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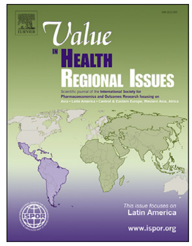

Economic Evaluation

Cost-Effectiveness of a Technology-Enhanced Diabetes Care Management Program in Mexico

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ABSTRACT

Background: The prevalence of diabetes has increased substantially in Mexico over the last 40 years, leading to significant impacts on population health and the healthcare system. Technology-based solutions may improve diabetes outcomes in areas where lack of efficient transportation creates barriers to care. **Objectives:** To estimate the lifetime cost-effectiveness of a technology-based diabetes care management program from the perspective of the Mexican healthcare system. **Methods:** Clinical outcomes and cost data from a 3-arm randomized clinical trial of Dulce Wireless Tijuana, a diabetes care management program incorporating short-term mobile technology, were used as inputs in a validated simulation model for type 2 diabetes. Study arms included a control group (CG), Project Dulce diabetes care management (PD), and Project Dulce with technology enhancement (PD-TE). **Results:** Intervention costs were $1448 for PD and $1740 for PD-TE compared with $740 for CG. Both intervention arms increased quality-adjusted life-years and costs. The incremental cost-effectiveness ratio for PD was $1635 and for PD-TE was $2220, both compared with CG. The incremental cost-effectiveness ratio for PD-TE versus PD was $4299. The results were sensitive to the time horizon. The PE and PD-TE interventions were cost-effective under time horizons of 15 to 20 years, but were not cost-effective under time horizons of 5 to 10 years. **Conclusions:** Both the PD and PD-TE were highly cost-effective from a Mexican health system perspective. Considering the economic impact of the diabetes epidemic and the widespread use of cellular technology in Mexico, implementation of PD-TE is warranted.
Keywords: cost-effectiveness, diabetes, technology

Introduction

The global diabetes epidemic has seen a quadrupling of cases in the last 30 years, with some of the largest increases occurring in low- and middle-income countries in Asia and Latin America.[1] Mexico leads the Latin American countries with the highest rates of adults being either obese (28.1%) or overweight (36.3%). More than 80% of adults older than 50 years in Mexico have prediabetes (44.2%) or diabetes (39.4%). By 2050, the lifetime risk of developing diabetes in Mexico is estimated to rise from 33% to 50%.[2–4] The economic burden due to diabetes represents more than 2% of the annual gross domestic product (GDP) of Mexico and costs are expected to double over the next decade.[3]

Patients with diabetes in Mexico are less likely to achieve evidence-based goals for glycemic control compared with patients with diabetes in the United States, with less than 30% having glycated hemoglobin A_{1c} (HbA_{1c}) value of less than 7%.[5–9] Previous studies have shown that culturally sensitive, community-based education programs can improve diabetic control and can be cost-effective in low- and middle-income countries.[10] The use of mobile health technologies has been shown to improve the management of chronic noncommunicable diseases such as diabetes in low- and middle-income countries[11,12] where the use of cellular technology is widespread and accessible.[13]

Project Dulce is an evidence-based and culturally sensitive diabetes care management program that was designed for low-income, Spanish-speaking Latinos in the US border region. Project Dulce is based in the Chronic Care Model[14,15] and aims to improve clinical outcomes and self-management skills through the use of nurse-led teams of peer community educators and a

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nutritionist. The Dulce Wireless Tijuana (DWT) study examined the clinical effectiveness of the Project Dulce intervention with enhanced mobile health technologies to address barriers in access to care in Tijuana, Mexico, and found that it was effective in improving HbA_{1c} in both standard and technology-enhanced arms.[16] This study examines the cost effectiveness of the DWT from the perspective of the Mexican healthcare system.

Methods

Dulce Wireless Tijuana

The DWT study is described in detail elsewhere.[16] Briefly, the DWT was a 3-arm randomized controlled trial (RCT) designed to test whether diabetes care management coupled with short-term technology intervention would improve clinical outcomes among patients with type 2 diabetes. Study participants were adults with type 2 diabetes who were recruited from the Family Medicine Unit 27 of the *Instituto Mexicano del Seguro Social* (IMSS) in Tijuana, Mexico. Study arms included Project Dulce diabetes care management (PD), Project Dulce with technology enhancement (PD-TE), and a control group (CG).

The PD group received multidisciplinary team-based care management and self-management training. Care management was delivered by clinicians and nurses who were trained to use the protocols in the Staged Diabetes Management model for stepped-care pharmacological management of glucose, lipid levels, and hypertension.[17] The goals of the project are to meet the American Diabetes Association (ADA) standards of care and to achieve improvements in HbA_{1c}, blood pressure (BP), and lipid parameters (HbA_{1c} <7%, BP <130/80 mm Hg, and low-density lipoprotein <100 mg/dL).[18]

In addition, the Project Dulce clinical team encourages patients to participate in a group self-management training program. The program consists of an 8-week curriculum delivered by trained peer educators (or promotoras). The peer educators have been diagnosed with type 2 diabetes themselves and complete a 4-month, competency-based training and mentoring program. Classes 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.

The PD-TE group received the PD intervention enhanced with a Bluetooth-enabled glucose meter, a 3G-enabled cell phone, and 80 glucose strips. Participants received a 2-hour orientation on how to use the technology and were asked to check their glucose level twice per day during the first month and twice per week during the second month. Results from the glucometer were automatically uploaded to the project's diabetes registry system. The project's clinical staff had access to this system to track patients' glucose readings during the visits and classes. Participants received interactive surveys and educational materials (eg, messages and videos) through the cell phones daily during the first month and twice a week during the second month. Project staff was alerted when the system reported out-of-range glucose readings or if the patients missed an appointment. The educational videos were available for participants in the PD-TE arm during the 10 months of the study.

The CG arm received the standard of care provided by IMSS guidelines as described in the DiabetIMSS technical guidelines.[19,20] Participants in this group were seen by a nutritionist once during the study period, and were seen by a family medicine physician and a nurse once per month to evaluate clinical data (body mass index, weight circumference, and BP) and biochemical parameters (glucose, total cholesterol, triglycerides, and HbA_{1c}). Patients were encouraged to participate in a monthly 3-hour group educational meeting led by a nurse to discuss basic information on diabetes treatment, self-care, hypoglycemia, physical activity, and nutrition.[21]

Patient Cohort

A patient cohort was derived from the RCT. This cohort included 301 patients with type 2 diabetes who were randomized to the PD (99), PD-TE (102), or CG (99) study arms. The RCT clinical data were used to assign demographic characteristics and clinical risk factors at baseline. The entire cohort was simulated for each of the 3 scenarios on the basis of clinical effectiveness described herein.

Clinical Effectiveness of DWT

The clinical effectiveness of the DWT intervention arms was determined using data from the RCT using multilevel modeling and an intent-to-treat approach and a 10-month follow-up. HbA_{1c} declined by 2.63 in the PD and 3.02 in the PD-TE arms compared with 1.03 in the CG arm (P<.001 each), with 33% in PD and 41% in PD-TE achieving the ADA's recommended HbA_{1c} level of 7% or lower compared with 16% in CG (P<.050 each). There were no statistically significant differences in other clinical risk factors including BP, cholesterol, triglycerides, or body mass index.

Intervention Costs

Intervention costs were estimated using an ingredient or stepdown approach.[22] Data to estimate costs for the PD and PD-TE interventions were obtained from administrative records from the DWT RCT and from the study site (IMSS Family Medicine Clinic). Costs associated with the standard-of-care diabetes program at IMSS (DiabetIMSS) were obtained from published reports and public Mexican government records. Costs of complications were estimated using a stepdown approach on the basis of average fair market costs and published reports. Data to estimate costs for diabetic complications were obtained from IMSS publicly accessible databases and published reports.[23–27]

Long-Term Cost-Effectiveness Analysis

We estimated the cost effectiveness of DWT using a simulation model designed to evaluate the long-term health outcomes and costs associated with interventions among patients with type 2 diabetes.[28] The United Kingdom Prospective Diabetes Study Outcomes Model (UKPDS-OM, version 2.0) uses an integrated system of parametric equations to estimate the absolute risk of the first occurrence of each of 7 diabetes-related complications (fatal or nonfatal myocardial infarction, other ischemic heart disease, stroke, heart failure, amputation, renal failure, and eye disease) and death on the basis of patient characteristics (eg, age and sex) and time-varying risk factors (HbA_{1c}, systolic BP, cholesterol, and smoking status). Data from the UKPDS trial were used to develop the predictive equations for diabetes-related complications, mortality, as well as progressive time paths for the risk factors, and to assign utilities conditional on disease state. In this study, the changes in clinical outcomes and costs that were observed in the RCT were used as inputs in the UKPDS-OM, which was then used to evaluate changes in life expectancy, quality-adjusted life-years (QALYs), and future costs related to the DWT interventions. The incremental cost-effectiveness ratio (ICER) was calculated and the differential in estimated costs divided by the differential in estimated QALYs between study arms.

Following recommendations from the World Health Organization (WHO),[29] we considered an intervention arm to be *highly cost-effective* if the incremental cost per QALY gained fell below the GDP per capita in Mexico ($9 064), and to be *cost-effective* if it was

Table 1 – Patient characteristics (N = 301).

Characteristic	Patient cohort
Age (y), mean ± SD	51.5 ± 10.7
Sex, female	67%
Clinical indicators, mean ± SD	
HbA_{1c}	11.2 ± 2.2
Systolic BP	122.2 ± 14.4
LDL	113.9 ± 34.4
HDL	41.5 ± 9.9

BP indicates blood pressure; HbA_{1c}, glycated hemoglobin A_{1c}; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SD, standard deviation.

higher than but less than 3 times the GDP in Mexico (between $9 065 and $27 192). We considered an intervention *not cost-effective* if the cost per QALY gained was higher than the threshold of 3 times the GDP in Mexico.[30,31]

Base-Case and Sensitivity Analyses

The cost-effectiveness analysis assumed a health system perspective, a lifetime time horizon, and a 3% discount rate for both QALYs and costs. This analysis used as inputs the effect on HbA_{1c} that was observed in the RCT. The base case assumed that the intervention effect would persist over time. Sensitivity analyses were performed to investigate the influence of time horizon and intervention costs.

A probabilistic sensitivity analysis was used to estimate second-order uncertainty. The UKPDS-OM provides a full set of equation parameters that were derived from bootstrap samples of the original UKPDS trial population. We created 1000 bootstrapped estimates drawing from the available set of model parameters. We used these estimates to calculate estimates of incremental costs and effects, which we plotted in a cost-effectiveness plane.

Table 2 – Per-capita costs for the Dulce Wireless in Tijuana intervention used as inputs to the UKPDS outcomes model.

Cost	CG	PD	PD-TE
Personnel training costs	$4	$11	$19
Outpatient clinical care	$0	$0	$0
Personnel time	$602	$1284	$1292
Laboratory/medication costs	$134	$153	$163
Technology enhancement			
Bluetooth-enabled glucose meter	NA	NA	$65
Glucose strips	NA	NA	$76
Bluetooth-enabled smartphone	NA	NA	$90
Internet voice/data services	NA	NA	$43
	$740	$1448	$1747

Note. Costs for the PD and PD-TE arms were estimated using administrative records from the Dulce Wireless in Tijuana RCT and from the study site (IMSS Family Medicine Clinic). Costs associated with the standard-of-care diabetes program (CG) at IMSS (DiabetIMSS) were obtained from published reports and public Mexican government records.[23–27]

CG indicates control group; IMSS, Instituto Mexicano del Seguro Social; NA, not applicable; PD, Project Dulce; PD-TE, Project Dulce with technology enhancement; RCT, randomized controlled trial; UKPDS, UK Prospective Diabetes Study.

Table 3 – Costs of complications used as inputs to the UKPDS outcomes model.

Complication	Fatal*	Nonfatal, initial*	Nonfatal, state†
Ischemic heart disease	3 955	8 817	1 710
Myocardial infarction	6 494	10 630	1 682
Heart failure	3 444	3 444	2 244
Stroke	4 359	6 429	1 737
Amputation	10 403	10 403	3 166
Blindness		2 580	967
Renal failure	16 695	16 695	16 695
Annual costs without complications			670

Note. Costs of diabetic complications were estimated using a step-down approach using IMSS publicly accessible databases and published reports.[24,27] Costs are presented in annual amounts in 2017 US dollars.

IMSS indicates Instituto Mexicano del Seguro Social; UKPDS, UK Prospective Diabetes Study.

* Costs in year of event.

† Costs per subsequent year.

Results

The study sample characteristics are presented in Table 1. The mean age was 51.5 ± 10.7 years, and 67% were female. Mean baseline HbA_{1c} was 11.2%, systolic BP was 122.2 mm Hg,

Table 4 – Cost-Effectiveness of Dulce Wireless Tijuana.

Study arm	Life expectancy	QALYs	Total cost	ICER ($/QALY)
		Base case		
CG	17.98	14.28	$44 943	$1 635 vs CG
PD	18.16	14.45	$45 230	$2 220 vs CG
PD-TE	18.21	14.50	$45 442	$4 299 vs PD
		Sensitivity analyses		
Time horizon of 20 y				
CG	13.64	10.88	$32 622	$5 679 vs CG
PD	13.70	10.94	$32 978	$7 443 vs CG
PD-TE	13.71	10.96	$33 185	$15 910 vs PD
Time horizon of 15 y				
CG	11.39	9.11	$26 595	$12 927 vs CG
PD	11.42	9.15	$27 302	$16 646 vs CG
PD-TE	11.43	9.15	$27 265	$36 237 vs PD
Time horizon of 10 y				
CG	8.42	6.75	$19 191	$34 566 vs CG
PD	8.43	6.76	$19 736	$36 278 vs CG
PD-TE	8.44	6.77	$20 008	$40 271 vs PD
Time horizon of 5 y				
CG	4.64	3.73	$10 526	$339 828 vs CG
PD	4.64	3.73	$11 163	$319 639 vs CG
PD-TE	4.64	3.73	$11 447	$282 034 vs PD

Note. Data from the UKPDS study were used to develop the predictive equations for diabetes-related complications and mortality, and to assign utilities conditional on disease state.

CG indicates control group; ICER, incremental cost-effectiveness ratio; PD, Project Dulce; PD-TE, Project Dulce with technology enhancement; QALY, quality-adjusted life-year; UKPDS, UK Prospective Diabetes Study.

Fig. 1 – Cost-effectiveness plane. *Note.* Bootstrapped estimates of incremental costs and QALYs are presented for PD vs CG (crosses), PD-TE vs CG (triangles), and PD-TE vs PD (diamonds). The angled solid line indicates the ICER threshold of $27 192 per QALY for being cost-effective, and the dashed line indicates the threshold of $9 065 for being very cost-effective. CG indicates control group; ICER, incremental cost-effectiveness ratio; PD, Project Dulce; PD-TE, Project Dulce with technology enhancement; QALY, quality-adjusted life-year.

low-density lipoprotein was 113.9 mg/dL, and high-density lipoprotein was 41.5 mg/dL.

Intervention costs are presented in Table 2. Annual costs were $740 for the CG, $1448 for the PD, and $1748 for the PD-TE arms, respectively. Outpatient clinical care costs were significantly higher for the PD and PD-TE groups compared with the CG. The PD-TE group has additional costs over the PD group related to technology enhancement. Costs of diabetes-related complications are presented in Table 3. Costs were greater for fatal than for nonfatal events, and event costs were greater than state costs.

Table 4 presents the results of the cost-effectiveness analysis. The CG had an estimated life expectancy of 17.98 years, 14.28 QALYs, and $44 943 in lifetime costs. The PD group was estimated to have 18.16 life-years, 14.45 QALYs, and $45 230 in costs. The PD-TE group was estimated to have 18.21 life-years, 14.50 QALYs, and $45 442 in costs. The estimated ICER for PD was $1635 and for PD-TE was $2220, both compared with CG. The ICER for PD-TE versus PD was $4299. Thus, all intervention options were highly cost-effective.

The cost effectiveness of the DWT program was sensitive to changes in the time horizon. Under a 20-year time horizon, the PD and PD-TE interventions remained very cost-effective, whereas the ICER for PD-TE versus PD was $15 910, indicating that it was cost-effective. Using a 15-year time horizon, the PD and PD-TE interventions were cost-effective, whereas the ICER for PD-TE versus PD was $36 237, indicating that it was no longer cost-effective. The PD and PD-TE interventions were not cost-effective under 10- and 5-year time horizons. We also examined the sensitivity of the findings to intervention costs and found that the findings remained consistent with 20% variation in intervention costs (data not shown).

Figure 1 presents results from our analysis of second-order uncertainty for the base case. Bootstrapped estimates of incremental costs and QALYs are presented for PD versus CG (crosses), PD-TE versus CG (triangles), and PD-TE versus PD (diamonds). The angled solid line indicates the ICER threshold of $27 192 per QALY for being cost-effective, and the dashed line indicates the threshold of $9 065 for being very cost-effective. All points on the cost-effectiveness plane for PD and PD-TE lie to the right of the $9 065 threshold, indicating that these interventions remain highly cost-effective under uncertainty related to estimates of the model parameters. Although the estimated incremental effects of PD-TE versus PD are closer to the thresholds overall, only 0.2% of estimates exceed the $9 065 threshold and 0.1% exceed the $27 192 threshold.

Discussion

The diabetes epidemic has grown rapidly in the last 10 years in Latin America, particularly in the northern Mexican border states such as Tijuana, Mexico. Increasing costs of diabetes care combined with the rising costs of healthcare overall are affecting the financial stability of public health systems in Mexico. A large proportion of the costs related to diabetes care in Mexico are associated with the management of diabetes complications and are thus a consequence of poor diabetes control.[32,33]

The PD intervention studied here is a culturally sensitive diabetes case management program that incorporates a peer-driven self-care empowerment training program with a multidisciplinary team approach through the coordinated efforts of family physicians, nurses, and peer educators that has shown to improve clinical outcomes among patients with diabetes in Mexico.[16] Findings from our cost-effectiveness analysis show that both the PD and PD-TE interventions are highly cost-effective over a lifetime time horizon from a health system perspective.

The results were sensitive to changes in the time horizon. Under the 20- and 15-year time horizons, the PD and PD-TE interventions were highly cost-effective and cost-effective, respectively. The PD-TE intervention was also cost-effective relative to PD only over a lifetime and 20-year time horizons. Nevertheless, in the short term of 5 to 10 years, the ICER for the PD intervention compared with the CG arm is higher than the accepted willingness-to-pay threshold of 3 times the GDP per capita in Mexico. Our results are consistent with previous reports that show that appropriate time horizons to evaluate the cost effectiveness for interventions designed for chronic diseases such as diabetes are much longer than for nonchronic diseases. As diabetes progresses gradually over time, the impact of an intervention has to be modeled accounting for the timing of costs and benefits from major complications.[34,35]

The long-term cost-effectiveness results showing that the PD-TE strategy is highly cost-effective compared with the PD strategy can be explained by several factors. First, providing access to glucometers and test strips for self-monitored glycemic control among participants in the PD-TE group can explain further reduction in HbA_{1c} compared with participants in the PD group as reported by previous studies.[36–38] Second, the use of mobile health strategies such as educational text messages and videos via cell phones in the PD-TE group can explain positive changes in lifestyle and has been shown to improve overall diabetes care indicators in the literature.[39] Finally, creating a feedback loop between the patients in the PD-TE group and the clinical team by bringing data actively generated by the patient into his or her own medical record via wireless technology, and actively involving patients in their own care, is likely to have enhanced self-efficacy and a patient-centered diabetes care approach, and thus improvement in long-term diabetes outcomes.[40]

This cost-effectiveness analysis has several limitations. The base case assumed that the intervention effects would persist over time. Our sensitivity analyses, however, showed that both interventions remain cost-effective except under very short time horizons. We used a simulation model (UKPDS-OM, version 2.0) that was not specifically designed to predict outcomes among adults in Mexico. Nevertheless, in contrast to other leading risk models such as the American College of Cardiology/American Heart Association model or the Framingham Risk Score, the UKPDS-OM incorporates weight and glucose levels as clinical risk factors and allows for a greater age range of patients by including those aged 18 to 39 years.[41,42] Furthermore, the UKPDS-OM diabetes risk equations have been retrospectively validated in cohort studies across 20 diverse countries.[43]

The perspective adopted for this cost-effectiveness analysis was that of the healthcare sector, and cost and benefits were limited to health services covered by the program. Thus, the analysis does not consider patients' time costs of participation or any benefits from mitigation of the productivity loss that had been shown to be associated with the development of diabetes. The analysis is also limited to acute care services. Thus, the model results may be conservative in not considering potential increases in long-term care that might result from more severe morbidity from diabetes-related complications.

Conclusions

Our findings support the adoption of the PD-TE, because it was found to be highly cost-effective compared with both the PD and CG. Proyecto Dulce™ improved the consistent use of evidence-based diabetes care management among clinicians (eg, increased use of insulin on the basis of current diabetes care guidelines) through the use of the Staged Diabetes Management model and training the clinical team on the use of updated clinical guidelines from the ADA,[44] and patients' self-efficacy skills and diabetes knowledge through the use of a nurse and family medicine physician team–led clinical care and peer diabetes education and support groups. A finding from the DWT RCT showed no significant impact between the number of peer-led educational/support meetings attended by participants and improvements in HbA_{1c}. The attendance to the peer-led meetings was reported with an uptake ranging between 43% and 56% in all groups. In contrast, the completion of interactive surveys and educational materials delivered via mobile technology to participants in the PD-TE group was very high, with a 75% reported uptake.[16] On the basis of these findings, additional trials should explore the impact of continued use of self-monitored glucose levels and the use of diabetes self-care training through the use of a combination of mobile technology and more flexible, less frequent peer-led self-efficacy and support group in-person meetings.

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