may be perceived as nonadherence. Despite these fundamental challenges, few diabetes interventions—even those explicitly targeting low-income populations—address the unique challenges faced by food-insecure patients with diabetes—in particular, their inability to afford diabetes-appropriate food.

As the diabetes epidemic worsens, a growing number of community-based organizations, employers, and payers are partnering with health care providers and systems to address diabetes outside of health care settings, often by providing diabetes self-management support. ^{12,13} Recently, food banks have begun to emerge as additional potential partners in this process. ¹⁴

Food banks are organizations that procure and distribute food to partnering local food pantries, which in turn distribute it directly to clients in need. As potential sites for providing diabetes interventions and self-management support, food pantries offer a number of unique advantages over health clinics and other community-based organizations.

First, the United States has a vast system for distributing free food. Feeding America, the nation's largest hunger-relief organization, uses a network of nearly two hundred food banks that provide food to more than forty-six million people annually (about one in six Americans, including more than one in four African Americans and one in six Latinos) through 58,000 food programs, most of which are food pantries. One-third of Feeding America's client households report having a member with diabetes. Thus, the system of food banks and food pantries reaches deep into the low-income population of adults with diet-sensitive chronic disease.²

Second, although food pantries were originally established to meet limited emergency needs, food insecurity in the United States today has become chronic. Thus, many food pantries serve the same clients repeatedly over months or even years. These pantries are often easily accessible in the neighborhoods of highest need and reach vulnerable and marginalized population groups (including people who have infrequent access to medical care, despite their high risk for dietsensitive disease). These characteristics make food pantries ideal sites for diabetes screening as well as for reaching and engaging vulnerable adults with diabetes.

Finally, food pantries have unique access to and expertise in the distribution of food, including items that are often financially and geographically otherwise out of reach for food-insecure individuals. For example, approximately one-quarter of the food distributed through the Feeding America network is fresh produce, which is generally unavailable in most foodinsecure households. Food pantries may thus be able to reach individuals with diabetes-appropriate food at critical times—when household food is not sufficient.

To our knowledge, no formal evaluation of diabetes interventions targeted to food-insecure populations has included the provision of food. We explored the feasibility of using food banks and their partner food pantries to provide diabetes support by implementing a pilot intervention with four major components: screening for diabetes and monitoring of glycemic control, distributing diabetes-appropriate food once or twice monthly (enough to last one or two weeks, depending on household size), referring clients who lacked a usual source of care to primary care providers, and providing diabetes self-management support and education.

The intervention was implemented at three food banks: the Food Bank of Corpus Christi (site 1), in Texas; the Redwood Empire Food Bank (site 2), in Santa Rosa, California; and the Mid-Ohio Foodbank (site 3), in Grove City. Partnering with each of these food banks were from three to thirty-two food pantries, which were used to reach clients to participate in the intervention.

Our goal was to provide information for programs and policies that address the development of diabetes self-management support in nontraditional and community-based settings—particularly food pantries, where food insecurity is addressed. Our rationale was that diabetes initiatives in low-income communities have not engaged directly with the need for healthy low-cost food.

Study Data And Methods

This pilot study was a partnership between the University of California, San Francisco, and Feeding America. The study design, implementation, data collection and analysis, and manuscript preparation were jointly conducted. All parties had free access to the data. The three participating food banks were chosen through a competitive selection process coordinated through Feeding America (online Appendix A provides a brief explanation of the process).15 To realistically simulate the implementation of diabetes self-management interventions among diverse pantry settings, the food banks were given flexibility in the intervention's design and implementation, including the selection of the affiliated food pantries in which to conduct the intervention. However, we required each food bank to implement core intervention elements and evaluation metrics.

The study protocol was approved by the Copernicus Group Independent Review Board.

participants between February 2012 and March 2014 as they came to receive food at food pantries affiliated with the participating food banks (sites 1 and 2) or if they were identified as food insecure at clinics that were partnering with food pantries (sites 2 and 3). Clinic partners at site 3 identified eligible participants and provided pantries with data from their medical records along with confirmation of their food-insecurity status; clinic partners at site 2 referred food-insecure patients who had diabetes without any additional records data.

During the enrollment period, food bank staff members also conducted free diabetes screening events that were available to all adults queuing for food at partner food pantries (sites 1 and 2). Food pantry clients who did not report having a previous diabetes diagnosis were screened for diabetes using blood glucose testing (Abbott Laboratories' Freestyle Lite or Accu-Chek Compact). Clients with elevated blood glucose values (random values ≥140 mg/dL or fasting values ≥120 mg/dL) were then tested with a point-ofcare hemoglobin A1c test. Initiating screening with blood glucose rather than HbA1c testing was a cost-saving protocol established to meet the high demand for screening that we encountered with the intervention's initial implementation. Clients who reported having a previous diagnosis of diabetes universally received HbA1c testing (Bayer A1C Now+).

Eligibility criteria for the intervention included HbA1c ≥6.5 percent or a self-reported diagnosis of diabetes plus presentation of one or more diabetes medication bottles. Primary care providers in the clinics verified whether people with diabetes were food insecure (sites 2 and 3). We excluded people who were younger than age eighteen, unable to complete surveys in English or Spanish, or pregnant and those whose cognitive status was so impaired as to interfere with survey administration.

abetes-appropriate food contained whole grains, lean meats, beans, low-sodium vegetables, no-sugar-added fruit, and shelf-stable dairy products. The boxes were supplemented with perishable food: fresh produce, milk, yogurt, cheese, bread, and frozen lean meat. The food boxes and perishable items included both items purchased by the food bank (costing the food bank an average of \$16 per box) and items donated to the food bank.

The contents of the boxes were planned by project personnel who were registered dietitians or certified diabetes educators. Each food box

Food pantries may be able to reach individuals with diabetes-appropriate food when household food is not sufficient.

was sufficient to last one to two weeks, depending upon household size, and included recipes and cooking tips to encourage recipients to eat healthy meals.

OUTCOMES OF INTEREST

▶ PRIMARY OUTCOME: Baseline HbA1c values were captured at food pantries during screening (sites 1 and 2) or by chart abstraction at partner clinic sites (site 3). Follow-up values were captured approximately six months after enrollment (median: 182 days; interquartile range: 126–265). We analyzed HbA1c both as a continuous variable and as a proportion of individuals with poor glycemic control—defined as those with HbA1c >9 percent, a widely established cutoff value. ¹⁶

▶ SECONDARY DIABETES SELF-MANAGEMENT OUTCOMES: Trained food bank personnel administered a fifty-six-item survey (Appendix B)¹⁵ in English or Spanish at baseline and at six-month follow-up (median follow-up: 196 days; interquartile range: 161–275). We examined a series of secondary diabetes self-management behaviors to explore mediating factors that might influence changes in glycemic control.

We determined the proportion of individuals with severe hypoglycemic episodes using a validated question: "In the past four weeks, how many times have you had a severe low blood sugar reaction, such as passing out or needing help to treat the reaction?" We used the brief modified Block seven-item diet screener with a four-week time horizon to determine the number of servings per day of fruit and vegetables. ¹⁸

We assessed diabetes self-efficacy (individuals' perception of their ability to manage their diabetes) with a validated eight-item scale scored from 0 to 10.7.19-22 We used a two-item screening tool scored from 1 to 6 to measure diabetes distress, a measure of the emotional burden of chronic disease self-management.²³

We measured adherence using the four-item Medication Adherence Questionnaire, scored

There is emerging recognition that the food bank network must support healthy nutrition and promote health.

from 0 to 4.^{24,25} We created our own measure of competing demands by asking how often the participant "put off buying food so that you would have money to buy medicines" or "diabetes supplies" or "put off buying medicines" or "diabetes supplies so that you would have money to buy food." We considered trade-offs to have occurred if participants answered "often" or "sometimes" (on a four-point Likert scale) to any item (Appendix B).¹⁵

FOOD BOX SATISFACTION We assessed participants' satisfaction with the food box and elicited their impressions of how having the box affected their own nutritional intake and the intakes of other household members. Satisfaction criteria included the extent to which participants and other members of their households liked the food box (compared to standard food pantry options), ate all or most of the food, or threw or gave away food from the box. Participants also reported the extent to which other household members changed their fruit and vegetable intake during the intervention.

additional survey variables Other variables captured on the baseline survey included age, sex, race/ethnicity, language (English or Spanish), education, body mass index (from self-reported height and weight), smoking status, and food security (measured using the Department of Agriculture's six-item Household Food Security Survey Module). The module divides households into food-secure, low-food-secure, and very-low-food-secure groups (the latter two constituting food-insecure households).

In general, low-food-secure households have reduced food quality to meet their food budget, while very-low-food-secure households have reduced both food quality and quantity. Both of these types of households also use additional coping strategies, such as delaying purchasing other items (including medications) to purchase food and seeking food from sources such as friends and family, food pantries, and soup

kitchens and through federal nutrition benefits.

EFFECTIVENESS ANALYSIS Baseline and followup HbA1c results were obtained for 768 participants. Survey completion was not mandatory to receive the intervention, and a number of participants did not complete one or both of the surveys. We had HbA1c and survey data at baseline and follow-up for 687 participants.

We used t-tests and chi-square tests to examine differences in demographic characteristics. We examined pre-post changes using paired t-tests for continuous variables and McNemar's tests for categorical variables. To more closely align our results with the body of existing literature on diabetes self-management support, we also conducted all analyses among the subset of participants with HbA1c \geq 7.5 percent.

We conducted additional analyses using generalized estimating equations with a main effect of time to determine whether changes in outcomes were significant after adjustment for covariates that either were potential confounders or addressed within-site clustering (Appendix C).¹⁵

INTERVENTION FEASIBILITY AND PUBLIC **HEALTH IMPACT** Although the three food banks in the intervention followed a similar general implementation plan, each tailored its program to fit its preferences, workflow, and capacity. We summarized the acceptability of the intervention and its potential for broad-scale public health impact using the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework, which is designed to capture data that will enhance the speed and quality of implementation and dissemination of public health interventions found to be effective.27-29 Because our primary analysis focused on the effectiveness component, the RE-AIM evaluation summarized the other components: reach (the number of people each component of the intervention served), adoption (the number of sites that initiated implementation of each intervention component), implementation (how consistently the sites performed planned intervention activities), and maintenance (program continuation after the pilot period). Reach and effectiveness were evaluated at the level of the individual client, while adoption, implementation, and maintenance were assessed at the level of the food bank.

Data for the RE-AIM analysis came from the fifty-six-item program survey administered quarterly, which included both closed- and open-ended questions addressing reach, successes, challenges, and protocol deviations. Program surveys were augmented by personal communication between the authors and food bank staff members.

LIMITATIONS The study had several limitations.

Because it was an observational pilot study without a control group, we were unable to definitively determine effectiveness. The lack of literature describing the general trajectory of HbA1c values in low-income and vulnerable populations also complicated our interpretation of the pre-post HbA1c data. Because the intervention was implemented as a bundle, we were unable to disentangle outcomes of the provision of diabetes-appropriate food from outcomes of the rest of the intervention. In addition, because of the pragmatic nature of the pilot, the intervention differed across study sites. This strategy was chosen to develop and refine best practices for future implementation across a heterogeneous network of food banks.

Finally, loss to follow-up differed significantly across sites. Fifty-four percent of the participants at site 1, 45 percent at site 2, and 16 percent at site 3 were missing either a follow-up survey or follow-up HbA1c screening, yielding an overall retention rate of 58 percent. Compared to participants with complete data, those lost to follow-up were more likely to be male, Latino, and Spanish-speaking and to have very low food security (Appendix D). Site differences in retention rates likely reflected differences in participant selection, outreach, and persistence of food pantry use. For example, site 1 reached a mobile population (Latino agricultural workers) that was less

EXHIBIT 1

Characteristics Of Study Participants At Baseline, Food Bank Clients With Diabetes

Characteristic	All participants (N = 687)	Participants with uncontrolled HbA1c (n = 396)
Mean age (years) Female	56.6 74%	54.3 75%
Race/ethnicity Latino or Hispanic White Black or African American Native American, Asian, or other	53% 25 12 10	56% 21 14 8
Spanish speaking	28	30
Education Less than high school or GED High school or GED More than high school or GED	41% 21 37	43% 18 38
Household food security status Very low secure Low secure Secure	39% 44 17	40% 43 16
Mean body mass index Current smoker	34.3 19%	34.8 21%

SOURCE Authors' analysis of study results. **NOTES** Percentages may not sum to 100 because of rounding. Uncontrolled hemoglobin A1c (HbA1c) is ≥7.5 percent. Levels of food security are explained in the text. GED is general educational development certificate.

frequently connected with health care than participants in site 3, who were already engaged in primary care.

Study Results

Our final analytic sample included 687 participants with HbAlc ≥6.5 percent or proof of diabetes (Exhibit 1). More than half of these participants were Latino or Hispanic, and 41 percent had less than a high school education. More than 80 percent were food insecure (44 percent were low food secure and 39 percent very low food secure).

In pre-post comparisons (Exhibit 2), there was significant improvement in mean HbA1c from baseline (8.11 percent) to follow-up (7.96 percent). The proportion of participants with very poor glycemic control (HbA1c >9 percent) declined from 28 percent to 25 percent. There were also significant improvements in fruit and vegetable intake, self-efficacy, diabetes distress, medication nonadherence, and trade-offs between buying food or medicine. The decline in severe hypoglycemic episodes did not reach significance, however.

Among the subset of participants with HbA1c ≥7.5 percent at baseline, mean HbA1c declined from 9.52 percent to 9.04 percent, and improvements in secondary outcomes persisted (Exhibit 2). Statistical adjustment for age, sex, race/ethnicity, education, language, and site did not substantially alter the results (Appendix E).¹⁵

Satisfaction with the food boxes was high. In follow-up surveys, most participants said that they preferred the diabetes food box to regular food pantry options (88 percent) and that they ate all or most of its contents (87 percent). Fewer than 10 percent of participants reported giving or throwing away food from their boxes.

We asked participants about general perceptions of changes in fruit and vegetable intake for themselves and household members resulting from the intervention. Sixty percent reported eating more fruit and vegetables themselves, 44 percent reported that other adults ate more fruit and vegetables, 51 percent reported that children ages 0–5 ate more fruit and vegetables, and 54 percent reported that children ages 6–18 ate more fruit and vegetables.

Our summary of the reach, adoption, implementation, and maintenance components of the intervention using the RE-AIM framework appears in Appendix F.¹⁵ All intervention components were adopted at each site, although one site (site 3) received HbA1c values from a clinic partner instead of performing on-site HbA1c testing at food pantries. The greatest implementation variation occurred in the diabetes educa-

Changes In Primary And Secondary Outcomes For Study Participants From Baseline To Follow-Up, Food Bank Clients With Diabetes

Outcome	All participants			baseline		
	No.	Baseline	Follow-up	No.	Baseline	Follow-up
UNADJUSTED MEAN CHANGE						
HbA1c (%)	768	8.11	7.96***	411	9.52	9.04****
Fruit and vegetable intake (servings per day)	677	2.8	3.1***	392	2.8	3.0**
Self-efficacy (on a scale of 1 to 10)	650	6.8	7.3****	382	6.7	7.2****
Diabetes distress (on a scale of 1 to 6)	649	3.1	2.7****	380	3.3	2.8****
Medication nonadherence (on a scale of 0 to 4)	629	1.2	1.1***	367	1.2	1.1*
UNADJUSTED CHANGE IN PROPORTION						
HbA1c >9%	768	28%	25%*	411	52%	43%****
Severe hypoglycemic episodes	646	15	11*	380	14	13
Trade-offs between food versus medicine or supplies	641	47	36****	379	51	40****

tion component of the intervention. Two of the three sites continued study activities after pilot completion.

Discussion

During the 1980s and 1990s the Feeding America network of food banks and pantries focused on providing short-term emergency food to households experiencing an acute food crisis. Distribution of shelf-stable, calorically rich food was the norm, given its practicality and the reliance on food donations from manufacturers. Over the past two decades, however, as food insecurity and poverty have increased, reliance on the food bank system has markedly increased as well. Feeding America's Hunger in America 2014 study estimated that the organization's clients were served an average of 8.5 times per year, and almost two-thirds of clients planned to regularly access food from a food pantry or similar program to help with their monthly food budgets.²

There is emerging recognition that the food bank network, which distributes food in nearly every US county and reaches many of the most vulnerable communities, must support healthy nutrition and promote health. Failing to do so may counteract broader efforts to address health disparities. This vision places a heavy burden on the food bank system to meet high demand while also improving the nutritional mix of the foods it distributes. A healthier product line often includes perishable food items, which adds additional cost and complexity to food bank operations. This complexity includes developing distribution channels and capacity to ensure that food safety and quality are maintained at all

points along the system for perishable food (including, for example, rapid transit, access to refrigerators and freezers, and more frequent distribution).

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This pilot study provided an opportunity for food banks and their partner food pantries to experiment with ways to consistently deliver healthier food—an ongoing concern in the public health community. The pilot offered concrete experience in working through challenges such as purchasing food when donated supplies were of inadequate quality, increasing the availability of fresh fruit and vegetables while managing perishability risks, and educating pantry staff members and volunteers about the needs of clients with diet-sensitive disease.

This study was designed to assess the feasibility of disseminating diabetes-appropriate food and self-management support by leveraging a system that has not historically had any role in health care or prevention but that consistently reaches vulnerable populations. Food banks (sites 2 and 3) succeeded in developing new referral systems with clinic partners that served overlapping vulnerable populations.

The study's observational results need confirmation in a controlled trial. Nonetheless, partnerships between food banks and health care providers or health plans constitute a clear leverage point for improving health in low-income communities. Ongoing efforts of the Feeding America network to respond to food insecurity and the diabetes crisis provide an opportunity to develop policies and practices that position food banks more centrally in efforts to reach target populations with healthy food and support for disease prevention and management.

Although the reductions in HbA1c that we observed were small, similar reductions can yield large benefits at the population level. The population-level benefit of disease prevention through increasing access to healthy food in food-insecure households at high risk of diabetes deserves further study. Recognition of the importance of the household context has largely been lacking in diabetes interventions, despite the fact that household members not targeted by these interventions (including household members without diabetes) may also be at risk for diet-related disease and may positively contribute to or undermine changes in diet management. Policy makers should consider how the development and maintenance of these interventions might positively affect community health.

Conclusion

We are aware of no previous evaluations of diabetes interventions conducted by food pantries. This pilot suggests that the provision of diabetes-appropriate food in association with on-site monitoring of HbA1c, self-management support,

and referral to primary care providers might result in improved glycemic control and self-management skills and competencies among adults with diabetes.

This intervention creates a model for food banks to use in responding to the rise in diet-sensitive disease in low-income communities. Of course, diabetes is only one of many illnesses directly affected by poor nutrition. Public health policies that engage food banks in efforts to reduce the burden of other diet-sensitive chronic diseases are important areas for potential expansion.

Although food pantries are a nontraditional setting for addressing diabetes, the translation of diabetes self-management support into these community-based settings could be a promising model for future health promotion, especially when targeting vulnerable populations. Policy makers should consider ways to leverage food bank assets (in particular, their reach into food-insecure populations and expertise in food distribution) when designing public health interventions aimed at addressing diet-sensitive chronic diseases such as diabetes.

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