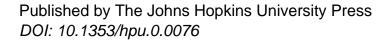


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Effectiveness of a Community Health Worker as Sole Diabetes Educator: Comparison of CoDE with Similar Culturally Appropriate Interventions

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Abstract: The feasibility of a newly designed Community Diabetes Education (CoDE) intervention was evaluated in preparation for the development of a pilot study of this program. A comparison between CoDE and similar culturally appropriate diabetes management programs developed specifically for Hispanic Americans demonstrates its unique features. Patient insurance status, duration of the intervention, delivery in individual and/or group settings, the characteristics of the diabetes educator(s), the other professional resources involved in these interventions, the associated costs, and the reported health outcomes were used in the comparison. The significant improvement in hemoglobin A1c observed in patients who completed one year of CoDE suggests that a community health worker can serve as the primary patient educator in the absence of more highly educated personnel required by American Diabetes Association–certified diabetes education programs. This low-cost model can be reproduced *de novo* in community health centers or inserted into existing diabetes management interventions.

Key words: Diabetes, disease management, underserved population, culturally appropriate program, community health worker.

Diabetes now affects 20.8 million children and adults in the United States, with 1.5 million cases diagnosed in 2005 in people over the age of 20.1 Approximately 24% of Mexican Americans ages 45–74 have diabetes, and the diabetes-related complications of retinopathy and end-stage renal disease are 2–4 times more prevalent in Mexican American patients with diabetes than in the rest of the diabetic population.^{2–4} Furthermore, Mexican Americans, the largest Hispanic/Latino subgroup in the U.S.,

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are more than 1.7 times as likely to have diabetes than non-Hispanic Whites of similar ages. In addition, low income and lack of health insurance are associated with worse health status among patients with diabetes. 5

Traditional approaches to diabetes education and long-term chronic disease management have been less effective when applied to the most vulnerable segments of the diabetes population than when applied to other segments.⁶⁻⁸ Culturally appropriate educational and management strategies to address the specific needs of underserved Hispanic populations have been developed and implemented in multiple locations in the United States.9-17 Favorable effects of these programs (which typically employed registered nurses, certified diabetes educators [CDEs] or dietitians as primary patient educators) on glycemic control and other health parameters have been reported. 9-12,14,16 The limited availability of CDEs in general, and bilingual or bicultural CDEs in particular, prompted many culturally appropriate diabetes education interventions to use promotoras, community health workers, and peer patient educators to handle group educational and skill reinforcement sessions as adjuncts to the primary educators. 9-11,14 Programs using specially trained promotoras as members of the clinical team to provide health information, to promote self-reliance, and to overcome barriers to care improved the success of chronic disease management programs by building a foundation of trust through personal contact with the patients.¹⁸ The terms community health worker and promotora are frequently used interchangeably. Strictly speaking, a promotora is a liaison between the underserved population and the medical system, complementing the health services rendered by more highly qualified personnel. A community health worker may encompass both the role of promotora and the much more formal role of diabetes health educator by actually substituting for more specialized personnel. The need for evidence of an effective protocol-based diabetes program that did not rely on any highly educated personnel such as CDEs and nurses for patient education and long-term case management led to the documentation and the study of the Community Diabetes Education (CoDE) program reported here.

CoDE, developed in Dallas, was the only culturally appropriate diabetes management care intervention that relied completely on the skills of a single specially trained community health worker to provide primary diabetes education classes and nutritional counseling, as well as quarterly case-management sessions.¹⁷ CoDE was designed to be an abbreviated, low-cost, one-to-one educational intervention directly integrated into an existing urban community clinic. The clinic structure included three full-time family practice physicians, one of whom was fluent in Spanish, a Class D pharmacy, and a support staff of bilingual medical assistants. Written protocols for the CoDE program were developed collaboratively by the community health worker and one of the authors (EAP, an endocrinologist) utilizing American Diabetes Association (ADA) Standards of Care, 19 Texas Department of Health Practice Guidelines, 20 and the National Standards of Diabetes Self Management Education.²¹ The bilingual CoDE program educator held a general educational development (GED) high school equivalency diploma and was certified by the State of Texas as a Community Health Worker. Uncompensated community health care providers (including a board-certified endocrinologist, CDEs, and registered dietitians from a local ADA-certified diabetes center) trained the CoDE educator.

Concomitant with the development of the CoDE intervention, a study was designed to determine the feasibility of the program as measured by its impact on diabetes-related outcomes for patients who participated in the intervention for at least 12 consecutive months and the costs of services provided. Funding for this program came directly from local private sources and offset the annual expenses of educator salary and some of the diagnostic supplies (glucose monitors, testing strips, HbA1c and microalbumin testing devices).

The purpose of this paper is to describe the innovative features of the CoDE program, to determine the effectiveness of the community health worker as the sole diabetes educator, and to compare salient features, strengths, and weakness of CoDE with other similar published culturally appropriate educational strategies.

Methods

Intervention. The CoDE program consisted of three 60-minute individual education visits, which addressed recommended diabetes knowledge and self-management skills, 19-22 followed by 60-minute quarterly assessment and case management visits. Maximum patient participation in the program required seven patient contact hours over 12 months. Educational and therapeutic guidelines for the three initial educational sessions and the subsequent quarterly educational and assessment components have been described in detail elsewhere.¹⁷ The bilingual community health worker was responsible for delivery of the entire intervention, documentation of all activities within the medical records, and direct, real-time communication with the clinic physicians to address acute medical issues. Health indicators, including a point-of-care HbA1c at baseline and quarterly using a Bayer DCA 2000+ Analyzer®, blood pressure measurements with a digital sphygmomanometer, height measurements with a stadiometer, weight measurements with a digital scale, and hand calculations of body mass index (BMI) using the standard formula (kg/m²) were performed by the community health worker during each patient encounter. Each study participant underwent urine microalbumin testing performed by the CoDE community health worker at the time of program entry and again after 12 months. Patient participation rates and direct program expenditures were recorded on a monthly basis by the clinic staff.

Study sample. To be eligible for referral to the CoDE program, patients were required to be enrolled as active clinic clients; older than 18 years of age; and diagnosed with either type 1 diabetes (T1DM) or type 2 diabetes (T2DM) treated with oral agents, insulin, or no medications; to have no advanced complications associated with diabetes and to have stable blood pressure (with or without medication); and to be not pregnant. Patients of all ethnic backgrounds were included, although the clinic primarily served a Hispanic community predominantly of Mexican origin. Nearly 20% of the clinic population of approximately 1,600 patients was known to have diabetes, with the majority having T2DM (99%). Out of 160 patients who were referred to CoDE, those who were enrolled at least 12 months before the conclusion of the project were included as the study sample (Figure 1). Full participators were those who attended all seven visits specified in the protocols for the CoDE program. Partial participators were patients who attended visits 1 through 3 and visit 7 and missed any of quarterly

follow up visits 4 through 6. *Drop-outs* were defined as patients who entered into the program at least 12 months before the conclusion of this study, who did not complete the program, and for whom no 12 month HbA1c value was available. Recruitment of patients took place at the clinic from July 2003 to March 2005. The Institutional Review Board at Baylor University Medical Center in Dallas approved the study. All study participants signed an informed consent form that was made available in both English and Spanish versions.

Data construction and analyses. The study examined one group of patients with diabetes using a pre-post quasi-experimental design. Data from participants were entered into an Excel²³ spreadsheet and analyzed in both Excel and SAS* 9.1.3, 2007.²⁴ The rationale of this study design was to determine the effectiveness of the CoDE program overall by identifying any potential dosage response in relation to the level of participation in the program. Patient presence in all types of clinic visits (physician, medication refill, and CoDE) was tracked using the computerized appointment scheduling system available in the clinic and the CoDE patient medical records.

Descriptive statistics were used to compare the socio-demographic characteristics of the subjects who participated in the CoDE program for at least 12 months with those who dropped out of the program, using chi-square tests for categorical variables. The group of *full participators* was compared with the group of *partial participators*

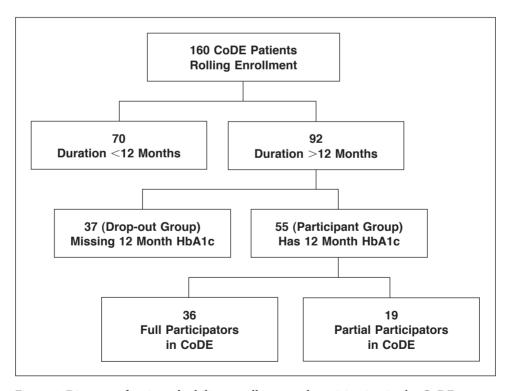


Figure 1. Diagram of patient eligibility, enrollment and participation in the CoDE program.

at baseline, six months, and 12 months with paired-samples t-tests to contrast health outcomes, while the mean percent change in HbA1c was calculated at six and 12 months. A logistic regression was performed to test the effectiveness of the CoDE program. The change in HbA1c at 12 months compared with the baseline value was examined in relation to the number of hours participated in the educational program. The analysis controlling for age, gender, smoking, exercise, the number of clinic visits for reasons other than the CoDE program, and the number of different diabetes medications prescribed at baseline was completed using SAS* 9.1.3, 2007. For the logistic regression, participation in CoDE visits, age, and the number of diabetes medications were treated as continuous variables. Gender, practicing exercise, smoking, and the total number of clinic visits for reasons other than diabetes management sessions were grouped in categorical variables. Exercising, smoking, and making more than 10 clinic visits during one year were represented by Yes/No variables. The cut-off point of 10 used to separate the clinic visits was based on the average number of visits patients were making to the clinic during the year prior to the CoDE program's launch. Missing cases were deleted list-wise.

Results

Study participants. A total of 160 patients with diabetes were referred to CoDE over 18 months (Figure 1). Of the 92 patients who were enrolled for at least 12 months in the program, 55 (60%) had a 12-month HbA1c value available for analysis. Of these 55 patients, 36 (65%) attended all seven hours of education and were designated as the *full participators* group. The *partial participators* group of 19 patients (35%) attended visits 1–3 and visit 7, but may have missed any of the visits 4 through 6. The 37 patients for whom no 12-month HbA1c value was available were designated as *drop-outs*.

No significant differences in age, race/ethnicity, gender, preferred language, literacy, exercise participation, or smoking were found at baseline between the patients who participated for at least 12 months and those who dropped out of the program (Table 1). Of the 55 patients who completed 12 months of the program, the *full participators* group had significantly fewer current smokers (p=.02) than the *partial participators* group but no other baseline differences were observed between these two groups (data not shown).

Clinical outcomes. No significant differences in HbA1c, weight, body mass index (BMI), diastolic blood pressure, or systolic blood pressure were found at baseline between those who participated for 12 months and those who dropped out (data not shown). The mean diastolic and systolic blood pressures at baseline were at or below recommended levels (<130/80 mmHg) for the entire population of 92 patients.

Changes were noted in the metabolic parameters HbA1c, and BMI, in addition to diastolic and systolic blood pressures for patients who were full or partial participators in CoDE for one year and had a 12-month HbA1c available (Table 2). There were significant reductions in mean HbA1c from baseline to six months (8.14% to 7.36%) and 12 months (8.14% to 7%) in the full participators group of patients who had attended all seven education and management visits. In the partial participators group, the mean HbA1c was not changed significantly from baseline to six months, but it was

Table 1.

DEMOGRAPHIC CHARACTERISTICS, CULTURAL AND BEHAVIORAL FACTORS OF THE CODE PATIENTS AT BASELINE

	Partici	oator group	Drop-		
CoDE program	n	%	n	%	p value
Age group					.41
18-44	22	40.00	18	48.65	
≥45	33	60.00	19	51.35	
Ethnicity					.35
African American	9	16.36	10	26.32	
Hispanic	42	76.36	27	71.05	
Other	4	7.27	1	2.63	
Gender					.35
Female	35	63.64	26	70.27	
Male	20	36.36	11	29.73	
Speak English					.77
No	25	45.45	12	33.33	
Yes	30	54.55	24	66.67	
Speak Spanish					.25
No	24	44.44	19	51.35	
Yes	30	55.56	18	48.65	
Bilingual					.91
No	48	87.27	32	86.49	
Yes	7	12.73	5	13.51	
Reading literacy					.58
English & Spanish	4	7.27	5	13.51	
English	14	25.45	11	29.73	
Spanish	36	65.45	21	56.76	
Neither	1	1.82	0	0.00	
Practicing exercise					.29
No	26	48.15	22	59.46	
Yes	28	51.85	15	40.54	
Smoking					.88
No	42	79.25	29	80.56	
Yes	11	20.75	7	19.44	

significantly reduced at 12 months when compared with baseline HbA1c (8.35% to 7.45%). Three patients in the partial participators group were missing HbA1c values at 6 months, which may have accounted for the lack of statistical significance at that time point. Comparisons between the full and partial participators groups revealed no significant differences in mean HbA1c values at six months (p=.098) or 12 months

Table 2.

CHANGES IN METABOLIC PARAMETERS OVER
12 MONTHS OF PARTICIPATION IN CODE PROGRAM

Outcome measure	Baseline	6 months	12 months	
HbA1c ^c				
Full participators	8.14 ± 1.65 $(n=36)$	$7.36 \pm 1.43^{**}$ $(n=36)$	$7.00 \pm 1.06^{**}$ $(n=36)$	
Partial participators	$^{a}7.9 \pm 2.00$ $(n=16)$	$^{a}8.21 \pm 1.96$ $(n=16)$		
	$^{\text{b}}8.35 \pm 2.18$ (n=19)	, ,	$^{b}7.45 \pm 1.35^{**}$ $(n=19)$	
BMI ^c	, ,		, ,	
Full participators	31.22 ± 5.99 ($n=35$)	31.29 ± 5.85 $(n=33)$	31.12 ± 6.22 $(n=33)$	
Partial participators	32.73 ± 6.59 $(n=18)$	33.72 ± 6.41 $(n=16)$	32.52 ± 6.30 $(n=15)$	
DBP ^c	(11 10)	(10)	(11 10)	
Full participators	79.71 ± 8.79 $(n=35)$	76.64 ± 9.56 ($n=33$)	76.64 ± 9.56 ($n=33$)	
Partial participators	80.11 ± 10.23 $(n=19)$	$75.88 \pm 11.26^{*}$ $(n=16)$	$75.88 \pm 11.26^{*}$ $(n=16)$	
SBP ^c	(** **)	(/		
Full participators	120.46 ± 11.99 ($n=35$)	118.44 ± 10.92 $(n=34)$	122.09 ± 13.77 $(n=32)$	
Partial participators	124.79 ± 12.26 $(n=19)$		$122.94 \pm 14.42^{**}$ $(n=16)$	

^{*}p<.10; **p<.05.

(p=.925) (data not shown). However, comparing the mean percent changes in HbA1c from the baseline in full participators and partial participators at six and 12 months did show improved outcomes, especially in the full participators group (Figure 2). The mean percent change in HbA1c was a significant decrease at six months for the full participators group (p<.01) while an increase was noted among the partial participators group (p=.39). At 12 months the mean percent change in HbA1c from baseline was a significant decrease in both the full participators group (p<.0001) and the partial participators group (p<.001).

Average body mass index was greater than 30 kg/m² (normal: 18.5–24.9 kg/m²) in both groups and did not change significantly over the 12 months. Significant changes in systolic blood pressure were observed at both six and 12 months, with marginally

^aBaseline and six months HbA1c of patients who had their HbA1c measured at six months only.

^bBaseline and 12 month HbA1c of all members of partial participators group.

^cHemoglobin A1C, Body Mass Index, Systolic and Diastolic Blood Pressure.

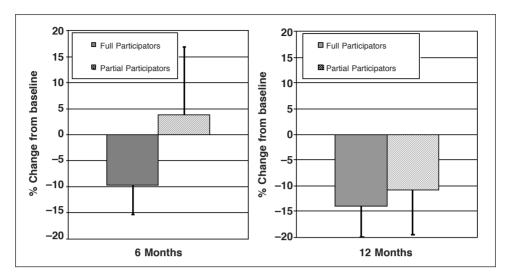


Figure 2. Changes from baseline HbA1c after 6 and 12 months of follow-up in the full vs. partial CoDE program participators.

significant reductions observed in diastolic pressure in the partial participators group. However, the changes observed were within the normal range for desired blood pressure control in patients with diabetes.

The logistic regression showed the effectiveness of having a community health worker as the sole diabetes educator delivering the CoDE educational program during the study period (Table 3). The odds of having a reduced level of HbA1c at the termination of the full set of seven educational sessions was significantly associated with participation in more CoDE visits in a dose–response relationship. Patients who visited the clinic to obtain their diabetes medication or for other medical reasons were also more likely to have a significant reduction in HbA1c, although these parameters were not significant. The logistic regression controlled for patient's age and gender; it did not find a relationship between accomplishing the desired reduction in HbA1c and adoption of other behaviors such as non-smoking and exercising.

Discussion

CoDE was initiated in 2003 as a grass-roots response to the local diabetes epidemic in the community health clinic, in which 20% of active patients were diagnosed with diabetes and were unable to access educational programs or other forms of diabetes management services. A community health worker was successfully trained by local volunteer community health care providers to execute effectively the responsibilities of a physician-supervised diabetes educator and nutritional counselor. The improvements observed in HbA1c level from baseline to 12 months in both the full and partial participator groups demonstrated that the specially trained CoDE educator was capable of assuming these essential roles, which are typically filled by higher-level personnel.

Table 3.

THE ODDS RATIOS OF SOME FACTORS ASSOCIATED WITH THE CHANGE IN HbA1c OVER ONE YEAR FOR CODE PROGRAM PARTICIPANTS (N=55)

Factors	OR	95% CI
CoDE visits*	4.29	1.03-17.80
Age*	1.01	0.93-1.08
Age* Gender#	3.57	0.65-19.66
Exercise#	0.54	0.1-2.69
Smoking#	0.39	0.05-3.16
Total clinic visits#	2.61	0.10-70.28
Diabetes medications*	1.82	0.54-6.18

^{*}Continuous variables

While the partial participator group achieved a notable decrease in HbA1c, after one year the full participator group nearly achieved the ADA target level of HbA1c<7%.

These results suggest a dose-response effect in that greater participation in the program produced a more favorable improvement in glycemic control. The multivariate analysis confirmed that better glycemic control was achieved by patients who attended more education sessions, which indicates the effectiveness of the community health worker in helping diabetic patients to self-manage their disease.

Lack of improvement in mean BMI over the 12 months was observed in spite of improvement in glycemic control. This result was not entirely unexpected as the emphasis during the meal planning process was identification of food groups, understanding portion sizes, and beverage choices, rather than calorie restriction. In addition, there were no indoor facilities or safe outdoor locations available for clinic-sponsored organized physical activities. Other culturally appropriate diabetes self-management interventions have reported similar experiences with respect to BMI among their program participants.^{9,11}

At baseline, we observed mean systolic and diastolic blood pressures that were at or below the recommended target level for patients with diabetes, and adequate blood pressure control was maintained throughout the study period. This was attributed to aggressive blood pressure treatment by the clinic physicians coupled with easy patient access to appropriate medications through the on-site pharmacy. In addition, all patients who developed microalbuminuria were treated with antihypertensive agents even in the absence of overt hypertension. These observations are consistent with the findings from other studies.^{11,12}

The CoDE program community health worker had a substantial patient capacity of

[#]Categorical variables (reference levels used: female, smoking, exercising, having less than 10 clinic visits in one year for reasons other than CoDE).

120 patients per month, which was not exceeded during the feasibility study period.¹⁷ The patient attrition rate of 22% was consistent with rates observed by other investigators.¹⁵ The results of our feasibility study suggested that patient participation in the CoDE program was influenced by continued patient contact with the community health worker. In a nurse-managed diabetes clinic in East Harlem, contact with a community health worker had a significant effect upon the proportion of Hispanic people who completed a diabetes education program (80%).²⁵

Comparison with similar programs. Similarities and differences between the CoDE program and other published strategies targeting low-income Hispanic patient populations were explored to identify its strengths and weaknesses (Table 4). Patient insurance status, duration of the intervention, delivery of the education program in individual and/or group setting, the characteristics of the diabetes educator(s), the other professional resources involved in these interventions, the associated costs, and the reported improvement of HbA1c levels are outlined. All the diabetes management programs included in this comparison addressed the issues of language barriers (by having bicultural educators and educational materials) and educational level (low-literacy materials, visual aids), and all were appropriate in terms of culturally specific matters such as diet, social emphasis, and importance of family in the care process. The majority of programs served a mixture of insured and uninsured patients, while CoDE assisted uninsured patients exclusively.

The low intensity of CoDE, which consisted of a maximum of seven one-to-one patient contact hours over 12 months, made it the most abbreviated among these programs. The Starr County Border Health Initiative, a longstanding diabetes self-management intervention located on the Texas-Mexico border, where 97% of the residents are Hispanic, provided an intensive instructional and support group intervention of 52 contact hours over 12 months using a team of bilingual Mexican American nurses, dietitians, and community workers. 9 A successful compressed version of this intervention took place over 16 hours of education with an additional six hours of group support in the same program. 10 Project Dulce in San Diego utilized a Nurse Case Management (NCM)/peer education approach in multiple community clinics.¹¹ Eight two-hour NCM sessions were scheduled over one year. Medication adjustments were made by the NCM with the approval of the primary care physician. Patients were then offered 12 group sessions (two hours each) over 12 weeks led by specially trained community health workers. In addition, a bilingual dietitian was available for two individual 45minute sessions. The total patient contact time for Project Dulce as initially designed was approximately 40 hours over 12 months. Project Dulce reported that patients completed an average of five NCM visits, 50% of patients consulted with a dietitian, and the average attendance at peer educator group sessions was four classes.²⁶ The peer educators were providing diabetes information to patients, but this was not directly connected with the NCM and dietitian services as the group sessions took place at locations outside of the clinic.¹¹ An intervention designed for Caribbean Hispanic people with T2DM that utilized a nutritionist, a nurse, and an intervention assistant was implemented in a Community Health Clinic (CHC).12 This program involved an initial one-hour individual session followed by 10 weekly 21/2 to 3-hour group sessions. Two additional 15-minute individual sessions held immediately prior to the group session took place

Table 4.

CULTURALLY APPROPRIATE DIABETES MANAGEMENT PROGRAMS SPECIFICALLY DEVELOPED FOR HISPANIC POPULATION

Program State Source/year	Subject insurance status	Intervention duration	Individual component	Group component	Primary diabetes educator	Direct physician involve- ment	Previous diabetes education	Cost per patient per year	Final HbA1c and change from baseline
Starr County TX; ^Ø Brown et al. 2002 ⁹	Low- income; most un- insured	52 hours over 12 months	None	12 weekly 2 hr sessions; 14 biweekly 2 hr support sessions	Nurses; Dietitians; Community Health Workers	No	None	\$384 per patient for personnel and food; does not include SBGM [#] Supplies [©]	Intervention Group: HbA1c=10.89% (-0.92%)*; Control Group: HbA1c=11.64% (-0.16%)
Starr County TX; Brown et al. 2005 ¹⁰⁰	Low- income; most un- insured	22 hrs over 12 months	None	8 weekly 2 hr education sessions; three 2 hr support sessions	Nurses; Dietitians; Community Health Worker	No	None	\$131 per patient for personnel and food; does not include SBGM [#] supplies [©]	Compressed Group: HbA1c=11.1% (-0.7%)***; Extended Group: HbA1c=10.5% (-1.0%)****
Project Dulce CA; Philis- Tsimikas et al. 2004 ¹¹ Gilmer et al. 2005 ^{25□}	County MIA 15%; MediCal 26%; uninsured 59%	40+ hrs (approximate) over 12 months	NCM initial evaluation: 2 hrs × 8 visits; Dietitian: 45 min × 2 visits over 12 months	12 weekly 2 hr sessions with peer educators	NCM: RN/CDE Dietitians Medical Assistants; Peer Educators	Yes: PCP	None	\$507 per patient for personnel and administrative costs□	Intervention Group: HbA1c=8.3% (-3.7%)**; Usual Treatment Group: HbA1c=10.4% (-1.1%)*

(Continued on p. 1087)

Table 4. (continued)

Program State Source/year	Subject insurance status	Intervention duration	Individual component	Group component	Primary diabetes educator	Direct physician involve- ment	Previous diabetes education	Cost per patient per year	Final HbA1c and change from baseline
CHC Springfield MA; Rosal et al. 2005 ¹²	Medicaid only: 40%; Medicaid and sup- plement 60%	26.5–31.5 hrs over 6 months	Initial 1 hr evaluation; 15 min × 2 follow-up visits	10 weekly 2.5–3 hr sessions	Diabetes Nurse; Nutritionist Assistant	No	None	Not reported	Intervention Group: HbA1c=6.85% (-0.85%)*; Control Group: HbA1c=9.18% (-0.12%)
La Diabetes Y La Unión Familiar AZ; Teufel-Shone et al. 2005 ¹³	Not reported	12 weeks; (time not specified)	None	3 home visits; 5 education sessions; 2 celebratory events	Promotoras	No	None	Not reported	Not reported
Border Health ¡Si! AZ; Ingram et al. 2005 ¹⁴	Insured: 60% in Yuma & 75% in Santa Cruz Counties	10 hrs over 5 weeks plus individual contact with community workers	Promotora contact for 6 months	5 weekly 2 hr sessions over 5 weeks	CDE; Health Educators; Promotoras	Located in community health center; use of tracking forms	None	Not reported	Program Participants: HbA1c=8.7% (-0.7%)**

(Continued on p. 1088)

Table 4. (continued)

Program State Source/year	Subject insurance status	Intervention duration	Individual component	Group component	Primary diabetes educator	Direct physician involve- ment	Previous diabetes education	Cost per patient per year	Final HbA1c and change from baseline
CDSMP/ Tomando Control TX, NM, & Mexico; Lorig et al. 2005 ¹⁵	Not reported	14 hrs over 6 weeks	None	6 weekly 2½ hr sessions	Trained Peer Leaders	No	None	Not reported	Not reported
Tomando Control CT; Mauldon et al. 2006 ¹⁶	Private ins. 50%; public ins. 38%; uninsured 12%	18 hrs over 6 weeks; follow-up for 6 months	None	6 weekly 3 hr sessions	Intervention Leader; Research Staff	No	Yes: 75% had received a one- to-one session before program	Not reported	Intervention Group: HbA1c=6.52% (-2.08%)**
CoDE- TX; Culica et al. 2007 ¹⁷	Uninsured 100%	7 hrs over the first 12 months; 1 hr quar- terly after 1st year	3 hrs education 4 hrs management for first 12 months; 1 hr quarterly after 1st year	None	Community Health Worker (<i>Promotora</i>)	Yes: PCP	None	\$461 per patient for personnel and SBGM# supplies	Compliant Group: HbA1c=7.0% (-1.14%)*; Non- compliant Group: HbA1c=7.45% (-0.9%)*

 $^{^{\}circ}$ & \square show in which published study the noted statement was mentioned * p<.05; ** p<.01; *** p \leq .05; **** p \leq .01 MIA = San Diego County Medically Indigent Adult # SBGM = Self Blood Glucose Monitoring

during the 10-week period for a total of at least 26.5 hours of patient contact time. Other strategies reported between 10 to 18 hours of patient contact time. ¹³⁻¹⁶

CoDE is the only program that utilized a community health worker as the sole patient educator. The American Association of Diabetes Educators²⁷ and the Institute of Medicine²⁸ have supported the use of community health workers to help provide diabetes education, as have other researchers in prior studies.^{29–32} Systematic reviews of the effectiveness of community health workers in the care of people with diabetes have documented improvements in patient knowledge and lifestyle changes following the contact with community health workers.^{31,32} Community health workers and peer group educators were clearly viewed as an integral part of the health care response to diabetes by Project Dulce11 (peer educators) and the Starr County Border Health Initiative9,10 (community health workers, trained peer leaders, and promotoras) though these lay health workers did not appear to take the lead role in patient education. Border Health ¡Si! defined the roles of promotoras in their program as outreach providers, and long-term advocates for reinforcement of participant lifestyle changes.¹⁴ Under limited circumstances, Border Health ¡Si! promotoras assumed some formal teaching duties in rural areas under the supervision of a non-English speaking certified diabetes educator. La Diabetes y la Unión Familiar exclusively used promotoras as educators, but the published research did not report metabolic health outcomes.¹³ The Tomando Control pilot test did not specify the educational background of the primary educators involved in the process.16

Project Dulce, Border Health ¡Si!, and CoDE were the only programs to report a direct connection between the primary care physician and the educational strategy. ^{11,14,17} However, the *Project Dulce* nurse case manager had the expertise and authority to make medication changes ¹¹ while the CoDE community health worker did not have such responsibilities. ¹⁷ The CoDE program physicians played a direct role in disease management, while disease management appeared to be taking place primarily within the NCM component of *Project Dulce*, with the physicians taking a more passive role in approving NCM recommendations. *Border Health ¡Si!* did not specify the connection between the diabetes care intervention and the health care providers except to state that referrals to the program increased opportunities for patient-provider communication. ¹⁴

Cost-conscious program development of culturally appropriate diabetes education interventions is critically important to sustain the interventions in the absence of academic or pharmaceutical industry financial resources. The national cost estimate for direct medical expenditures and indirect expenditures related to diabetes care in the United States was \$174 billion in 2007, an amount that is expected to rise given the growing prevalence of diabetes and the increasing cost of health care services.³³ During the same year, patients diagnosed with diabetes encountered annual expenses that amounted to \$11,744, while the cost directly related to the disease was \$6,649.³³ The reported costs per patient of \$461 for the CoDE program included the community health worker salary, glucose monitors, and testing strips, but excluded medication expenses.¹⁷ The cost of glucose monitors and testing strips was the largest CoDE program expenditure. *Project Dulce* reported an annual expenditure of \$507 per patient which included personnel and administrative costs only.¹¹ The annual costs reported by the Starr County Border Health Initiative of \$384 per patient for the extended version

and \$131 per patient for the compressed version included only the costs of teaching personnel for the educational sessions (and excluded the costs of support sessions and glucose monitors and testing strips). While, on the surface, it would appear that group education would be more cost-effective than individual education, this has not been documented. We believe that diabetes is fundamentally a disease faced by an individual and the minimal fixed cost per patient of the long-term individual follow-up inherent in our program and the critical trust established between patient and CoDE educator justify the strategy of one-to-one educational sessions in the CoDE Program.

CoDE program participants experienced reductions in HbA1c at the conclusion of the study, which is consistent with findings from the other programs. 9-12,14,16 This result is even more meaningful given the increased level of risk in the studied group that had an average value of HbA1c at baseline of 8.57%. The Starr County Border Health Initiative reported that "study participants on average did not achieve the national HbA1c target of ≤7 percent,"^{10, p. 531} in spite of anywhere from 22 to 52 hours of patient contact time with the intervention. Project Dulce also reported a large decrease in HbA1c though the mean value did not reach the recommended ADA target of <7%. 11 The target level was achieved in one pilot study¹² and in another intervention in which 50% of the patients were privately insured and 75% of those patients had received previous one-to-one diabetes education. 16 HbA1c levels at six months were available for only some patients enrolled in Border Health ¡Si!14 Metabolic outcomes reported by this study were not stratified to separate the patients who received only the promotora delivered diabetes education classes from the group as a whole. La Diabetes y la Unión Familiar investigation did not report any metabolic health outcomes.¹³ Good results were recorded by CHC and Tomando studies reflected in HbA1c below 7% and significant decreases in its values at the end of the observation period. 12,16

The magnitude of improvement in glycemic control attributed in part to the immediate availability of appropriate medications in *Project Dulce* was observed in our study as well. On-site access to medications was a feature of *Project Dulce* and the CoDE program, both of which provided prescription refills to patients on the same date of service as the educational sessions. It is not possible for many community clinics to maintain in-house pharmacies. This major barrier of immediate access to low-cost medication refills has been alleviated somewhat by improved accessibility to very-low-cost medications through major retail and wholesale chains nationwide. Strategies to assist patients in acquiring off-site medication refills in a timely fashion could be as simple as arranging a patient prescription pick-up day at the clinic, as some local pharmacies make deliveries.

It seems obvious that patients with diabetes would benefit from regularly scheduled reinforcement sessions as part of the chronic disease management strategy to maintain or to improve their condition. The CoDE Program was designed and structured to continue indefinitely after the first 12 months. All enrolled patients were encouraged to continue with individual one-hour quarterly assessment sessions that followed the same protocol as the first year quarterly assessment visits. The Starr County Border Health Initiative recommends "reinoculation at key intervals, such as annually," for patients who come from "impoverished backgrounds and who have few resources." From an economic perspective, Medicare allows reimbursement annually for up to four hours

of self-management skill reinforcement classes and nutritional counseling, though the effectiveness of this approach has not been documented.³⁴ CoDE is a low-cost mechanism for follow-up and provides continuity of care and a high level of accessibility to the physician for this group of underserved patients.

Diabetes care is time consuming when done well, and the CoDE community health worker has the opportunity to converse with each patient for 60 minutes, a luxury that busy community practitioners can rarely afford. Furthermore, it became evident from the structure of the CoDE program that a distinction can be made between community health worker and *promotora* roles in diabetes education programs. A *promotora* usually plays an important role in client outreach and encouragement for follow up, acting as a "natural helper" for patients in need to alleviate possible obstacles to care. ^{18, p. 256} However, in all of the diabetes programs described and published so far, *promotoras* were not responsible for the solo delivery of a comprehensive program. In our program, the community health worker appeared to fulfill the *promotora* role of increasing patient awareness by encouraging them to attend scheduled physician visits and regularly obtain medication refills. As a corollary, the current study shows that a community health worker can carry out a complex job, by not only providing culturally appropriate educational information to the specific population, but also by acting as a case manager for individual patients to help them self-manage their disease.

CoDE is also the only program that was provided exclusively through individually scheduled appointments that included evening time slots to accommodate working patients and those needing childcare during the day. Childcare and work schedules are important barriers to attendance at diabetes education classes. While much credit has been given to group counseling programs and peer support education for their beneficial impact, it has also been suggested that patients feel more comfortable in individual sessions. 16

In summary, the strengths of the CoDE Program are (1) low intensity of patient contact time (a maximum of seven hours over 12 months); (2) community health worker as patient educator, with resulting low personnel costs; (3) combination of educational and case management components both delivered on an individual basis; (4) visit scheduling made by appointment with flexible hours; (5) continuity of the program on a quarterly basis after completion of the first 12 months; (6) potential achievement of recommended HbA1c target levels after completion of 12 months in the program; (7) closed-loop system involving the patient, the educator, and the clinician, which facilitates timely medical management decisions; and (8) low annual expenditures per patient (\$461) which includes educator salary, home glucose monitoring supplies, five HbA1c measurements, and two microalbumin tests.

A program weakness resulting from the nature of the particular community health center clinic involved is that CoDE serves only uninsured patients. However, this is a limitation common to all the diabetes programs that depend on community health workers. As the evidence of the effectiveness and efficiency of the community health worker model continues to grow, such weaknesses should be addressed through obtaining funding from public insurance mechanisms. Another area of weakness is that CoDE does not, at present, incorporate any formal exercise component. It has been shown that it is possible to connect an existing community exercise facility with

a cohort of patients with diabetes to achieve improvement in overall health.³⁶ Resources to support individual or group exercise programs are currently unavailable to CoDE clinic patients. This problem must be addressed in the future in order to help patients achieve a reduction in body weight and improve overall fitness. It will also be necessary to incorporate group nutrition classes and cooking demonstrations to reinforce culturally appropriate lifestyle changes further.

Streamlining scheduling and appointment confirmations and the establishment of an electronic medical records system would also improve the CoDE program. Instruments to assess diabetes knowledge, diabetes health beliefs, diabetes quality of life, patient satisfaction, and assessment of social habits and lifestyle choices are important components to be added to the CoDE intervention during the next phase of development. Formal assessment of CoDE educator skills and competence will be needed to allow generalization of this intervention to other settings.

Conclusion. CoDE was initiated to improve access to diabetes educational services and to reduce health disparities affecting the uninsured, underserved Hispanic population living in East Dallas. The significant improvement in HbA1c observed in patients who completed one year of CoDE imparted confidence that a community health worker, under controlled circumstances, could serve as the primary patient educator in the absence of more highly educated personnel such as registered nurses, certified diabetes educators, and registered dietitians. We attribute the success of the CoDE program intervention at the conclusion of this feasibility study to the closed-loop system maintained between patient, community health worker, and physician. The unimpeded flow of clinical information among these three individuals facilitated real-time patient management decision-making by the physicians and removed the barriers of disjointed, uncoordinated care and the problem of mixed messages that might occur between health care providers and patients.

There remains a dearth of literature concerning the evaluation of community health worker performance with respect to improvements in both processes (program participation rates) and outcomes (health indicators and costs). Using community health workers in roles such as that described in the present study can be problematic due to expectations of job performance that may exceed the ability of a high school graduate. This challenge might be overcome by a clear job description for the CoDE educator and adequate documentation of outcome measures. Funding from several sources was secured for developing a pilot study in the next stage of the program to explore these issues further. A randomized controlled design to evaluate rigorously the effectiveness and efficiency of the CoDE program will be employed based on this feasibility study. Improvement in quality of care and health-related outcomes is expected to reduce diabetes-associated morbidity and mortality among low-income Hispanic residents of the U.S., at minimal expense. This low-cost reproducible model may have wide applicability in other community health centers.

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