The Community Diabetes Education (CoDE) Program

Cost-Effectiveness and Health Outcomes

Elizabeth A. Prezio, MD, PhD, José A. Pagán, PhD, Kerem Shuval, PhD, Dan Culica, MD, PhD

Background: Limited evidence exists regarding the long-term effects of community health worker–led diabetes management programs on health outcomes and cost-effectiveness, particularly in low-income, ethnic minority populations.

Purpose: To examine the long-term cost-effectiveness and improvements in diabetes-related complications of a diabetes education and management intervention led by community health workers among uninsured Mexican Americans.

Methods: Clinical data, changes in hemoglobin A1c over 12 months, and costs from an RCT of 180 uninsured Mexican Americans with type 2 diabetes conducted in 2006 were utilized for secondary analyses in 2012. Simulation modeling was used to estimate long-term cost and health outcomes using the validated Archimedes Model. The absolute differences for the incremental cost-effectiveness ratios and cumulative incidence of diabetes-related complications were derived by comparing intervention and control groups.

Results: During a 20-year time horizon, participants who received the intervention would be expected to have significantly lower hemoglobin A1c levels ($p < 0.001$), fewer foot ulcers ($p < 0.001$), and a reduced number of foot amputations ($p = 0.005$) in comparison with a control group receiving usual medical care. An incremental cost-effectiveness ratio of $355 per quality-adjusted life year gained was estimated for intervention participants during the same time period.

Conclusions: A simulated clinical trial suggests that a community health worker–led diabetes intervention is a cost-effective way to reduce diabetes-related complications for uninsured Mexican Americans during a 20-year horizon in comparison to usual medical care.

(Am J Prev Med 2014;47(6):771–779) © 2014 American Journal of Preventive Medicine

Introduction

Diabetes affects 25.8 million children and adults in the U.S. and the implementation of intensive evidence-based strategies for diabetes care and prevention have the potential to save up to $250 billion in healthcare spending during the next 10 years.[1–3] In order to effectively allocate resources, it is important to know the potential long-term effects of these strategies to inform health policy. As extended observational follow-up of participants in RCTs is rarely feasible, computer simulation modeling has emerged as a powerful tool for testing alternative approaches to diabetes care before implementation on a broader scale.[4]

The U.S. Hispanic population suffers from a larger burden of diabetes prevalence and complications compared to non-Hispanic whites, coupled with limited access to the quantity and quality of diabetes self-management education (DSME) necessary to maintain health and prevent long-term complications from the disease.[1,5,6] In response to the increasing demand for DSME, community health workers (CHWs) have emerged as an available resource to reduce diabetes disparities.[7–10] Evidence-based strategies to deliver culturally appropriate DSME interventions to socially disadvantaged patients with diabetes utilizing CHWs as diabetes educators have been developed and evaluated over time using RCTs.[11–16] The Community Diabetes Education (CoDE) program, a CHW-led DSME intervention, was implemented in 2003 with the aim of improving health outcomes and quality of diabetes care

From the Department of Epidemiology (Prezio), University of Texas Health Science Center, Dallas; TMF Health Quality Institute (Culica), Austin, Texas; Center for Health Innovation (Pagán), The New York Academy of Medicine, New York, New York; Leonard Davis Institute of Health Economics (Pagán), University of Pennsylvania, Philadelphia, Pennsylvania; and the Intramural Research Department (Shuval), Economics and Health Policy Research Program, American Cancer Society, Atlanta, Georgia

Address correspondence to: Elizabeth A. Prezio, MD, PhD, Department of Epidemiology, University of Texas Health Science Center, 6011 Harry Hines Boulevard, Suite V8.112, Dallas TX 75390. E-mail: eaprezio@sbcglobal.net.

0749-3797/$36.00
http://dx.doi.org/10.1016/j.amepre.2014.08.016

provided to uninsured predominantly Mexican-American patients with type 2 diabetes mellitus (T2DM).[17,18] The effectiveness of the CoDE CHW in the primary role of diabetes educator and case manager was tested in an RCT completed in 2006.[16] In this study, the mean hemoglobin A1c (HbA1c) levels at baseline in the intervention and control groups were 8.9% and 8.7%, respectively. Mean changes for HbA1c during 12 months showed a significant intervention effect (−0.7%, p=0.02) in the CoDE intervention group compared with a control group receiving usual medical care. To provide context, a meta-analysis of culturally tailored diabetes education interventions targeted to ethnic minorities with T2DM revealed an overall intervention effect of −0.29%, with the highest-quality studies achieving an intervention effect of −0.41%.[19]

Although computer simulation modeling has been used to project long-term improvements in diabetes-related complications and cost-effectiveness for CHW-led diabetes interventions specifically targeted to low-income ethnically diverse patients, no models have been implemented in the context of an RCT.[20,21] The purpose of this study was to evaluate the long-term cost-effectiveness and health outcomes of a diabetes education and management intervention targeting uninsured Mexican Americans delivered by CHWs. Computer simulation modeling was used to forecast incremental health outcomes, quality-adjusted life years (QALYs), and medical costs during a 20-year time horizon using results observed in both CoDE RCT trial arms.[22–24]

Methods

Design

The RCT,[16–18] completed in 2006, was performed in an urban community clinic serving uninsured patients with T2DM of largely Mexican-American origin to compare: (1) an intervention group (n=90) that received a one-to-one culturally tailored diabetes education and management program (CoDE) along with usual medical care and (2) a waitlisted control group (n=90) that received usual medical care during 12 months. Outcome measures were recorded daily by two trained research assistants. The University of Texas Health Science Center at Houston IRB approved the recruitment materials, study protocol, and consent documents for primary data collection (2005) and secondary analyses (2012).[16]

Study Measures

Demographic information and clinical measures, including HbA1c, blood pressure, height, and weight were collected at baseline and quarterly for 12 months.[16]

A health system perspective was used to assess the cost-effectiveness of the CoDE program by determining measurable costs for all activities and individuals involved with the intervention. Staff and participant time, and supplies specifically used during CoDE program sessions, were included in the total annual costs inflated to 2012 U.S. dollars. The first year of the program involved seven CoDE sessions and 1 hour of physician time for CHW supervision, CoDE chart review, and medical decision making in excess of usual medical care.[17] Salaries plus fringe benefits for the physicians ($66.31 per hour) and CoDE CHWs ($17.55 per hour) were paid by the community clinic. Participant time was valued based on occupation reported at baseline. The Metropolitan and Non-Metropolitan Area Occupational Employment and Wage Estimates (from the Bureau of Labor Statistics)[25] for the Dallas−Plano−Irving Metropolitan Statistical Area were used to calculate a weighted average wage for study participants ($15.65 per hour). Federal Insurance Contributions Act taxes were added to the base salaries for physicians, CHWs, and time valued for participants. The annual costs for diabetes supplies for each participant ($51.07) were paid for by the RCT funding sources. Training of CHWs to implement the intervention was provided at no cost using local resources (by an endocrinologist, Certified Diabetes Educators, and Registered Dietitians), thus CHW training costs were not included in the model.[17] Transportation costs were not included in the valuation of patient participation owing to the small geographic area served by the clinic.

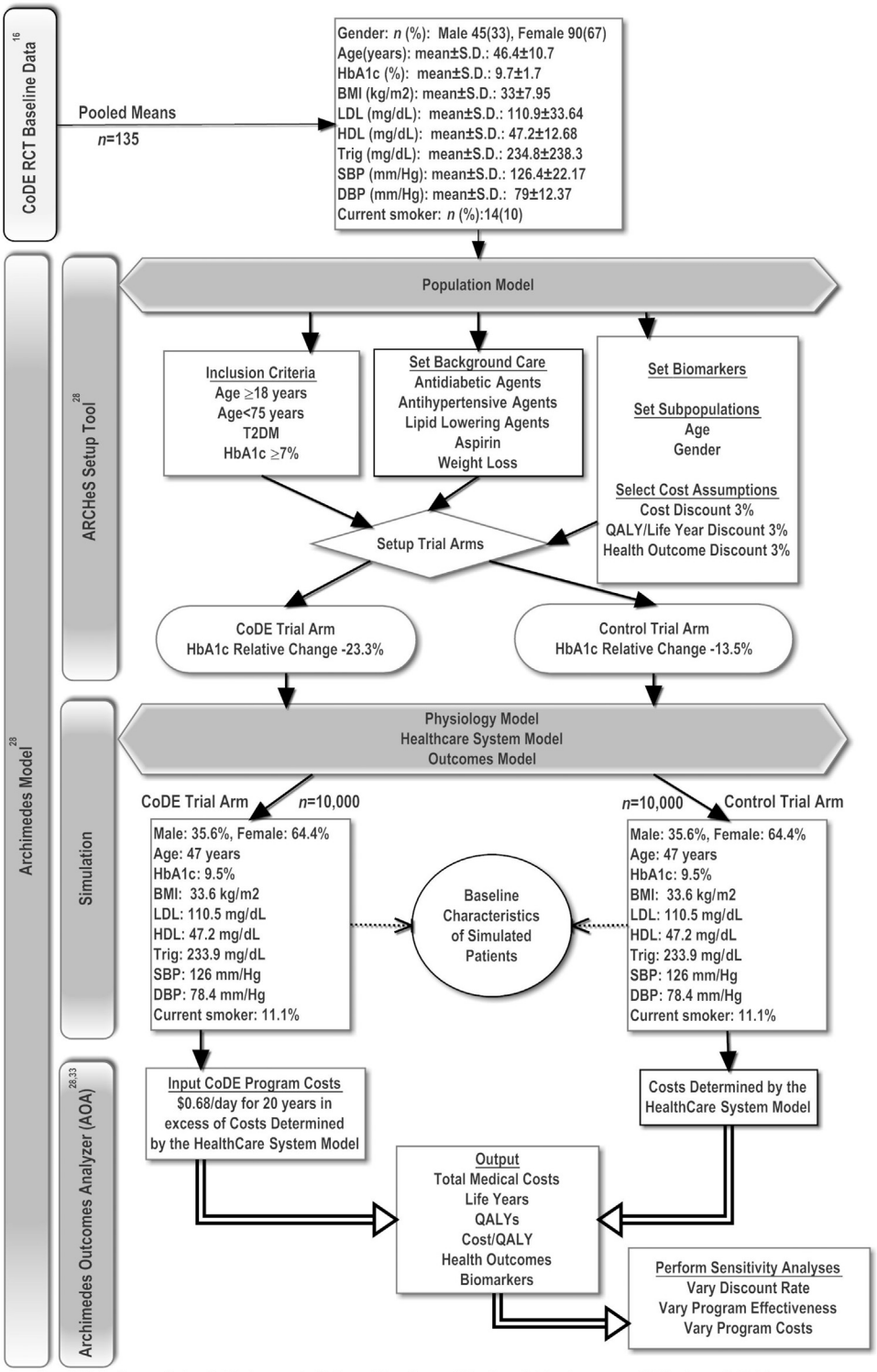
The opportunity cost for each CoDE participant during the first year was $435. The CoDE program was designed to continue after the first year on a quarterly basis at an annual cost of $316 per participant. Based on the current cost structure, the estimated costs for each CoDE program participant over 20 years were calculated to be $4,958 ($0.68 per day) at net present value and discounted at a 3% rate.[26]

Simulation Modeling

The Archimedes Model[27] is an individual-level simulation model of human physiology, disease progression, and healthcare utilization. It addresses risk factors, interventions, and outcomes related to cardiometabolic risk using detailed biological, clinical, and healthcare system utilization information.[28] Simulated individuals have personal characteristics that permit modeling of the variability observed in clinical trial participants. Each simulated person with diabetes has a unique physiology that evolves over time and may result in health-related outcomes, such as foot amputations. The Archimedes Model takes into account changes in behaviors of simulated patients and allows HbA1c to vary over time as it will for the National Health and Nutrition Examination Survey U.S. population from which the study population is simulated, and also includes information on healthcare utilization patterns that are all simulated for each individual using national healthcare guidelines.[29] Utilization rates are modeled by the healthcare system component of the model so that they represent the average level of care people receive in the U.S. consistent with nationally recommended guidelines.[29]

Long-term health and cost outcomes from an RCT are estimated by designating details specific to the trial arms from an RCT, in addition to the standard healthcare utilization and disease progression within the model. The model tracks utilization of services, health outcomes, quality of life, and costs.[28] Quality of life is calculated by multiplying the time a patient spends with a particular symptom or health outcome by the associated decrease in quality of life.[30,31] Costs are calculated by multiplying cost-generating events by the cost of events based on 2006 Medicare data inflated to 2012 dollars.[32] The model has been rigorously validated by comparing the known outcomes from more than 50 clinical trials and cohort studies with model-projected outcomes.[27,33–36]

The Archimedes Model (ARCHeS Simulator 2.4, Archimedes, Inc., San Francisco CA) was used to forecast the incremental lifetime health outcomes, medical costs, and QALYs over a 20-year time horizon.[28] The Archimedes Healthcare Simulator (ARCHeS) Setup Tool was used to input clinical and demographic parameters of the pooled sample of CoDE RCT study participants (Figure 1).



Note. BMI=body mass index; CoDE=Community Diabetes Education; DBP=diastolic blood pressure; HbA1c=hemoglobinA1c ; HDL=high density lipoprotein; LDL=low density lipoprotein; RCT=randomized controlled trial; SBP=systolic blood pressure; T2DM=type 2 diabetes mellitus;Trig= triglycerides ; QALY=quality adjusted life-year.

Figure 1. Flow diagram for Archimedes inputs and outputs.

Using these inputs, the model created the project population by selecting individuals who met those criteria from respondents to the 1999–2006 National Health and Nutrition Examination Survey.[37] The project population was narrowed to a target population that included only individuals with T2DM aged 20–75 years with a baseline HbA1c ≥7%. The relative changes in HbA1c over the 12-month study period observed during the RCT for the CoDE group (−23.3%) and control group (−13.5%) were used as outcomes to set up the two trial arms.[16]

The Archimedes Model used these parameters to create simulated adults with diabetes for the intervention (n=10,000) and control (n=10,000) trial arms with similar distributions and correlations of risk factors, behaviors, medication costs and usage, and medical histories as in the RCT for the CoDE and control groups.

Outcome Analyses

Results from the simulation of both trial arms were evaluated using the Archimedes Outcomes Analyzer, a set of web-based analytic tools to evaluate data and conduct sensitivity analyses.[28,33] HbA1c was predicted for the CoDE and control groups over various time horizons and subpopulations. Expected outcomes for diabetes-related microvascular (retinopathy, nephropathy, and neuropathy) and macrovascular (cardiovascular and cerebrovascular disease) complications, and mortality related to those complications, were evaluated at 5-, 10-, and 20-year time horizons. Expected health outcomes stratified by age and gender were assessed at the 20-year time horizon.

Incremental cost-effectiveness ratios (ICERs) for the simulated trial arm populations and for subpopulations at 5-, 10-, and 20-year time horizons were derived by measuring the medical costs projected for the CoDE program in excess of medical costs projected for the usual medical care control group, divided by the estimated incremental improvement in QALYs associated with the intervention. Medical costs and QALYs were discounted at a 3% rate.[26] Disutility weights used by the model to estimate health utility scores were based on the presence or absence of diabetes-related complications and other cardiometabolic conditions.[30,31]

Sensitivity Analyses

Sensitivity analyses were conducted to evaluate how the results would change from the base-case reference scenario under different assumptions over the 5-, 10-, and 20-year time horizons. The discount rate was changed from 3% to 0% or 6% to investigate the influence of discounting for medical costs and QALYs. Non-adherence to this behavioral intervention was addressed by decreasing program effectiveness from the base-case reference scenario in 10% increments until the cost per QALY was determined to exceed $50,000 (based on the usual $50,000 per QALY gained ICER threshold used in cost-effectiveness analyses).[38] Program costs were varied by ±50% to investigate the influence of program costs.

Results

The simulated population of adults with T2DM reflected the pooled sample means observed in the CoDE RCT (Figure 1). The majority of simulated participants were middle-aged, nonsmoking women with poor glycemic control and high BMI.

HbA1c estimated by Archimedes was significantly lower for CoDE intervention participants than recipients of usual medical care at 5, 10, and 20 years ($p<0.001$) (Figure 2). Compared with the usual medical care recipients, CoDE intervention participants would experience significantly fewer foot ulcers at 5 years (p=0.014), 10 years ($p<0.001$), and 20 years ($p<0.001$). Reduced numbers of foot ulcers were estimated for women ($p<0.001$) (data not shown). At 20 years, there would be significantly fewer foot amputations among CoDE intervention participants (p=0.005) (Figure 3). Over all time horizons, CoDE intervention participants would be expected to experience less frequent myocardial infarctions, cerebrovascular accidents, and end-stage renal disease.

Expected outcomes stratified by age and gender were forecasted up to a 20-year time horizon (Table 1). HbA1c would be significantly lower for CoDE

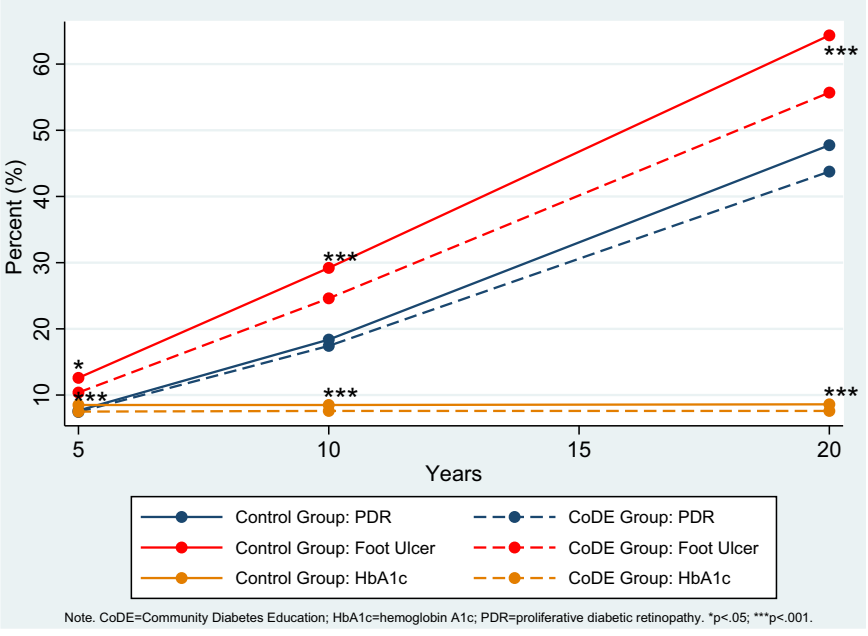


Figure 2. Diabetes complications and HbA1c estimated by Archimedes over various time horizons.

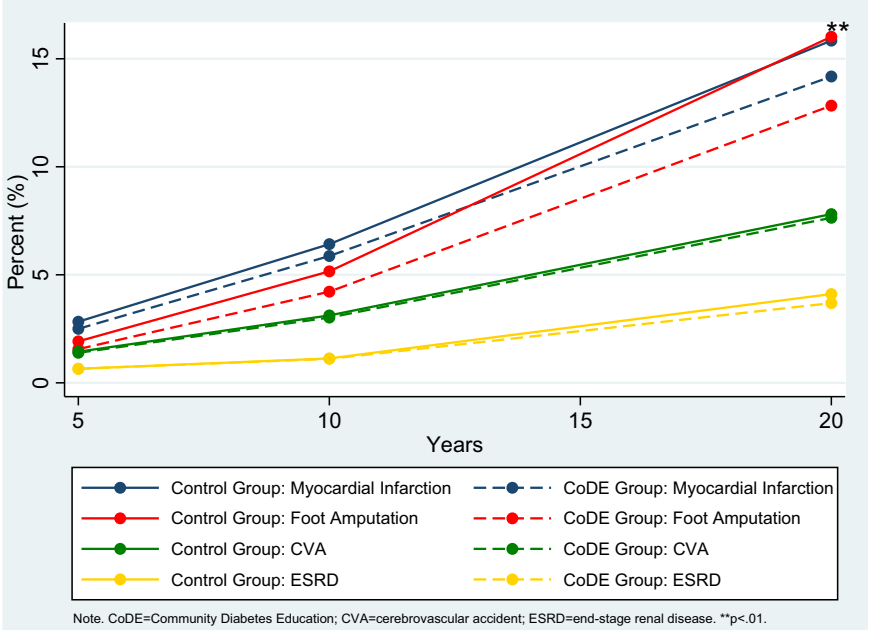


Figure 3. Diabetes complications estimated by Archimedes over 5-, 10-, and 20-year time horizons.

intervention participants compared with the control group over all subpopulations ($p<0.001$). CoDE intervention participants aged younger than 35 years ($p=0.04$), those aged 35–54 years ($p<0.00$), women ($p<0.001$), and men ($p=0.014$) would experience significantly fewer foot ulcers than the corresponding control group ($p<0.01$). Significantly fewer foot amputations would be expected for CoDE intervention participants aged 35–54 years ($p=0.02$), women ($p=0.04$), and men ($p=0.04$) than those in the corresponding control group.

The ICERs were determined for the population as a whole as well as for subpopulations stratified by age and gender, over various time horizons (Table 2). The ICER for the 20-year period was $355 per QALY gained for CoDE intervention population. Furthermore, the ICERs over the 10- and 5-year time horizons were $38,726 and $100,195 per QALY gained, respectively. For individuals aged 55–75 years, the ICER was $37,221 per QALY gained for the 5-year time period and was cost saving over 20 years. For women, the ICER was $45,243 per QALY gained over 10 years, and $1320 per QALY gained over 20 years. The ICER for men was $27,813 per QALY gained over 10 years and was cost saving for men over 20 years.

The results from the sensitivity analyses remained consistent with the base-case reference scenario as adjustments were made to several parameters (Table 3). The CoDE intervention became cost saving when the discount rate was decreased to 0%, whereas increasing the discount rate to 6% raised the ICER to $4471 per QALY gained. Raising program costs by 50% increased the ICER to $30,267 per QALY gained, whereas lowering program costs by 50% resulted in the program becoming cost saving. To investigate the influence of program effectiveness, this parameter was reduced incrementally by 10% from the reference scenario of 100% adherence (relative change in HbA1c, −23.3%). The intervention was cost-effective ($33,703 per QALY gained) when program effectiveness was reduced by 25% (relative change in HbA1c, −17.5%). When program effectiveness was reduced by 30%, the ICER increased to $55,061 per QALY gained.

Discussion

The development and implementation of culturally tailored and clinically effective, evidence-based strategies for diabetes management are essential to improve health outcomes. Using the Archimedes Model of disease progression and healthcare utilization to simulate health and cost outcomes within an RCT, this study contributes to the limited body of evidence regarding the long-term effect on health outcomes and cost-effectiveness of community-based CHW-led diabetes management programs carried out in low-income, ethnically diverse populations.[17,18,39]

The main findings of this simulated RCT reveal that participation in the CHW-led CoDE intervention is cost-effective over a 20-year time horizon in comparison with the usual medical care control group ($50,000 per QALY gained ICER threshold).[38] Therefore, the cost per additional QALY gained over 20 years compares satisfactorily with other interventions, and is very competitive and consistent with the cost-effectiveness of case management for underserved patients with diabetes reported elsewhere.[17,18,38,39] However, the original RCT was not designed to be a cost-effectiveness study and there are no available data to enable comparison of the impact and cost-effectiveness of CHWs versus case-management interventions among Mexican Americans. The findings further indicate that participation in the CoDE intervention is cost-effective within 10 years, and may be cost saving at the 20-year time horizon for intervention participants aged 55–75 years as well as for all men.

Although average predicted HbA1c values for the CoDE intervention group did not reach the target level (HbA1c <7%), reductions in the cumulative incidence of

Table 1. Development of diabetes complications and hemoglobin A1c predicted by Archimedes over a 20-year time horizon

	Trial arm populations		Subpopulations by age (years)						Subpopulations by gender			
	Control	Code	Control	Code	Control	Code	Control	Code	Control	Code	Control	Code
Simulated patients	All	All	20–34	20–34	35–54	35–54	55–75	55–75	Female	Female	Male	Male
PDR	47.75 (43.97, 51.53)	43.76 (40.11, 7.40)	29.37 (22.41, 36.3)	23.95 (17.68, 30.2)	48.12 (43.35, 52.9)	43.62 (39.01, 48.23)	56.77 (48.56, 64.98)	55.24 (47.13, 63.35)	46.94 (42.39, 51.49)	42.98 (38.57, 47.39)	49.21 (42.47, 55.95)	45.18 (38.7, 51.6)
ESRD	4.11 (3.44, 4.77)	3.69 (3.04, 4.34)	0.31 (−0.04, .66)	0.31 (−0.04, .66)	3.57 (2.79, 4.35)	3.25 (2.49, 4.01)	7.90 (6.04, 9.76)	6.96 (5.2, 8.72)	3.27 (2.52, 4.01)	2.91 (2.2, 3.61)	5.62 (4.27, 6.97)	5.11 (3.84, 6.38)
Foot ulcer	**64.34***** **(61.5, 67.2)**	**55.69***** **(52.98, 58.39)**	**48.74*** **(42.68, 54.8)**	**40.27*** **(34.7, 45.86)**	**65.43***** **(61.86, 69)**	**56.51***** **(53.1, 59.92)**	69.64 (63.86, 75.42)	61.74 (56.04, 67.44)	**60.52***** **(57.15, 63.89)**	**51.99***** **(48.78, 55.21)**	**71.26*** **(66.2, 76.4)**	**62.39*** **(57.5, 67.3)**
Foot amp	**16.02**** **(14.39, 17.65)**	**12.85**** **(11.38, 14.32)**	6.48 (4.09, 8.87)	5.28 (3.08, 7.44)	**15.67*** **(13.65, 17.7)**	**12.48*** **(10.66, 14.3)**	22.42 (18.54, 26.3)	18.22 (14.73, 21.71)	**9.94*** **(8.39, 11.48)**	**7.76*** **(6.39, 9.13)**	**27.00*** **(23.5, 30.4)**	**22.00*** **(10.4, 25.3)**
MI	15.84 (14.44, 17.23)	14.18 (12.84, 15.51)	4.20 (2.75, 5.65)	3.66 (2.29, 5.03)	14.65 (12.94, 16.4)	13.00 (11.38, 14.64)	26.03 (22.69, 29.46)	23.69 (20.4, 26.98)	14.05 (12.48, 15.61)	12.58 (11.09, 14.07)	19.09 (16.4, 21.8)	17.09 (14.5, 19.7)
CVA	7.81 (6.81, 8.81)	7.64 (6.64, 8.64)	3.13 (1.66, 4.6)	3.05 (1.6, 4.5)	6.29 (5.15, 7.43)	6.14 (5.02, 6.58)	15.16 (12.43, 17.88)	14.86 (12.16, 17.56)	7.91 (6.68, 9.15)	7.72 (6.51, 8.94)	7.64 (5.88, 9.4)	7.49 (5.76, 9.21)
CHD mortality	4.02 (3.35, 4.69)	3.74 (3.11, 4.37)	0.69 (0.08, 1.23)	0.69 (0.08, 1.23)	2.95 (2.26, 3.64)	2.74 (2.09, 3.39)	9.21 (7.21, 11.21)	8.54 (6.6, 10.48)	3.57 (2.81, 4.33)	3.32 (2.59, 4.05)	4.83 (3.58, 6.08)	4.50 (3.28, 5.71)
CVA mortality	1.15 (0.8, 1.5)	1.11 (0.75, 1.46)	0.23 (−0.12, 0.58)	0.23 (−0.12, 0.58)	0.72 (0.39, 1.05)	0.72 (0.39, 1.05)	2.97 (1.83, 4.12)	2.80 (1.68, 3.92)	1.16 (0.75, 1.57)	1.12 (0.71, 1.53)	1.12 (0.47, 1.77)	1.10 (0.47, 1.73)
Mortality[a]	20.66 (19.29, 22.03)	20.41 (19.04, 21.78)	6.56 (4.7, 8.42)	6.56 (4.7, 8.42)	16.07 (14.56, 17.6)	15.82 (14.31, 17.33)	42.80 (39.43, 46.17)	42.42 (39.07, 45.77)	19.37 (17.72, 21.01)	19.09 (17.46, 20.72)	22.99 (20.5, 25.5)	22.82 (20.3, 25.3)
HbA1c	**8.55***** **(8.5, 8.6)**	**7.61***** **(7.56, 7.65)**	**8.14***** **(8.05, 8.22)**	**7.24***** **(7.16, 7.32)**	**8.53***** **(8.47, 8.58)**	**7.58***** **(7.53, 7.64)**	**9.14***** **(9.02, 9.26)**	**8.15***** **(8.08, 8.27)**	**8.43***** **(8.38, 8.49)**	**7.49***** **(7.44, 7.55)**	**8.77***** **(8.69, 8.85)**	**7.83***** **(7.75, 7.9)**

Note. Values are % (95% CI). Boldface indicates statistical significance ($^{*}p<0.05$; $^{**}p<0.01$; $^{***}p<0.001$).

[a]Mortality due to microvascular and macrovascular diabetes complications.

amp, amputation; CHD, coronary heart disease; CoDE, Community Diabetes Education; CVA, cerebrovascular accident; ESRD, end-stage renal disease; HbA1c, hemoglobin A1c; MI, myocardial infarction; PDR, proliferative diabetic retinopathy.

Table 2. Incremental cost-effectiveness estimated by Archimedes for CoDE versus control group

	Age (years)			Gender		
	20–34 *n*=1,192	35–54 *n*=6,667	55–75 *n*=2,141	Female *n*=6,441	Male *n*=3,559	All *n*=10,000
Life years gained	6.80	165.33	182.01	199.68	154.81	354.00
Undiscounted QALYs gained	65.12	516.22	260.55	506.77	335.73	841.99
QALYs (discounted 3%) gained	43.29	342.80	175.19	337.40	224.26	561.33
Cost per QALY-20 years, $	12,870	6010	Cost saving	1,320	Cost saving	355
Cost per QALY-10 years, $	53,715	51,766	8002	45,243	27,813	38,726
Cost per QALY-5 years, $	143,883	139,388	37,221	118,659	71,971	100,195

CoDE, Community Diabetes Education; QALY, quality-adjusted life year.

foot ulcers and amputations were statistically significant over 20 years, with reductions in the incidence of foot ulcers becoming evident in as few as 5 years of participation. Reductions in the cumulative incidence of proliferative diabetic retinopathy, bilateral blindness, end-stage renal disease, and myocardial infarction were also observed for the CoDE intervention group compared with the control group, although these results did not reach statistical significance. Furthermore, both genders would be expected to benefit from the CoDE intervention.

The modeling strategy employed in this cost-effectiveness analysis was unique in that it incorporated baseline characteristics and outcomes obtained from an actual RCT of a CHW-led culturally tailored DSME intervention and a usual medical care control group to simulate both trial arms. The relative change in HbA1c was used as the trial outcome—rather than a specific target for HbA1c—to more accurately model what was observed during the RCT. Participants with a baseline value of HbA1c <7% were not included in the Archimedes Model simulation because it was unreasonable to assume that patients who were below this recommended target would experience significant reductions in HbA1c levels or derive any added health benefits.

Table 3. Sensitivity analysis: ICER (Cost per QALY [$])

	CoDE group versus control group		
	Time horizon		
	5 Years	10 Years	20 Years
Reference scenario	100,195	38,726	355
Discount rate: 3%			
Program effectiveness: 100%			
Program cost: $0.68/day			
Discount rate for cost and quality of life			
0%	96,058	35,338	Cost saving
6%	104,401	42,415	4,471
Program effectiveness			
80%	NA	94,813	21,386
75%	NA	NA	33,703
70%	NA	NA	55,061
Program cost			
50% increase	NA	103,389	30,267
50% decrease	Cost saving	Cost saving	Cost saving

CoDE, Community Diabetes Education; ICER, incremental cost-effectiveness ratio; NA, Not applicable; QALY, quality-adjusted life year.

This study has its limitations. The results obtained from this simulated RCT may not represent diabetes care delivered outside the context of a clinical trial. Participants were uninsured Mexican Americans from an urban setting, which may limit generalizability of these findings. As Mexican Americans experience a greater burden of diabetes complications than other ethnic/racial groups, the results obtained through this simulation

may have underestimated long-term health and cost outcomes.[5,40] In addition, the Archimedes Model predicted a lower average HbA1c than the pooled sample of RCT participants. This may have resulted in more favorable estimates of long-term health and cost outcomes. Additionally, inherent uncertainty exists when using computer simulation modeling to predict long-term outcomes from short-term data.[41] The model is based on current knowledge and cannot predict an adverse event for which there is no prior existing evidence.[28] The model also cannot account for losses to follow-up through any mechanism other than death from macrovascular diseases and diabetes and its complications.[28] In addition, CHWs must be specially trained to act as diabetes educators/case managers as an integral part of the clinical team to ensure appropriate oversight and intervention fidelity. The CoDE program has been in operation since 2003 and has relied exclusively on the availability of no-cost community resources to provide training. This free training model may be difficult to replicate, as previous research on CHWs indicates that training and oversight can often be intensive, resulting in higher estimated costs than the current study.[42]

Conclusions

Based on these findings, CHWs may be able to deliver successful, cost-effective DSME interventions for uninsured Mexican Americans with diabetes when these interventions are carefully designed. Although nonadherence to behavioral interventions has often been reported, the one-to-one encounters between the CoDE CHW and the diabetes patient promotes both patient and provider accountability. This strategy may be expanded to similar communities to test the impact on other ethnically diverse patient populations. Larger clinical trials are recommended to validate and generalize these findings. The Archimedes Model makes it possible for community-based interventions to routinely forecast health outcomes and cost benefits that become evident at longer time horizons. Such information is essential for health policy decisions related to program design, funding, sustainability, and return on investment. Although this study provides evidence that the CHW model functions when implemented within an integrated system of care, simulations of other DSME interventions that utilize CHWs may lead healthcare providers and other organizations to formally integrate CHWs into the diabetes care team and inform reimbursement decisions by third-party payers for CHW-led interventions.

Primary data collection was funded by the University of Texas School of Public Health and the Institute for Faith-Health Research-Dallas. These sponsors did not play a role in the design of this study.

The authors received no funding in support of this work. The study sponsors had no role in study design; collection, analysis, and interpretation of data; writing the report; or the decision to submit this manuscript for publication.

No financial disclosures were reported by the authors of this paper.

References

1. American Diabetes Association. Diabetes statistics. 2014. www.diabetes.org/diabetes-basics/statistics/?loc=db-slabnav.
2. UnitedHealth Center for Health Reform and Modernization. The United States of diabetes: Challenges and opportunities in the decade ahead. Working Paper 5. Minnetonka, MN: UnitedHealth Group, 2010. www.unitedhealthgroup.com/~/media/UHG/PDF/2010/UNH-Working-Paper-5.ashx.
3. Rowley WR, Bezold C. Creating public awareness: state 2025 diabetes forecasts. Popul Health Manag 2012;15(4):194–200.
4. Herman WH. Diabetes modeling. Diabetes Care 2003;26(11):3182–3.
5. Umpierrez GE, Gonzalez A, Umpierrez D, Pimentel D. Diabetes mellitus in the Hispanic/Latino population: an increasing health care challenge in the United States. Am J Med Sci 2007;334(4):274–82.
6. Shaw K, Killeen M, Sullivan E, Bowman P. Disparities in diabetes self-management education for uninsured and underinsured adults. Diabetes Educ 2011;37(6):813–9.
7. Hunt CW, Grant JS, Appel SJ. An integrative review of community health advisors in type 2 diabetes. J Community Health 2011;36(5):883–93.
8. Witmer A, Seifer SD, Finocchio L, Leslie J, O'Neil EH. Community health workers: Integral members of the health care work force. Am J Public Health 1995;85(8 Pt 1):1055–8.
9. Norris SL, Chowdhury FM, Van Le K, et al. Effectiveness of community health workers in the care of persons with diabetes. Diabet Med 2006;23(5):544–56.
10. Glazier RH, Bajcar J, Kennie NR, Willson K. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. Diabetes Care 2006;29(7):1675–88.
11. Babamoto KS, Sey KA, Camilleri AJ, Karlan VJ, Catalasan J, Morisky DE. Improving diabetes care and health measures among Hispanics using community health workers: results from a randomized controlled trial. Health Educ Behav 2009;36(1):113–26.
12. Lorig K, Ritter PL, Villa FJ, Armas J. Community-based peer-led diabetes self-management: a randomized trial. Diabetes Educ 2009;35(4):641–51.
13. Rosal MC, Ockene IS, Restrepo A, et al. Randomized trial of a literacy-sensitive, culturally tailored diabetes self-management intervention for low-income Latinos: Latinos en control. Diabetes Care 2011;34(4):838–44.
14. Spencer M, Rosland A, Kieffer E, et al. Effectiveness of a community health worker intervention among African American and Latino adults with type 2 diabetes: a randomized controlled trial. Am J Public Health 2011;101(12):2253–60.
15. Phillis-Tsimikas A, Fortmann A, Lleva-Ocana L, Walker C, Gallo L. Peer-led diabetes education programs in high-risk Mexican Americans improve glycemic control compared with standard approaches: a Project Dulce promotora randomized trial. Diabetes Care 2011;34(9):1926–31.
16. Prezio EA, Cheng D, Balasubramanian BA, Shuval K, Kendzor DE, Culica D. Community diabetes education (CoDE) for uninsured Mexican Americans: a randomized controlled trial of a culturally tailored diabetes education and management program led by a community health worker. Diabetes Res Clin Pract 2013;100(1):19–28.

17. Culica D, Walton JW, Prezio EA. CoDE: community diabetes education for uninsured Mexican Americans. Proc (Bayl Univ Med Cent) 2007;20(2):111–7.
18. Culica D, Walton JW, Harker K, Prezio EA. Effectiveness of a community health worker as sole diabetes educator: comparison of CoDE with similar culturally appropriate interventions. J Health Care Poor Underserved 2008;19(4):1076–95.
19. Nam S, Janson SL, Stotts NA, Chesla C, Kroon L. Effect of culturally tailored diabetes education in ethnic minorities with type 2 diabetes: a meta-analysis. J Cardiovasc Nurs 2011;27(6):505–18.
20. Gilmer TP, Roze S, Valentine WJ, et al. Cost-effectiveness of diabetes case management for low-income populations. Health Serv Res 2007;42(5):1943–59.
21. Brown HS 3rd, Wilson KJ, Pagan JA, et al. Cost-effectiveness analysis of a community health worker intervention for low-income Hispanic adults with diabetes. Prev Chronic Dis 2012;9:E140.
22. Sun X, Faunce T. Decision-analytical modelling in health-care economic evaluations. Eur J Health Econ 2008;9(4):313–23.
23. Eddy D. Bringing health economic modeling to the 21st century. Value Health 2006;9(3):168–78.
24. Mount Hood 4 Modeling Group. Computer modeling of diabetes and its complications: a report on the fourth Mount Hood challenge meeting. Diabetes Care 2007;30(6):1638–46.
25. US Bureau of Labor Statistics. May 2013 metropolitan and nonmetropolitan area occupational employment and wage estimates, Dallas-Plano-Irving, Texas. 2014. http://www.bls.gov/oes/current/oessrcma.htm.
26. Gold M, Siegel J, Russell L, Weinstein M, eds. Cost-effectiveness in health and medicine. New York NY: Oxford University Press, 1996.
27. Eddy DM, Schlessinger L. Archimedes: a trial-validated model of diabetes. Diabetes Care 2003;26(11):3093–101.
28. Eddy D, Cohen M. Description of the Archimedes model: ARCHeS simulator 2.5. San Francisco, CA: Archimedes, 2013. archimedesmodel.com/sites/default/files/Archimedes-Model-Description-ARCHES-Simulator-2.5.pdf.
29. Eddy D, Cohen M, Dziuba J. Care processes: calibration methodology and results. San Francisco CA: Archimedes, 2014. archimedesmodel.com/sites/default/files/Archimedes-Calibration-ARCHeS-Simulator-2.5.pdf.
30. Coffey JT, Brandle M, Zhou H, et al. Valuing health-related quality of life in diabetes. Diabetes Care 2002;25(12):2238–43.
31. Sullivan PW, Ghushchyan V. Preference-based EQ-5D index scores for chronic conditions in the United States. Med Decis Making 2006;26(4):410–20.
32. Eddy DM, Shah R. A simulation shows limited savings from meeting quality targets under the Medicare Shared Savings Program. Health Aff (Millwood) 2012;31(11):2554–62.
33. Eddy D, Cohen M, Shum K, Dziuba J. Validation methodology and results. San Francisco, CA: Archimedes, 2013. archimedesmodel.com/sites/default/files/Archimedes-Validation-ARCHeS-Simulator-2.5.pdf.
34. Eddy DM, Hollingworth W, Caro JJ, et al. Model transparency and validation: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force-7. Value Health 2012;15:843–50.
35. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346(6):393–403.
36. Colhoun HM, Betteridge DJ, Durrington PN, et al. Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Study (CARDS): multicenter randomised placebo-controlled trial. Lancet 2004;364(9435):685–96.
37. National Health and Nutrition Examination Survey 1999—2014. 2014. www.cdc.gov/nchs/nhanes/about_nhanes.htm.
38. Li R, Zhang P, Barker LE, Chowdhury FM, Zhang X. Cost-effectiveness of interventions to prevent and control diabetes mellitus: a systematic review. Diabetes Care 2010;33(8):1872–94.
39. Brownson CA, Hoerger TJ, Fisher EB, Kilpatrick KE. Cost-effectiveness of diabetes self-management programs in community primary care settings. Diabetes Educ 2009;35(5):761–9.
40. USDHHS. Office of Minority Health: diabetes data/statistics. 2013. minorityhealth.hhs.gov/templates/browse.aspx?lvl=3&lvlid=62.
41. Eddy DM, Schlessinger L. Validation of the Archimedes diabetes model. Diabetes Care 2003;26(11):3102–10.
42. Viswanathan M, Kraschnewski JL, Nishikawa B, et al. Outcomes and costs of community health worker interventions: a systematic review. Med Care 2010;48(9):792–808.