Improvement in Diabetes Care of Underinsured Patients Enrolled in Project Dulce

A community-based, culturally appropriate, nurse case management and peer education diabetes care model

ATHENA PHILIS-TSIMIKAS, MD
CHRIS WALKER, MPH
LISA RIVARD, RN/CDE
GREGORY TALAVERA, MD, MPH
JOACHIM O.F. REIMANN, PHD
MICHELLE SALMON, MPH
RACHEL ARAUJO

OBJECTIVE — To improve clinical diabetes care, patient knowledge, and treatment satisfaction and to reduce health-adverse culture-based beliefs in underserved and underinsured populations with diabetes.

RESEARCH DESIGN AND METHODS — A total of 153 high-risk patients with diabetes recruited from six community clinic sites in San Diego County, California were enrolled in a nurse case management (NCM) and peer education/empowerment group. Baseline and 1-year levels of HbA_{1c}, lipid parameters, systolic and diastolic blood pressure, knowledge of diabetes, culture-based beliefs in ineffective remedies, and treatment satisfaction were prospectively measured. The NCM and peer education/empowerment group was compared with 76 individuals in a matched control group (CG) derived from patients referred but not enrolled in Project Dulce.

RESULTS — After 1 year in Project Dulce, the NCM and peer education/empowerment group had significant improvements in HbA_{1c} (12.0–8.3%, $P < 0.0001$), total cholesterol (5.82–4.86 mmol/l, $P < 0.0001$), LDL cholesterol (3.39–2.79 mmol/l, $P < 0.0001$), and diastolic blood pressure (80–76 mmHg, $P < 0.009$), which were significantly better than in the CG, in which no significant changes were noted. Accepted American Diabetes Association standards of diabetes care, knowledge of diabetes ($P = 0.024$), treatment satisfaction ($P = 0.001$), and culture-based beliefs ($P = 0.001$) were also improved.

CONCLUSIONS — A novel, culturally appropriate, community-based, nurse case management/peer education diabetes care model leads to significant improvement in clinical diabetes care, self-awareness, and understanding of diabetes in underinsured populations.

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The incidence of diabetes is rapidly increasing in Western societies. Specific racial and ethnic groups, such as Mexican Americans, African Americans, Asian Americans, and Native Americans, are disproportionately affected by diabetes (1,2). The adverse impact on health of uncontrolled diabetes in these groups is compounded by lack of access to traditional primary care and preventive health care services (3–5).

In response to this lack of adequate care for the uninsured, there is an increasing impetus for defining and implementing additional methods of improving diabetes care. The Centers for Disease Control and Prevention's national health objectives for year 2010 include increasing the percentage of individuals with diabetes who achieve specific standards of diabetes care (6). Diabetes management and education programs have been shown to have a significant impact on improving health outcomes (7–10). However, there remains a significant gap in translating and implementing effective approaches in the treatment of diabetes, particularly in underserved racial and ethnic groups (11–13). There is limited experience and available data assessing nontraditional approaches to diabetes self-management and empowerment models in diverse ethnic groups and none testing a comprehensive management approach (14–17). Project Dulce was designed to test the effectiveness of a culturally sensitive, nurse case management (NCM)/peer education approach to improving diabetes care and health status among underserved racial and ethnic populations.

RESEARCH DESIGN AND METHODS

— Primarily Latino patients with type 1 and 2 diabetes, aged 18–80 years, from six community clinic sites in North San Diego County, California were enrolled in Project Dulce from June 1998 to June 2000. Funding allowing entry of ~300 patients was available, and the goal was to evenly distribute the participants among the three categories of payers: *1*) state Medicaid (MediCal); *2*) San Diego County Medically Indigent Adult (MIA) health services program; and

From The Whittier Institute for Diabetes, La Jolla, California.
Address correspondence and reprint requests to Athena Philis-Tsimikas, MD, Chief Medical Director, The Whittier Institute for Diabetes, 9894 Genesee Ave., La Jolla, CA 92037. E-mail:philis-tsimikas.athena@scrippshealth.org.
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Abbreviations: ADA, American Diabetes Association; CG, control group; MIA, Medically Indigent Adult; NCM, nurse case management; PEER, peer education component; RN/CDE, registered nurse/certified diabetes educator; SDM, staged diabetes management.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.
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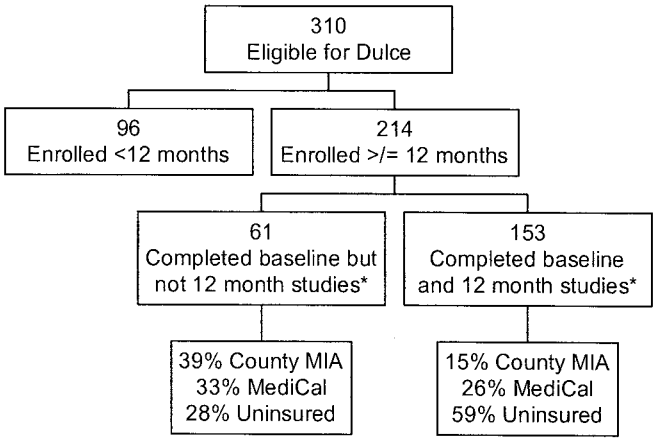

Figure 1—*Eligibility, enrollment, and completion of subjects. There was no significant difference in baseline age, sex, ethnicity, and A1c between the final completers and noncompleters.*

3) completely uninsured with incomes below the federal poverty level. The first 310 patients referred to the program that met the inclusion/exclusion criteria were enrolled. A total of 214 patients were enrolled within the first year of recruitment and, therefore, were eligible for a 12-month analysis of their clinical findings. Of these 214 patients, 153 participants completed baseline and 1-year visits (Fig. 1). Of participants who did not finish 1 year of follow-up, 14% (30 of 214) completed 3- or 6-month visits and 15% (31 of 214) completed the baseline visit and never returned for any follow-up visits. The most common reason for not following up with Project Dulce was a loss of health coverage by either MediCal or the county's MIA health services program, which led to disenrollment from the Project Dulce program. Other reasons for lack of follow-up included return of participants to Mexico and one death.

Participants were recruited through direct referral from their primary care providers at the community clinics, by the county's MIA program, or by a review of recently recorded laboratory values. All participants gave written informed consent to participate in the protocol, which was approved by the Committee for the Protection of Human Subjects in Research at the Scripps Memorial Hospital–La Jolla Campus. Exclusion criteria included diabetes in pregnancy, severe medical conditions that might preclude frequent visits to the community clinic, poor short-term prognosis (expected death in <2 years), serum creatinine level >3.5 mg/dl, active alcohol or drug abuse, or lack of permanent residency in San Diego County.

Because this was a program evaluation of a service project rather than a randomized trial, patients who were referred to Project Dulce but could not be accommodated were used as the usual treatment control group (CG). Chart reviews were conducted on 312 patients with similar demographic characteristics who were followed in the same community clinics and over the same 2-year period. A total of 76 subjects were found to have baseline HbA_{1c} values ≥9% and were used to compare changes in HbA_{1c} and lipid parameters.

A community-based steering committee composed of community health leaders, clinic providers, Project Dulce team members, and program participants provided oversight to the program on a quarterly basis.

Project Dulce protocol

NCM component and CG. The clinical goals of Project Dulce were to meet the American Diabetes Association (ADA) standards of care and to achieve improvements in HbA_{1c}, blood pressure, lipid parameters, and health behaviors (18). Project Dulce's methods of care include a combination of nurse case management and group education delivered by specially trained peer educators to achieve self-empowerment. The NCM component consisted of a nurse-led team with a registered nurse/certified diabetes educator (RN/CDE), bilingual/bicultural medical assistant, and bilingual/bicultural dietitian who traveled to a different clinic site each day to see patients. The RN/CDE had extensive experience in diabetes education and was further trained to use the protocols in Staged Diabetes Management (SDM) for glucose levels, lipid levels, and hypertension management (19). Each participant underwent a 2-h baseline visit to assess demographic information, history of diabetes, weight, blood pressure, foot status (including neurosensory and vascular examinations), HbA_{1c}, chemistry and lipid panel, results of liver function tests, and proteinuria.

At each subsequent visit, the RN/CDE reviewed self-monitored blood glucose results, self-management, and guidelines and goals; provided recommendations for changes in diabetes medications following SDM protocols; and ordered follow-up laboratory studies and return visits. Prescriptions were approved and signed by the primary care physician. For patients with complicated cases, follow-up visits were scheduled within 2 weeks. A minimum of four visits per year was advised. Blood pressure, weight, and HbA_{1c} values were obtained at each quarterly visit and additional laboratory studies were ordered as dictated by SDM protocols.

A medical assistant was responsible for translation (Spanish to English), recording of vital signs, phlebotomy, and patient reminder calls. A bilingual dietitian was available for two 45-min sessions per year for nutrition education. Laboratory tests were measured at one laboratory (UniLab, Tarzana, CA). All patients had access to medications and testing supplies through Medicaid, the County of San Diego's MIA program, or pharmaceutical indigent care programs. All patients had access to at least one screening retinal examination and podiatric care. All patients were referred to the empowerment/peer education program.

Peer education component (PEER). We expanded the traditional role of community health workers by providing them with extensive training to be effective diabetes peer educators. Individuals with diabetes who exemplified the traits of a "natural leader" were identified from the clinic's patient population and trained initially using a program developed by Latino Health Access Program (Orange County, CA). The peer educators were subsequently required to complete the Project Dulce training curriculum and meet established competencies before teaching classes on their own. The curriculum consisted of 12 2-h sessions (1 per week). Classes were taught in patient's

Table 1—*Baseline demographics and laboratory data*

Demographics	Project Dulce group	CG	*P*
Women (%)	69	67	NS
Age (years)	51 ± 12.9	50 ± 12.0	NS
Ethnicity (% Latino)	72	69	NS
HbA_{1c} (%)	11.8 ± 1.78	11.5 ± 1.73	NS
Total cholesterol (mmol/l)	5.66 ± 1.00	5.72 ± 1.38	NS
LDL cholesterol (mmol/l)	3.26 ± 1.01	3.23 ± 1.14	NS

Data are means ± SD.

and promotora's native language and covered diabetes and its complications, the role of diet, exercise, and medication, and the importance of self-monitoring of blood glucose. Classes included interactive sessions in which the patients discussed their personal experiences, fears, and beliefs about diabetes. An emphasis was made to overcome noncongruent cultural beliefs, such as the fear of using insulin or the use of nopales (prickly pear cactus) in an attempt to cure diabetes. Visual demonstrations enhanced the dietary and exercise components. All elements of ADA-recognized teaching programs were covered during the course of the classes. Peer educators were familiar with the community health care clinic system and encouraged the patients to return for visits with their providers for more information about their diabetes management. HbA_{1c} and lipid levels were measured before and immediately after completion of classes.

Satisfaction, knowledge, and beliefs measurements. A diabetes-related knowledge and beliefs protocol was administered to all participants before starting Project Dulce group classes and at the end of their participation. Embedded scales included the previously validated Diabetes Treatment Satisfaction Questionnaire and the Multi-Dimensional Health Locus of Control instrument as well as items assessing basic diabetes knowledge and cultural beliefs (20–23). The latter items were developed for Project Dulce by behavioral scientists at the San Diego State University. They formed scales assessing participants' knowledge about diabetes and culture-based attitudes toward diabetes care. Items such as "Diabetes is elevated sugar in the blood" and "Foot problems are caused by diabetes" measured diabetes-related knowledge. Questions including "Eating *nopales* can cure diabetes" assessed culture-specific practices that pose barriers to effective treatment regimens. It is noteworthy that investigators did not assume all culture-based approaches to be automatically problematic. Instead, they focused on a subset known to pose specific difficulties and provided the participants with new knowledge as opposed to attempting to dispel their cultural belief system.

All items were presented on a five-point Likert-type scale (strongly disagree to strongly agree). Because the questionnaires were first developed in English, they were translated into Spanish using standard back-translation techniques. The scales were reviewed for content validity and cultural acceptability by three Latinos with expertise in diabetes. Reliability analyses using the present sample yielded Cronbach's α of 0.81 for the knowledge and 0.80 for the cultural practices scale.

Statistical analysis

Basic summary statistics including frequency distributions, means, and other descriptive analyses of variables were conducted to provide an overview of the sample characteristics. Parametric and nonparametric statistics were used as appropriate. These descriptive statistics were also used to compare the usual treatment (CG) and Project Dulce groups for adherence to ADA standards of care. Two sets of primary analyses were then conducted. The first assessed Project Dulce's effectiveness on physiological dimensions. It did so by comparing baseline and 1-year follow-up differences on biochemical and physical measures using paired-sample Student's *t* tests. Independent-sample Student's *t* tests were used to check for differences between CG and NCM groups at baseline and 1-year follow-up.

The second set of analyses assessed changes in psychosocial dimensions. Specifically, paired-sample Student's *t* tests compared baseline and 1-year follow-up scores on patient satisfaction, health locus of control, belief in culture-based diabetes remedies, and knowledge of diabetes. Considering the previously described lack of data on psychosocial dimensions for usual care patients, comparisons with the usual care (CG) group were not possible.

Results are shown as means ± SD. Two-tailed $P < 0.05$ values were considered statistically significant.

RESULTS — Demographics and baseline laboratory data are shown in Table 1. The group comprised mostly individuals who were women (69%), of Latino descent (72%), had type 2 diabetes (82%), with annual income <$10,000 (68%), and education level of 8th grade or lower (51%). No significant differences were noted in sex, age, ethnicity, HbA_{1c}, or lipid levels between the Project Dulce group and the CG. Other socioeconomic data were not available for the CG.

Diabetes care outcomes

The participants underwent an average of eight NCM visits per year and 56% (86 of 153) attended the PEER classes. Changes in BMI, blood pressure, HbA_{1c}, and lipid parameters at baseline and at 1-year follow-up are shown in Table 2. Significant within-group improvements were noted in HbA_{1c}, diastolic blood pressure, total cholesterol, LDL cholesterol, and triglycerides. Trends in improvement were noted for systolic blood pressure and HDL cholesterol.

Average BMI was 35 kg/m^2, and no significant change was noted over a 1-year period despite improvement in HbA_{1c} values.

The changes from baseline in HbA_{1c} and lipid parameters were compared between the Project Dulce group and CG at 1 year (Fig. 2). The Project Dulce group had significantly improved HbA_{1c} (8.3 ± 1.72 vs. 10.4 ± 2.50%, $P < 0.0001$), total cholesterol (4.81 ± 0.93 vs. 5.68 ± 1.27 mmol/l, $P = 0.0001$), LDL cholesterol (2.79 ± 0.78 vs. 3.46 ± 1.82 mmol/l, $P = 0.03$), and triglycerides (2.04 ± 1.23 vs. 2.80 ± 1.58 mmol/l, $P = 0.007$) compared with the CG at 1 year. Changes in HDL were not significant (1.20 ± 0.38 vs. 1.13 ± 0.30 mmol/l, $P = 0.27$). There were no significant changes between

Table 2—*Changes in BMI, blood pressure, and metabolic parameters in the Project Dulce group at baseline and 1 year*

Measures	Baseline	1 year	*P*
BMI	35.3 ± 17.6	34.7 ± 8.6	0.70
Systolic blood pressure (mmHg)	128 ± 20.5	123 ± 19.0	0.06
Diastolic blood pressure (mmHg)	80 ± 11.8	76 ± 9.5	0.009
HbA_{1c} (%)	12.0 ± 1.8	8.3 ± 1.7	<0.0001
Total cholesterol (mmol/l)	5.79 ± 1.37	4.81 ± .93	<0.0001
LDL cholesterol (mmol/l)	3.35 ± 1.03	2.79 ± .78	<0.0001
Triglycerides (mmol/l)	3.58 ± 5.20	2.04 ± 1.23	0.0005
HDL cholesterol (mmol/l)	1.07 ± .31	1.13 ± 0.30	0.09

Data are means ± SD.

baseline and 1 year in the HbA_{1c} and lipid levels in the usual treatment control group.

Adherence to ADA standards

Adherence to ADA standards of care for the Project Dulce participants was noted to be 100% for the following areas: HbA_{1c} twice per year, lipid panel, urinary microalbumin-to-creatinine ratio, foot examination, monofilament examination (all at least yearly), but adherence was only 28, 46, 31, 33, and 14%, respectively, in the CG (n = 312). Documented eye examinations were performed in 81% of patients in the Project Dulce group compared with 6% for the CG. A further breakdown of the eye examinations shows that 90% of patients underwent a retinal examination within 18 months of their initial visit with the Project Dulce program.

Satisfaction, knowledge, and beliefs

A total of 92% (79 of 86) of the individuals who participated in both the NCM and PEER groups responded to the questionnaires. Not all individuals fully completed the questionnaire; therefore, the *N* is variable for each of the individual components. There was no significant difference in demographics and HbA_{1c} between the patients who did or did not choose to participate in the peer education classes and no difference between respondents and nonrespondents. Results are shown in Table 3. Treatment satisfaction and knowledge of diabetes increased significantly over the course of Project Dulce enrollment. Respondents demonstrated reduced beliefs in culture-based remedies and demonstrated significant gains in internal health locus of control (and to a less definitive extent, in powerful others health locus of control).

No significant differences between individuals were noted at pretest on any of the psychosocial dimensions included in this report. We can conclude that, on average, those participating in the combination of NCM and PEER did increase their belief that more personal control over their health is possible and that contact with medical service providers is important in maintaining health.

CONCLUSIONS — This study demonstrates that underserved and underinsured patients enrolled in Project Dulce, a culturally sensitive, community-based, NCM/PEER diabetes care model, demonstrate improvements in health status, knowledge of diabetes, and self-efficacy. Patients enrolled in Project Dulce demonstrated consistent ability to meet the measured ADA standards of care. Although participants did not meet the ADA goals of HbA_{1c} <7% and LDL cholesterol <100 mg/dl, the 30% decrease in HbA_{1c} and 12% decrease in LDL cholesterol represents a clinically significant improvement. In addition, they overcame many cultural barriers to care and understanding that can result in poor adherence to medical advice. Participants demonstrated enhanced ability to manage their own health more effectively (empowerment). These results confirm that the Project Dulce approach may be an effective method of delivering diabetes care to culturally diverse populations and those without access to traditional health care.

The model addressed specific barriers to care commonly experienced by underserved populations. Medications and glucose testing strips were provided on the same day as the visit. The proper use and safety precautions of the medications and strips were explained in the patient's native language. It is likely that the immediate availability of medications was responsible for the dramatic improvements in clinical outcomes. Detailed medication use was not captured in this study. Optometry and podiatry services were performed on site, often the same day as another scheduled clinic visit. The nurse team developed a close partnership with the primary care providers at the community clinics. The providers gained trust in

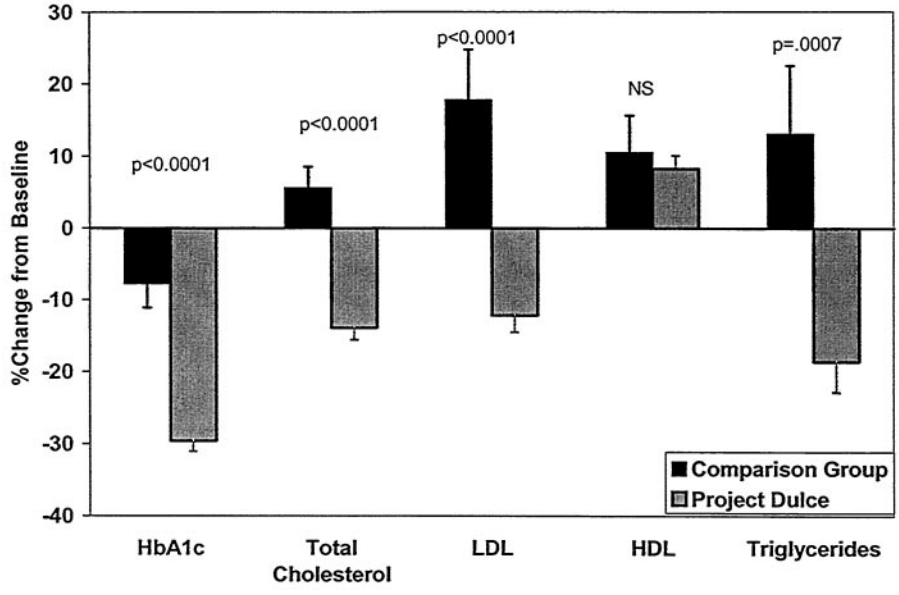

Figure 2—*Changes from baseline in HbA_{1c} and lipids in the Project Dulce group and the CG at baseline and after 1 year of follow-up.*

Table 3—*Psychosocial outcomes of Project Dulce*

Psychosocial measure	Participants in PEER education and nurse managed components				
	n†	Pretest mean	Posttest mean	*t*	*P*
DTSQ score	68	4.83	5.41	4.21	<0.001
Internal HLOC	59	4.67	4.95	2.14	0.04
Powerful others HLOC	70	4.75	4.93	1.98	0.05*
Chance HLOC	58	3.48	3.55	0.40	0.69
Culture-based remedies	67	3.35	2.96	−3.32	0.001
Diabetes knowledge	65	4.18	4.47	3.59	0.001

**P* value falls right at the 0.05 level; †available sample sizes vary due to missing data. DTSQ, Diabetes Treatment Satisfaction Questionnaire; HLOC, health locus of control.

the diabetes nurse's expertise and, despite initial reservations to others making medication adjustments, quickly accepted and appreciated the role of the nurse manager. It is notable that eight NCM visits, on average, were required over the year by this high-risk group to achieve the observed outcomes.

There is clear evidence that interventions using community health workers can result in changes in knowledge and health practices (24,25). Community health workers, or "promotoras," have been used effectively in many different countries to increase awareness in their communities to the risk of certain diseases, link people to the health system, provide social support, and provide cultural mediation between their communities and the traditional Western health system (26–32). Project Dulce built upon the wealth of information supporting the effectiveness of community health workers by further developing their role as diabetes-specific peer educators. Although not necessarily highly educated professionals, Project Dulce's peer educators had the qualities of natural leaders and were motivated to complete an intensive competency-based training program to qualify them as diabetes peer educators. They were supported as part of a multidisciplinary diabetes care team and had access to continuing diabetes education and training. The peer educators were trained to refer any clinical questions to the nurse or physician.

Diabetes education and management programs are increasingly being recognized as beneficial to the control of diabetes. However, several obstacles exist for the development and implementation of these programs, particularly in diverse ethnic and racial groups (33). First, minority groups have disproportionately high rates of either lack of medical insurance or underinsurance and poor or inconsistent access to the health care system (34). Second, reimbursement for diabetes programs varies but is virtually nonexistent for the uninsured and underinsured. In California, for example, Medicaid fee-for-service has no method for reimbursing diabetes education programs and almost no payer specifically covers a diabetes disease management program. Despite recent encouraging evidence demonstrating decreased short-term costs associated with improved diabetes care, the health care systems that deliver care to low-income patients have been slow to adopt programs that require a significant up-front financial investment (35,36). Often, the institutions that pay for the initiation of diabetes programs are not the ultimate beneficiaries of potential future cost reductions; therefore, justification of these programs in simply economic terms is difficult. Finally, there is a lack of culturally appropriate diabetes programs designed for the racial and ethnic groups at greatest risk that have been evaluated in a scientific manner, and there is minimal documentation of whether these approaches can be replicated or adapted in a community setting (37–39).

This study has several limitations. The lack of a randomized CG can lead to significant bias in the results. Although patients were followed prospectively, the CG was an observational CG derived from patients referred but not enrolled in Project Dulce due to lack of space and resources. Therefore, patients were not randomly allocated to each of the interventions. A prospective, randomized trial that would more rigorously test this approach is being planned. Self-selection bias to be willing to enroll in Project Dulce may have favorably influenced the results. Additionally, all members of the Project Dulce team were highly dedicated in caring for the enrolled patients. Whether this can be reproduced in other community settings is unknown and deserves further study. Finally, the cost-effectiveness of this approach has not been evaluated yet. Because these patients obviously cannot afford this care, this study was funded by external grant support as a feasibility study. Initially, implementation of such a program would be cost-incurring. However, the ultimate cost of caring for these patients is borne by the entire U.S. health care system. Ultimately, this approach may be cost-effective and potentially cost-saving if the clinical benefits are sustained long-term and significant reductions in complications are documented. In addition, diabetes management by nurse diabetes educators working independently but closely with community clinic physicians is likely to be a cost-effective strategy in this particular population.

In conclusion, programs such as Project Dulce can be used as models to administer diabetes care to underserved populations and can potentially be adapted to the needs of underserved communities throughout the U.S. Development and funding of similar programs may result in significant improvements in health status and quality of life among the nation's most vulnerable populations.

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