

Cost-Effectiveness of Diabetes Case Management for Low-Income Populations

Todd P. Gilmer, Stéphane Roze, William J. Valentine, Katrina Emy-Albrecht, Joshua A. Ray, David Coben, Lars Nicklasson, Athena Philis-Tsimikas, and Andrew J. Palmer

Objective. To evaluate the cost-effectiveness of Project Dulce, a culturally specific diabetes case management and self-management training program, in four cohorts defined by insurance status.

Data Sources/Study Setting. Clinical and cost data on 3,893 persons with diabetes participating in Project Dulce were used as inputs into a diabetes simulation model.

Study Design. The Center for Outcomes Research Diabetes Model, a published, peer-reviewed and validated simulation model of diabetes, was used to evaluate life expectancy, quality-adjusted life expectancy (QALY), cumulative incidence of complications and direct medical costs over patient lifetimes (40-year time horizon) from a third-party payer perspective. Cohort characteristics, treatment effects, and case management costs were derived using a difference in difference design comparing data from the Project Dulce program to a cohort of historical controls. Long-term costs were derived from published U.S. sources. Costs and clinical benefits were discounted at 3.0 percent per annum. Sensitivity analyses were performed.

Principal Findings. Incremental cost-effectiveness ratios of \$10,141, \$24,584, \$44,941, and \$69,587 per QALY gained were estimated for Project Dulce participants versus control in the uninsured, County Medical Services, Medi-Cal, and commercial insurance cohorts, respectively.

Conclusions. The Project Dulce diabetes case management program was associated with cost-effective improvements in quality-adjusted life expectancy and decreased incidence of diabetes-related complications over patient lifetimes. Diabetes case management may be particularly cost effective for low-income populations.

Key Words. Diabetes, case management, cost effectiveness, modeling, health insurance

Diabetes is a common and costly chronic disease that increasingly affects low-income and minority populations (Hogan, Dall, and Nikolov 2003). The Centers for Disease Control and Prevention have estimated that the lifetime

risk of developing diabetes for individuals born in the United States in 2000 is 32.8 percent for males and 38.5 percent for females (Narayan et al. 2003). These risks are greatest for Latinos, among whom they are 45.4 percent and 52.5 percent, respectively. The importance of ethnic differentials has been supported by findings from the UCLA Center for Health Policy and Research that show among adults in California age 50 and over, the 1 year prevalence of diagnosed diabetes is 21.2 percent among those who report Mexican ancestry, compared with 10.1 percent among non-Latino whites (Diamant et al. 2003).

Recent studies have shown that culturally specific diabetes management programs can be effective at improving clinical outcomes among ethnic groups disproportionately affected by diabetes. The California Medi-Cal type 2 diabetes study group found that providing case management to an ethnically diverse population of Medicaid beneficiaries at clinical sites in southern California resulted in improved levels of glycosylated hemoglobin (A1c) (2004). Philis-Tsimikas et al. (2004) examined the provision of case management and self-management training to a high risk, low-income, and predominately Latino population in San Diego County and observed significant improvements in A1c and total cholesterol, and demonstrated increases in diabetes knowledge and a reduction in misrepresented cultural beliefs and the use of cultural based remedies (Philis-Tsimikas et al. 2004). Gilmer, Philis-Tsimikas, and Walker (2005) studied the same program in a more general low-income population and found improvements in clinical outcomes along with increased costs for pharmaceuticals and supplies. The per-capita cost of the program itself was relatively modest (\$507 in 2002 dollars).

Simulation models are currently being used to estimate the long-term cost-effectiveness of improvements in diabetes care. These models employ data from large-scale clinical trials such as the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) along with smaller observational studies, survey-based QALY measures, and cost data from claims databases in order to construct statistical models that provide estimates of long-term outcomes associated with diabetes interventions. A model developed by the CDC Diabetes Cost-Effectiveness

Address correspondence to Todd P. Gilmer, Ph.D., Department of Family and Preventive Medicine, University of California, San Diego, La Jolla, CA 92093-0622. Stéphane Roze, M.Sc., William J. Valentine, Ph.D., Katrina Emy-Albrecht, Joshua A. Ray, M.Sc., and Andrew J. Palmer, M.B., B.S., are with the CORE—Center for Outcomes Research, Binningen, Switzerland. David Coben, M.Sc., M.P.H., and Lars Nicklasson, M.Sc., are with Novo Nordisk Inc., Princeton, NJ. Athena Philis-Tsimikas, M.D., is with The Whittier Institute for Diabetes, La Jolla, CA.

Workgroup has been used to demonstrate differences in the cost-effectiveness for intensive glycemic control (\$41,484/QALY, 1997 dollars), blood pressure control (cost saving), and lipid control (\$51,889/QALY) compared with usual care, as well as variations in cost-effectiveness by age (2002). A model developed by CORE—Center for Outcomes Research (a unit of IMS Health) has been used to project the long-term clinical outcomes, cost, and cost-effectiveness of alternative diabetes interventions (Palmer, Roze, Lammert et al. 2004; Palmer, Roze, Valentine, Smith et al. 2004; Minshall et al. 2005; Roze et al. 2005; Valentine et al. 2005). The CDC, CORE, and Archimedes models have been used to estimate the long-term cost-effectiveness of diabetes prevention (Palmer, Roze, Valentine, Spinaz et al. 2004; Eddy, Schlessinger, and Kahn 2005; Herman et al. 2005).

Less attention has been paid to the cost-effectiveness of providing care to differing populations, particularly the relative cost-effectiveness of improving diabetes management for those populations that have low-incomes, are ethnically diverse, and who are often uninsured or underinsured. In this paper, we provide an economic evaluation of the relative long-term cost-effectiveness of Project Dulce, a case management and self-management training program, as provided to four cohorts defined by insurance status in San Diego County: those who are uninsured, those covered by County Medical Services (CMS), those who have Medi-Cal coverage (California's Medicaid Program), and those who have commercial insurance. These populations differ in their demographics and their clinical indicators at baseline. This study examines their long-term outcomes when exposed to the same diabetes management model.

METHODS

Project Dulce

The clinical component of Project Dulce consists of team led by a registered nurse/certified diabetes educator (RN/CDE), and a bilingual/bicultural medical assistant (MA) and a bilingual/bicultural registered dietitian (RD). The RN/CDE is trained by an endocrinologist to use the protocols in Staged Diabetes Management[®] (SDM) for stepped care pharmacological management of glucose, lipid levels, and hypertension (Mazze et al. 1994). The goals of the project are to meet the American Diabetes Association standards of care and to achieve improvements in A1c, blood pressure (BP), and lipid parameters: A1c < 7 percent, BP < 130/80 mm Hg, and low-density lipoprotein cholesterol < 100 mg/dL (American Diabetes Association 2003). Patients have an initial (50 minute) visit with a nurse and are asked to return for

additional (50 or 25 minute, as required) visits with the nurse and for a (25 minute) visit with a dietitian. On average, participants have five visits with the nurse and 50 percent consult with a dietitian. Telephone contact is used for appointment reminders and to answer specific questions.

In addition to the one-on-one visits with the Project Dulce team, patients are encouraged to participate in a group self-management training program: approximately 50 percent participate in the class and average attendance is four classes. The program consists of an 8-week curriculum delivered by trained peer educators (or promotoras). The peer educators are recruited from the patient population, have diabetes themselves, and are of the same cultural/ethnic group as the participants. They complete a 4-month, competency-based training and mentoring program. Classes are taught in the patient's native language, and cover diabetes and its complications, the role of diet, exercise, and medication, and the importance of self-monitoring. The classes are collaborative, including interactive sessions in which the patients discuss their personal experiences and beliefs about diabetes. An emphasis is made to overcome misrepresented cultural beliefs and to encourage patients to take charge of managing their disease.

Simulation Model

Long-term projections were made using a simulation model designed to evaluate the long-term health outcomes and economic consequences of interventions in type 1 and type 2 diabetes. The model structure and validation procedures have been published previously, although a brief overview is provided here (Palmer, Roze, Valentine, Minshall et al. 2004a, b). The CORE Diabetes Model is based on 15 inter-dependent sub-models that run in parallel to simulate the complications of diabetes (angina, myocardial infarction, congestive heart failure, stroke, peripheral vascular disease, diabetic retinopathy, macula edema, cataract, hypoglycemia, ketoacidosis, lactic acidosis, nephropathy, neuropathy, foot ulcer and amputation, and non-specific mortality). Each one of the sub-models is a Markov model created using time and state dependent probabilities taken from published clinical and epidemiological studies. Monte Carlo simulations are used to simulate large groups of patients, incorporating randomness at the event level but not uncertainty in input parameter values. The model can take into account the complete range of diabetes interventions, including screening and treatment programs. The model was designed to assess diabetes specific interventions and therefore only outcomes related to diabetes complications are projected. The model does not

consider costs or complications of nondiabetes related disease or death. In the present analysis, the model was used to evaluate life expectancy, quality-adjusted life expectancy, lifetime cost of complications and cost-effectiveness associated with the Project Dulce diabetes management program versus a usual care control group. A detailed overview of the CORE Diabetes Model is provided in the Technical Appendix.

Patient Cohorts

Patient cohorts were defined using baseline and follow-up data on demographics, clinical indicators, and diabetes complications derived from the Project Dulce database. Four cohorts were defined by health insurance plan: uninsured ($N=760$), CMS ($N=1,345$), Medi-Cal ($N=1,213$), and commercial ($N=575$). CMS is San Diego County's medical insurance program available to low-income adults who are not eligible for Medi-Cal.

Intervention effects were calculated using a difference-in-difference (DID) design for each of the health insurance cohorts. Changes in clinical indicators from baseline were observed among Project Dulce participants over a 3–18 month period. Follow-up visits in this range were examined, and the dates closest to 12 months past the baseline (first) visit were defined as the post intervention visit. For example, a participant with a follow-up visit at month 1 and every 3 months thereafter would have their postintervention clinical values defined at the 13th month visit. The average follow-up interval using this method was 289 days (SD = 108; minimum = 90, maximum = 539).

DID estimates were calculated by subtracting the clinical changes observed in a usual care control group from a previous study (Gilmer, Philis-Tsimikas, and Walker 2005). Mean DID estimates associated with the Dulce diabetes management program specific to each of the cohorts were applied to A1c, systolic BP, and serum lipid levels. No substantial changes in body mass index were reported in the trial and therefore none were applied in the present simulations. The simulation projected results to a lifetime perspective. We assume that the intervention effects (and a proportion of the case management costs) noted in the short-term study would be maintained long-term. Additional details regarding the development of the DID estimates are provided in the Technical Appendix.

Case Management Costs

Costs of nurse case management were similarly estimated using a DID procedure and data from a previous study (Gilmer, Philis-Tsimikas, and Walker

2005). Compared with a set of historical controls, total costs were \$1,383 higher among participants during the first year of case management (2003 dollars). This included \$507 for the costs of visits to the RN/CDE and RD, participation in group classes, and administrative overhead including visit scheduling, coordination of care with the primary care physician, management of referrals, and support of the database registry; \$1,582 in increased costs for pharmaceuticals and supplies (strips); and an offset of \$707 in reduced hospital and emergency room expenditures, which although not statistically significant ($p = .06$), suggests that substantial improvements in coordination of care for those who currently receive little or no disease management may have an immediate effect on rates of hospitalization. We have re-estimated the cost of Project Dulce using recent data on program expenditures. Prices for RN/CDE visits have increased similarly to overall medical prices. However, costs for RDs and peer educators have increased more rapidly as the available labor pool has acquired more advanced training. Thus, we estimate the current cost of the program to be \$662 and our base case analysis assumes a net cost of program intervention of \$1,537 in the first year.

We assume that disease management under project Dulce continues in the following years. According to the administrative data used in this study, Dulce participants average four RN/CDE visits in the following years. We assume that in the second year and beyond, these four RN/CDE visits will substitute for two regular physician visits as the Project Dulce care team assumes the routine duties of diabetes care management. This assumption is supported by substantial anecdotal evidence that Dulce RN/CDEs increased referrals to physicians in the first year to obtain approval for medication changes. These approvals would not be required in the following years. We assume no change in real pharmaceutical prices. Finally, we assume that the cost offset from lower hospital and emergency room expenditures will continue into the following years. The target population of Project Dulce is primarily low-income Latino underinsured, and it is likely that the hospital cost-offset in the first year is an immediate (and real) effect of providing very organized case management to a population that does not typically receive coordinated care that is independent of reductions in complications that occur from achieve clinical goals. Thus, we assume the net cost of Dulce in years 2 and beyond to be \$1,110 including \$1,582 in pharmacy, \$235 in Dulce nursing and administrative costs net of reduced physician costs, less \$707 in reduced hospital and ER expenditures. We assumed the same costs of case management, estimated using the CMS cohort, for each of the four health insurance cohorts. We test this assumption using sensitivity analyses.

Additional details regarding the estimates of case management costs are provided in the Technical Appendix.

Medical Costs, Perspective, Time Horizon, and Discounting

Diabetes-specific costs of complications for 2003 in the United States were taken from published sources and have been previously described (Palmer, Roze, Valentine, Minshall et al. 2004). A third-party payer perspective was taken for the analysis. Only direct medical costs of complications were taken into account (treatment costs plus the costs of complications). The time horizon was set to cover patient lifetimes (40 years) to capture all relevant long-term complications and their associated costs, and to assess their impact on life expectancy and quality-adjusted life expectancy. Costs and clinical benefits were discounted at 3 percent per annum in the base case analysis, in line with the current recommendations for the U.S. setting. For each simulation performed in the present study (base case and sensitivity analyses), 1,000 patients were run 1,000 times through the model, and mean results and standard deviations generated using a nonparametric bootstrapping approach (Briggs, Wonderling, and Mooney 1997).

Sensitivity Analyses

Sensitivity analyses were performed to investigate the influence of the time horizon, treatment effects, intervention costs, and discount rates. Sensitivity analyses were performed on time horizon by reducing it to 20 years. A sensitivity analysis on the main clinical input, A1c, was performed by reducing the treatment effect by 50 percent. To investigate our assumption of constant cohort costs, a sensitivity analysis was performed by assuming 50 percent higher case management costs in the uninsured cohort and 25 percent lower case management costs in the commercially insured cohort. To investigate the influence of discounting on the base case analysis outcomes, simulations were performed varying discount rates on costs and clinical benefits between 0 and 6 percent per annum.

RESULTS

Clinical Input from Project Dulce

Tables 1 and 2 provide baseline demographic and clinical characteristics and baseline complications, respectively, for each of the four health insurance cohorts. Overall, the mean age was 51.2 (SD = 12.7), 61 percent were female,

Table 1: Baseline Characteristics of the Health Insurance Cohorts

	<i>Uninsured Cohort</i>	<i>CMS Cohort</i>	<i>Medi-Cal Cohort</i>	<i>Commercial Cohort</i>
<i>N</i>	760	1,345	1,213	575
Mean age (years)	47.1 (11.9)	51.4 (10.0)	51.8 (14.5)	55.2 (14.0)
Mean duration of diabetes (years)	5.9 (6.3)	6.8 (7.5)	8.2 (9.1)	6.3 (9.0)
Percentage male (%)	36	41	32	51
Mean body mass index (kg m ²)	31.4	32.2	33.3	31.7
Current smoker (%)	12	23	17	11
Non-Latino White (%)	13	25	22	61
African American (%)	3%	8	10	10
Latino (%)	81	48	53	16
Asian (%)	3	19	14	13
Mean A1c (%-points)	9.4 (2.5)	8.6 (2.4)	8.2 (2.2)	7.8 (1.9)
Mean systolic blood pressure (mmHg)	123.8 (18.2)	128.9 (20.5)	126.7 (20.4)	122.6 (14.2)
Mean total cholesterol (mg/dL)	208.7 (48.5)	205.2 (46.8)	202.1 (58.9)	195.5 (43.4)
Mean HDL-C (mg/dL)	46.1 (14.2)	47.9 (15.9)	47.8 (16.3)	46.2 (11.8)
Mean LDL-C (mg/dL)	119.1 (34.1)	117.4 (37.3)	113.5 (39.3)	120.2 (35.2)
Mean triglycerides (mg/dL)	232.5 (192.9)	225.9 (182.0)	220.9 (210.5)	179.1 (121.9)

N, patient number; HDL-C, high density lipoprotein cholesterol; LDL-C, low density lipoprotein cholesterol; CMS, County Medical Services. Values are given as mean (SD).

and 48 percent were Latino. The CMS and Medi-Cal cohorts had similar demographic and clinical characteristics. The uninsured cohort has the highest percentage of Latinos (81 percent) and the highest baseline A1c (9.4). The commercial cohort had the lowest percentage of Latinos (16 percent) and the lowest baseline A1c (7.8). Interestingly, the uninsured cohort had the lowest levels of cardiovascular complications at baseline. Table 3 shows the observed clinical changes in the four cohorts. The largest decreases in A1c were seen among the uninsured cohort, (− 1.3 percent), followed by the CMS (− 0.8 percent), Medi-Cal (− 0.5 percent), and commercial cohorts (− 0.4 percent).

Long-Term Simulation Results

The Dulce diabetes case management program was projected to improve life expectancy in all four cohorts defined by medical insurance coverage in the base case analysis (Table 4). The standard deviations represent the expected distribution of results for simulations of large groups of patients at the mean value of input parameters without uncertainty in these parameter values. Thus, although they are small compared with the means within each group,

Table 2: Baseline Complications in the Health Insurance Cohorts

<i>Health Insurance</i>	<i>Uninsured Cohort (%)</i>	<i>CMS Cohort (%)</i>	<i>Medi-Cal Cohort (%)</i>	<i>Commercial Cohort (%)</i>
Myocardial infarction	2	4	5	4
Angina	3	7	8	6
Peripheral vascular disease	3	10	11	9
Stroke	1	3	6	3
Congestive heart failure	1	2	3	2
Atrial fibrillation	0	1	1	0
Left ventricular hypertrophy	1	2	3	2
No nephropathy	88	86	86	93
Microalbuminuria	9	11	11	6
Gross proteinuria	2	3	3	2
End-stage renal disease	0.1	0.2	0.2	0.1
No retinopathy	93	89	87	94
Background diabetic retinopathy	6	9	11	6
Proliferative diabetic retinopathy	0.5	0.7	0.9	0.4
Severe visual loss	0.3	0.5	0.6	0.3
Neuropathy	37	43	35	20

CMS, County Medical Services.

they represent a higher proportion of the mean differences between groups. Projected gains in life expectancy were highest in the uninsured cohort (mean 1.1 years), followed by the CMS cohort (0.6 years), the Medi-Cal cohort (0.3 years) and the commercial cohort (0.2 years). These differences in

Table 3: Estimated Treatment Effects Associated with Project Dulce in Health Insurance and A1c Simulation Cohorts

<i>Health Insurance</i>	<i>Uninsured Cohort</i>	<i>CMS Cohort</i>	<i>Medi-Cal Cohort</i>	<i>Commercial Cohort</i>
Change from baseline in A1c (%-points)	- 1.3 (2.5)	- 0.8 (2.3)	- 0.5 (1.9)	- 0.4 (2.0)
Change from baseline in systolic blood pressure (mm Hg)	- 3.1 (17.9)	- 2.8 (21.5)	- 1.9 (21.2)	- 0.0 (16.8)
Change from baseline in total cholesterol (mg/dL)	- 21.5 (52.3)	- 12.9 (74.7)	- 12.6 (53.9)	- 4.1 (54.8)
Change from baseline in HDL-C (mg/dL)	- 0.7 (12.2)	- 1.9 (13.9)	- 1.9 (3.6)	0.0 (8.0)
Change from baseline in LDL-C (mg/dL)	- 10.6 (40.4)	- 8.0 (41.8)	- 4.3 (42.1)	- 2.2 (38.1)
Change from baseline in triglycerides (mg/dL)	- 46.5 (162.2)	- 26.0 (198.5)	- 24.7 (175.9)	- 11.3 (579.9)

HDL-C, high density lipoprotein cholesterol; LDL-C, low density lipoprotein cholesterol. Values shown are means with standard deviation in parentheses.

Table 4: Summary of Results for the Health Insurance Cohorts

<i>Health Insurance</i>	<i>Project Dulce</i>	<i>Control</i>	<i>Difference</i>
Uninsured cohort			
LE, years	12.7 (0.17)	11.6 (0.17)	1.1 (0.24)
Quality-adjusted LE (QALYs)	8.5 (0.12)	7.7 (0.11)	0.9 (0.16)
Total lifetime direct costs (\$)	82,225 (2,309)	73,233 (2,188)	8,991 (3,204)
ICER	\$7,933 per life year gained \$10,141 per QALY gained		
CMS cohort			
LE (years)	11.6 (0.18)	11.0 (0.17)	0.6 (0.26)
Quality-adjusted LE (QALYs)	7.6 (0.12)	7.1 (0.12)	0.4 (0.17)
Total lifetime direct costs (\$)	80,157 (2,421)	69,236 (2,219)	10,921 (3,254)
ICER	\$18,976 per life year gained \$24,584 per QALY gained		
Medi-Cal cohort			
LE (years)	11.3 (0.18)	11.0 (0.17)	0.3 (0.25)
Quality-adjusted LE (QALYs)	7.4 (0.12)	7.2 (0.12)	0.3 (0.17)
Total lifetime direct costs (\$)	81,365 (2,374)	69,573 (2,268)	11,792 (3,328)
ICER	\$36,056 per life year gained \$44,941 per QALY gained		
Commercial cohort			
LE (years)	11.3 (0.18)	11.1 (0.18)	0.2 (0.24)
Quality-adjusted LE (QALYs)	7.5 (0.12)	7.4 (0.12)	0.2 (0.16)
Total lifetime direct costs (\$)	69,898 (2,119)	57,530 (2,105)	12,368 (2,973)
ICER	\$57,587 per life year gained \$69,587 per QALY gained		

QALY, quality-adjusted life years; ICER, incremental cost-effectiveness ratio; LE, life expectancy; CMS, County Medical Services. Values shown are means with standard deviation in parentheses; Years, QALYs, and costs are discounted at 3% per annum.

improvements in life expectancy are the result of differences between cohorts at baseline. For example, mean age and duration of diabetes was lower, and baseline A1c was higher, in the uninsured cohort than in the other three groups, leading to greater clinical benefits with treatment. Mean baseline A1c, SBP, and other risk factors were lowest in the commercial insurance cohort, and therefore smaller incremental gains were observed in this patient group. Similarly, the Dulce intervention was associated with improvements in quality-adjusted life expectancy in all four insurance cohorts. The largest improvement was observed in the uninsured cohort (0.9 QALYs), then in the CMS cohort (0.4 QALYs), the Medi-Cal cohort (0.3 QALYs), and the commercial cohort (0.2 QALYs).

Mean direct medical costs over patient lifetimes ranged from \$57,530 to \$82,225 per patient. The Dulce diabetes treatment program was associated with higher lifetime costs than control in all four health insurance cohorts.

Lifetime incremental (net) costs were comparable in all three insured cohorts, with the largest incremental cost projected for the commercial cohort (\$12,368 per patient), followed by the Medi-Cal cohort (\$11,792), the CMS cohort (\$10,921), and the uninsured cohort (\$8,991). A breakdown of costs showed that approximately one-third of the additional costs of implementing the Dulce intervention were offset by reduced costs of diabetes-related complications over patient lifetimes.

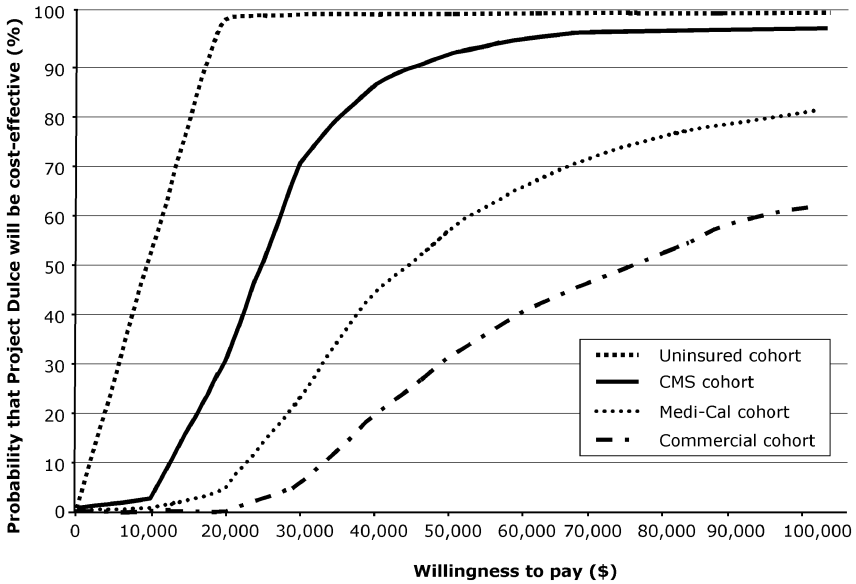
Calculation of incremental cost-effectiveness ratios (ICERs) for each of the health insurance cohorts showed that the Dulce intervention was in the range considered to represent a good value by currently accepted standards. The lowest ICER for Dulce versus control was projected for the uninsured cohort (\$10,141 per QALY gained), followed by the CMS cohort (\$24,584 per QALY gained), the Medi-Cal cohort (\$44,941 per QALY gained) and the commercial cohort (\$69,587 per QALY gained).

Plotting the incremental costs and incremental effectiveness (in terms of quality-adjusted life expectancy) for each of the 1,000 mean values generated by the model allowed us to evaluate the percentage of these values that fall below a specific willingness to pay values and to generated acceptability curves for each of the four cohorts (Figure 1). These cumulative probabilities in the acceptability curves represent the expected distribution of results for simulations of large groups of patients, with no uncertainty in the value of input parameters. With a willingness to pay of \$50,000 per QALY gained, the acceptability curves indicate that the Dulce intervention had a 100 percent likelihood of being cost-effective versus control in the uninsured cohort, a 92 percent probability in the CMS cohort, a 57 percent probability in the Medi-Cal cohort, and a 31 percent probability in the commercial cohort. With a willingness to pay of \$100,000 per QALY, these probabilities were 100, 98, 81, and 62 percent, respectively.

Sensitivity Analyses

Decreasing the time horizon to 20 years reduced the improvements in life expectancy and quality-adjusted life expectancy as well as incremental costs with Dulce versus control compared with base case (Table 5). These changes led to a lower ICER in the uninsured cohort, but an increased ICER values in the commercial cohort. Reducing the A1c treatment effect by 50 percent raised the ICERs for all groups to the point where treatment for commercial populations was not cost-effective. Introducing cohort specific case management costs slightly increased (reduced) the ICER for the uninsured (commercial) cohort. Varying

Figure 1: Base Case Acceptability Curves



the discount rate between 0 and 6 percent per annum on costs and clinical outcomes did not substantially change the outcomes from base case.

DISCUSSION

The prevalence of diabetes is rapidly rising in the United States, particularly in our ethnically diverse communities, many of who are under or uninsured (Diamant et al. 2005). Costs related to the care and complications of diabetes are rising as well, and thus the management of these high-risk populations should be addressed with cost-effective, quality programs that are implemented in a systematic manner (Hogan et al. 2003). The analysis presented in this article demonstrates that a culturally sensitive nurse case management and self-management training program, Project Dulce, can achieve improved clinical and cost effective results across a broad range of payers, and that it is especially cost-effective for under and uninsured groups. Of particular interest is the fact that the uninsured population demonstrated the greatest mean change in A1c, lipid levels, and BP values after the intervention. They also had the lowest mean age. An intervention provided early in their life has a high potential for providing long-term health gains, and may additionally positively

Table 5: Sensitivity Analyses

	<i>D Qale (QALYs)</i>	<i>D Costs (\$)</i>	<i>ICER/Outcome (\$/QALY gained)</i>
Medical insurance cohorts (Time horizon 20 years)			
Uninsured	0.562	3,017	5,367
CMS	0.297	7,980	26,839
Medi-Cal	0.188	9,601	51,104
Commercial	0.113	10,977	97,568
Medical insurance cohorts (HbA1c treatment effect reduced by 50%)			
Uninsured	0.528	11,177	21,157
CMS	0.270	12,026	44,502
Medi-Cal	0.163	12,675	77,805
Commercial	0.095	12,818	135,613
Medical insurance cohorts (cohort specific cost of treatment)			
Uninsured	0.887	10,771	12,148
CMS	0.444	10,921	24,584
Medi-Cal	0.262	11,792	44,941
Commercial	0.178	11,234	63,202
Medical insurance cohorts (discount rates 0% [clinical] and 0% [costs])			
Uninsured	1.524	16,734	10,981
CMS	0.746	16,480	22,081
Medi-Cal	0.590	16,914	38,036
Commercial	0.382	17,109	57,619
Medical insurance cohorts (discount rates 6% [clinical] and 6% [costs])			
Uninsured	0.550	5,800	8,768
CMS	0.281	8,071	28,714
Medi-Cal	0.165	8,958	54,395
Commercial	0.113	9,566	84,522

D, difference between Project Dulce and control value; CMS, County Medical Services; QALY, quality-adjusted life years; ICER, incremental cost-effectiveness ratio. ICER values are given as cost per QALY gained with Project Dulce versus control.

impact their employment productivity as well as translate into positive role modeling and life style modifications within their family unit.

A limitation of this study is that it relies largely on observational data—rather than, for example, an RCT—to estimate the clinical outcomes related to the case management intervention. Thus, it may be that the changes in clinical outcomes observed in this paper are applicable to people who would participate in such a program, rather than to the population more generally. In addition, the use of mean treatment effects in the simulation may underestimate uncertainty surrounding the projected outcomes. Also, it is possible that part of the observed improvements in clinical outcomes resulted from patient motivation independent of the program. That is, motivated people may be both more determined to take control of their disease and more likely to enrol

in a program. However, given the limited resources available to these populations, the program focus on pharmacotherapy and self-management, and the dramatic clinical improvements associated with participation, we believe that the clinical outcomes observed are a direct result of the program.

Another limitation of this analysis is that it only considers direct costs from a third party payer perspective. The study does not include nonmedical costs such as lost productivity or transport costs, and therefore is likely to underestimate costs from a societal perspective. Another limitation, applicable to most modeling studies, was the inherent uncertainty around projecting long-term outcomes based on clinical input data from a short-term study. In the absence of lifetime follow-up data from a well-designed clinical or epidemiological study, computer simulation modeling using the best (usually short-term) data available is currently one of the only methods available to estimate long-term clinical and cost outcomes. Every effort has been made to utilize the most accurate and up-to-date data sources in the present analysis to provide a realistic simulation of type 2 diabetes in the U.S. setting. A final limitation of the study was the inability to break down the cost-effectiveness of the individual components of the intervention to determine the impact of the RN/CDE visits or peer educator-led group classes. Further studies are being planned that will allow the determination of cost-effectiveness of individual components of the Project Dulce chronic care model.

In spite of these limitations, the results of this cost-effectiveness study should encourage health systems to consider establishing such methods of care for their high-risk populations. This study should also inform the debate regarding the effect of health insurance on health (Hadley and Waidmann 2006a, b; Kronick 2006). We found providing diabetes case management to uninsured persons to be very cost-effective at \$10,141 per QALY gained. Case management for uninsured persons with chronic conditions has the potential to dramatically improve clinical outcomes and result in long term gains in life expectancy and health. The cost-effectiveness of case management for uninsured persons should be considered when planning expansions of these services to insured populations.

ACKNOWLEDGMENT

This study was supported by an unrestricted grant from Novo Nordisk Inc., Princeton, NJ, USA.

Disclosures: None.

Disclaimers: None.

REFERENCES

- American Diabetes Association, 2003. "Standards of Medical Care for Patients with Diabetes Mellitus." *Diabetes Care* 26 (suppl 1): S33–50.
- Briggs, A. H., D. E. Wonderling, and C. Z. Mooney. 1997. "Pulling Cost-Effectiveness Analysis up by Its Bootstraps: A Non-Parametric Approach to Confidence Interval Estimation." *Health Economics* 6 (4): 327–40.
- California Medi-Cal Type 2 Diabetes Study Group. 2004. "Closing the Gap: Effect of Diabetes Case Management on Glycemic Control among Low-Income Ethnic Minority Populations: The California Medi-Cal Type 2 Diabetes Study." *Diabetes Care* 27 (1): 95–103.
- CDC Diabetes Cost-Effectiveness Group. 2002. "Cost-Effectiveness of Intensive Glycemic Control, Intensified Hypertension Control, and Serum Cholesterol Level Reduction for Type 2 Diabetes." *Journal of the American Medical Association* 287 (19): 2542–51.
- Diamant, A., S. Babey, E. R. Brown, and N. Chawla. 2003. *Diabetes in California: Findings from the 2001 California Health Interview Survey*. Los Angeles: UCLA Center for Health Policy Research.
- Diamant, A., S. Babey, E. Brown, and T. Hastert. 2005. *Diabetes on the Rise in California*. Los Angeles: UCLA Center for Health Policy Research.
- Eddy, D. M., L. Schlessinger, and R. Kahn. 2005. "Clinical Outcomes and Cost-Effectiveness of Strategies for Managing People at High Risk for Diabetes." *Annals of Internal Medicine* 143 (4): 251–64.
- Gilmer, T. P., A. Philis-Tsimikas, and C. Walker. 2005. "Outcomes of Project Dulce: A Culturally Specific Diabetes Management Program." *Annals of Pharmacotherapy* 39 (5): 817–22.
- Hadley, J., and T. Waidmann. 2006a. "Health Insurance and Health at Age 65: Implications for Medical Care Spending on New Medicare Beneficiaries." *Health Services Research* 41 (2): 429–51.
- . 2006b. "Commentary—Response to Richard Kronick." *Health Services Research* 41 (2): 461–6.
- Herman, W. H., T. J. Hoerger, M. Brandle, K. Hicks, S. Sorensen, P. Zhang, R. F. Hamman, R. T. Ackermann, M. M. Engelgau, and R. E. Ratner. 2005. "The Cost-Effectiveness of Lifestyle Modification or Metformin in Preventing Type 2 Diabetes in Adults with Impaired Glucose Tolerance." *Annals of Internal Medicine* 142 (5): 323–32.
- Hogan, P., T. Dall, and P. Nikolov. 2003. "Economic Costs of Diabetes in the US in 2002." *Diabetes Care* 26 (3): 917–32.
- Kronick, R. 2006. "Commentary—Sophisticated Methods but Implausible Results: How Much Does Health Insurance Improve Health?" *Health Services Research* 41 (2): 452–60; discussion 61–6.
- Mazze, R. S., D. D. Etwiler, E. Strock, K. Peterson, C. R. II McClave, J. F. Meszaros, C. Leigh, L. W. Owens, L. C. Deeb, A. Peterson, et al. 1994. "Staged Diabetes Management. Toward an Integrated Model of Diabetes Care." *Diabetes Care* 17 (suppl 1): 56–66.

- Minshall, M. E., S. Roze, A. J. Palmer, W. J. Valentine, V. Foos, J. Ray, and C. Graham. 2005. "Treating Diabetes to Accepted Standards of Care: A 10-Year Projection of the Estimated Economic and Health Impact in Patients with Type 1 and Type 2 Diabetes Mellitus in the United States." *Clinical Therapy* 27 (6): 940–50.
- Narayan, K. M., J. P. Boyle, T. J. Thompson, S. W. Sorensen, and D. F. Williamson. 2003. "Lifetime Risk for Diabetes Mellitus in the United States." *Journal of the American Medical Association* 290 (14): 1884–90.
- Palmer, A. J., S. Roze, M. Lammert, W. J. Valentine, M. E. Minshall, L. Nicklasson, M. A. Gall, and G. A. Spinas. 2004. "Comparing the Long-Term Cost-Effectiveness of Repaglinide Plus Metformin versus Nateglinide Plus Metformin in Type 2 Diabetes Patients with Inadequate Glycaemic Control: An Application of the CORE Diabetes Model in Type 2 Diabetes." *Current Medical Research and Opinion* 20 (suppl 1): S41–51.
- Palmer, A. J., S. Roze, W. J. Valentine, M. E. Minshall, V. Foos, F. M. Lurati, M. Lammert, and G. A. Spinas. 2004a. "The CORE Diabetes Model: Projecting Long-Term Clinical Outcomes, Costs and Cost-Effectiveness of Interventions in Diabetes Mellitus (Types 1 and 2) to Support Clinical and Reimbursement Decision-Making." *Current Medical Research and Opinion* 20 (suppl 1): S5–S26.
- . 2004b. "Validation of the CORE Diabetes Model against Epidemiological and Clinical Studies." *Current Medical Research and Opinion* 20 (suppl 1): S27–40.
- Palmer, A. J., S. Roze, W. J. Valentine, I. Smith, and K. U. Wittrup-Jensen. 2004. "Cost-Effectiveness of Detemir-Based Basal/Bolus Therapy versus NPH-Based Basal/Bolus Therapy for Type 1 Diabetes in a UK Setting: An Economic Analysis Based on Meta-Analysis Results of Four Clinical Trials." *Current Medical Research and Opinion* 20 (11): 1729–46.
- Palmer, A. J., S. Roze, W. J. Valentine, G. A. Spinas, J. E. Shaw, and P. Z. Zimmet. 2004. "Intensive Lifestyle Changes or Metformin in Patients with Impaired Glucose Tolerance: Modeling the Long-Term Health Economic Implications of the Diabetes Prevention Program in Australia, France, Germany, Switzerland, and the United Kingdom." *Clinical Therapy* 26 (2): 304–21.
- Philis-Tsimikas, A., C. Walker, L. Rivard, G. Talavera, J. O. Reimann, M. Salmon, and R. Araujo. 2004. "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." *Diabetes Care* 27 (1): 110–5.
- Roze, S., W. J. Valentine, K. E. Zakrzewska, and A. J. Palmer. 2005. "Health-Economic Comparison of Continuous Subcutaneous Insulin Infusion with Multiple Daily Injection for the Treatment of Type 1 Diabetes in the UK." *Diabetes Medicine* 22 (9): 1239–45.
- Valentine, W. J., A. J. Palmer, M. Lammert, L. Nicklasson, V. Foos, and S. Roze. 2005. "Long-Term Clinical and Cost Outcomes of Treatment with Biphasic Insulin Aspart 30/70 versus Insulin Glargine in Insulin Naive Type 2 Diabetes Patients: Cost-Effectiveness Analysis in the UK Setting." *Current Medical Research and Opinion* 21 (12): 2063–71.

SUPPLEMENTARY MATERIAL

The following supplementary material for this article is available:

Technical Appendix for “Cost-Effectiveness of Diabetes Case Management for Low-Income Populations”

Table A1: Demographic and Clinical Characteristics of the CMS Study Groups

Table A2: Pre- and Postclinical Values for the Usual Care and Dulce CMS Current Study Groups, and DID Estimates

Table A3: Adjusted cost components and total costs between Dulce-CMS and usual care groups

This material is available as part of the online article from <http://www.blackwell-synergy.com/doi/abs/10.1111/j.1475-6773.2007.00701.x> (this link will take you to the article abstract).

Please note: Blackwell Publishing is not responsible for the content or functionality of any supplementary materials supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author for the article.