Dulce New Jersey: Diabetes Disease Management Program

Final Report

December 2009

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BACKGROUND

Diabetes mellitus is one of the most prevalent chronic diseases. In New Jersey, more than nine percent of the adult population (age 18 years or older) has been diagnosed with diabetes, according to Behavioral Risk Factor Surveillance System data for 2007. Overall diabetes prevalence has been on the rise since the mid-90s, consistent with the aging population, increased obesity and growing minority populations (NJDHSS, 2008). In the last ten years, adult diabetes prevalence in New Jersey has gone up 77 percent (CDC, 2009). Diabetes is the fifth and sixth leading cause of death by disease in New Jersey and the U.S., respectively (NJDHSS, 2006; CDC, 2008) – the risk of death among people with diabetes is about two times that of those without the disease (CDC, 2008).

In addition, diabetes increases morbidity associated with chronic conditions, resulting in very costly care, especially if the condition is not managed effectively and leads to complications, including heart disease, stroke, high blood pressure, blindness, kidney disease, nerve disease and amputations. In fact, average direct medical expenditures for the nearly 18 million people diagnosed with diabetes in the U.S. are more than double the expenditures of otherwise similar people without diabetes, not including the indirect costs such as disability, lost productivity and premature mortality (CDC, 2008).

Minorities are at higher risk for development of diabetes and its complications. Diabetes disproportionately affects ethnic and racial minorities, with an age-adjusted 2007 diabetes prevalence rate in New Jersey of 16.8 percent among African-Americans and 11.0 percent among Hispanics compared to 7.6 percent among whites (CDC, 2009). These populations are also documented to have persistent health and social issues, inadequate diabetes management and poor clinical outcomes. Minority patients with diabetes are more likely to be low-income and uninsured/underinsured with barriers to accessing healthcare services (e.g., education, language and transportation), which hinder successful control and management of the disease (Phillis-Tsimikas and Walker, 2001).

Despite the potentially serious complications and high costs associated with the disease, diabetes can often be effectively managed and its complications kept under control. Specifically, controlling glucose levels, blood pressure, cholesterol and lipid levels and receiving preventive care for eyes, kidneys and feet can reduce the incidence of diabetes-related complications, sometimes by as much as 85 percent (CDC, 2008).

EFFECTIVE CHRONIC DISEASE CARE MODELS

Studies on chronic disease care models have demonstrated that successful management and improved outcomes of care not only rely heavily on a close partnership between healthcare and community organizations and use of appropriate policies and resources on both ends, but also put emphasis on the important role of patients to self manage their condition and on productive interactions between informed, activated patients and prepared, proactive provider teams. Specifically, diabetes management programs that empower patients and support their self-

management skills, including those employing nurse case management, have been effective at improving glycemic control and monitoring of lipids and at increasing rates of screening for other diabetes-related complications. The Task Force on Community Preventive Services recommends disease management for patients with diabetes mellitus (CDC, 2003), and diabetes self-management education (DSME) – the process of teaching people to manage their diabetes – is considered an important part of the clinical management of diabetes. The American Diabetes Association (ADA) recommends assessing self-management skills and knowledge of diabetes at least annually and providing or encouraging continuing education (ADA, 2001).

Patient education and self-management of diabetes and its complications are key to improving disease outcomes and containing the cost of care for this chronic condition (Gilmer, 2005). Given the growing immigrant population and their unique cultural experiences and communication barriers, there is a tremendous need for culturally appropriate diabetes care and education that targets these populations. In response, a culturally specific diabetes management program, titled Project Dulce, has been developed and implemented in California and found to be effective at improving clinical outcomes among ethnic groups disproportionately affected by diabetes.

The Dulce model works to improve diabetes care and outcomes through two major strategies – nurse-managed clinical care and community-based diabetes education and health promotion. Participating patients receive regular nurse-managed clinical care on a quarterly basis, along with routine specialist visits (exam/care for eye, foot, etc.) and lab work. This care follows American Diabetes Association (ADA) and American Association of Clinical Endocrinologists (AACE) guidelines and is provided with the support of a culturally competent team that includes a physician, nurse, dietician, certified diabetes educator and bilingual/bicultural medical assistants. Patients have an initial (50 minute) visit with a nurse and are asked to return for additional (25 minute) visits with the nurse and/or dietitian. The participants' lab work and other health indicators are tracked in an electronic registry, and case management is provided to ensure appointments are kept, support self-management efforts and help resolve any barriers. The goals of the project are to meet the ADA/AACE standards of care and to achieve improvements in A1c, blood pressure (BP), and lipid parameters: HbA_{1c} <7 percent, BP <130/80mmHg, and low-density lipoprotein cholesterol <100 mg/dl (ADA, 2003).

The unique feature of this model is the educational component, which uses trained peers (or *promotoras*) for community-based, culturally appropriate group diabetes education/self-management training. These peer educators are patients or med techs recruited from the diabetes population who have learned to effectively manage their own diabetes, represent a prominent minority group in the area and communicate in the language of the population served. After a four-month, competency-based training and mentoring program, the peer educators lead comprehensive eight-week diabetes education sessions at community sites. The education component follows a tested curriculum, uses handouts with universal pictorial depictions, promotes healthy lifestyles, addresses misrepresented cultural beliefs and encourages patients to take charge of managing their disease. Topics include diabetes and its complications, the role of diet, exercise and medication, and the importance of self-monitoring. The classes are given in the participants' native language, include interactive sessions in which the patients discuss their

personal experiences and beliefs about diabetes and form an informal support network for participants.

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 HbA_{1c} (California, 2004). They 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 culturally-based remedies (Phillis-Tsimikas et al., 2004).

To demonstrate the effectiveness of this model in the New Jersey environment and two of its most prevalent minority populations, the Health Research and Educational Trust of New Jersey pilot tested a modified version of the Dulce model in three hospital-based clinics.

RESEARCH DESIGN AND METHODS

This study examines the effectiveness of adopting the Dulce model in New Jersey, particularly in urban inner-city areas served by three large hospitals. From January 2008 to June 2009, the Dulce New Jersey project was piloted in these hospitals. The pilot sites were selected from hospitals that expressed interest, agreed to commit resources, had primary care clinics and ADA-recognized diabetes education programs and were serving counties with high number of minorities and poor/low-income populations. The selected hospitals were Saint Michael's Medical Center in Essex County, Newark Beth Israel Medical Center in Essex County and St. Joseph's Regional Medical Center in Passaic County. The pilots each committed half time of a registered nurse/certified diabetes educator (RN/CDE), and grant funds were provided to cover hiring peer educators and data collection staff.

The target populations were Hispanic and African American adult patients (age 19 – 75) with type 2 diabetes. The goal was to recruit and enroll approximately 300 patients (approximately 100 per site), with about two-thirds going through the clinical component and about half completing the peer education component. Participants were recruited through direct referral from their providers in the hospitals' primary care clinics and partnering community sites or through direct contact following a review of recently recorded laboratory values among clinic patients. Patients that met the inclusion/exclusion criteria were enrolled in the program. The inclusion criteria included age and baseline HbA_{1c} value greater than nine percent. Exclusion criteria included diabetes in pregnancy, severe medical conditions that might preclude frequent visits to the clinic, poor short-term prognosis (expected death in <2 years) or active alcohol or drug abuse. All participants gave written informed consent to participate in the protocol, which was approved by official review at the pilot hospitals.

The research design developed to evaluate the effectiveness of the program model did not include assignment of patients to experiment and control groups through a randomized trial. Instead, patients with similar demographic characteristics and baseline HbA_{1c} values who were referred to the program but were not interested in participating in the community-based education classes, or could not be accommodated, were included in the "control group." Chart reviews were conducted on these clinic patients over the same 18-month period to monitor their

office visit and lab results for the purpose of comparing their care outcomes with those of project patients.

Evaluation Plan and Measures. A three-pronged evaluation system was designed to measure and assess the effectiveness of the Dulce New Jersey program processes, patient outcomes and the overall impact of the program Following the project's data collection guidelines, pilot staff collected, recorded and submitted to HRET quarterly data on participants' biological markers, including levels of HbA1c, lipid parameters, systolic and diastolic blood pressure and other outcomes measures using the Chronic Disease Electronic Management System (CDEMS). Similar data was also collected on diabetes patients who serve as the control group. The means of measures on biological markers were tracked over time and compared to the control group to assess the impact of the project's interventions.

In addition, participating patients' knowledge and diabetes self-care behavior were measured before and after completing the eight-week education classes, using two instruments, which were developed and validated by California's Project Dulce and available in English and Spanish. A diabetes-related knowledge instrument was designed to measure patients' knowledge on diabetes and diabetes care and included 13 open-ended and multiple choice questions. The instrument was administered during the first clinical visit or the first class, as well as at the end of the course. The scores for each patient, pre and post, were calculated as the total number of correct responses to the questions and ranged from zero to 31 points.

A self-care behavior instrument included questions on four dimensions – nutrition, exercise, glucose monitoring and diabetes medication – to measure frequency of patients' diabetes self-care routines/behavior during the previous week, using four- to seven-point scales. The instrument was administered during the first clinical visit or the first class, as well as at the end of the course. The scores for each patient, pre and post, were calculated as a mean of responses (scale points) to all questions within each dimension.

In addition, HRET obtained data on diabetes-related hospitalizations and emergency department visits at pilot hospitals (using appropriate ICD-9 codes for 15 conditions), before and after project interventions (2005 to 2008), to assess any changes/trends that would indicate whether the project has had an impact on controlling diabetes and related complications and containing healthcare expenditures.

The outcomes of care, success of disease management of project participants and overall impact of the project's interventions was assessed by tracking patients' clinical indicators over time and comparing them to those of the control group, using parametric and non-parametric statistics, independent or paired sample Student t tests and analysis of variance. In addition, mean scores of diabetes knowledge and self-care behaviors of participating patients were compared, pre and post, to determine the impact of the education component. The ED visit and hospitalization rates for diabetes-related conditions at project sites, along with associated costs, were compared over times to determine the project's impact on cost of diabetes care.

RESULTS

Of the 301 patients referred to the project, 279 participated in the clinical component and received a one-hour baseline initial clinic visit. Approximately 165 project patients participated in the education component and attended classes. The most common reason for not following up with the Dulce New Jersey project or completing classes was the transient nature of the population served.

Table 1. Demographic Profile of Patients

	Participating Patients				Control Group
	Saint Michael's	Newark Beth	St. Joseph's	Total	
Agreed to Participate	94	113	94	301	-
Patients Enrolled	79	70	130	279	173
Average Patient Age	56	53	55	54	53
Gender					
Male	43%	47%	37%	41%	48%
Female	57%	53%	63%	59%	52%
Race & Ethnicity					
African-American	15%	77%	14%	30%	21%
Hispanic	78%	16%	80%	63%	63%
Patient Primary Language: *Spanish*	77%	7%	73%	58%	60%
Insurance Coverage					
Hospital Charity Care	63%	70%	76%	71%	42%
Medicaid	2%	10%	11%	8%	17%
Medicare	14%	7%	11%	11%	9%
Private Health Plan	8%	6%	0%	4%	4%

Note: Percentages reflect the proportion of patients in each category.

Table 1 displays the demographic profile of the project's participating patients and control group. The participating patients were predominantly female, of Hispanic origin and uninsured or on hospital Charity Care. The population's ethnic mix varied by pilot site, with Newark Beth's patients being predominantly African American and Saint Michael's and St. Joseph's being predominantly Hispanic. The average age of participants was 54 (standard deviation = 10.6) and ranged from 24 - 75 years. In total, 173 patients were included and tracked in the control group. As shown in Table 1, the profile of patients in control group was identical to the participating patients for most demographic characteristics, except for insurance coverage, which represented fewer uninsured and Charity Care patients and more Medicaid.

Diabetes Care Outcomes

The participants underwent an extensive initial clinical visit and quarterly follow-ups and attended the peer education classes. Changes in HbA_{1c}, fasting blood sugar and lipid parameters at baseline (pre) and at follow-up (post), for total patients and broken down by pilot site, are shown in Table 2. Statistically significant improvements (as measured by percent change towards the healthy target) were noted in HbA_{1c}, fasting blood sugar and triglycerides. Trends in improvement were noted for HDL and LDL cholesterol, although these changes were not statistically significant.

Table 2. Healthcare Outcomes of Participating Patients

	Pre Mean	Post Mean	% Change
HbA1c (healthy target < 7.0%)	10.6	8.9	- 15%**
Fasting Blood Sugar (target: 90-130 mg/dL)	224.2	180.2	- 20%**
Cholesterol – HDL (good) (healthy target > 40 mmol/l)	41.2	42.5	+ 3%
Cholesterol – LDL (target < 100 mmol/l)	118.7	114.6	- 3%
Triglycerides (healthy target < 150 mmol/l)	158.6	143.3	- 10%*

Note: Percentages reflect the rate of change from the patient's initial visit (pre) to the last follow-up visit (post) for each measure.
* Percent change of mean results from pre to post is statistically significant at p=<0.05 level based on T-test statistic.
** Percent change of mean results pre to post is statistically significant at p=<0.01 level based on T-test statistic.

Table 3 shows that the proportion of patients with healthy target blood pressure increased significantly from the baseline for total participating patients, with patients from Saint Michael's experiencing the highest percentage change. The proportion of patients with very high (unhealthy) blood pressure decreased significantly from the baseline for total participating patients, with patients from Saint Michael's experiencing the greatest reduction of patients with very high blood pressure.

Table 3. Healthcare Outcomes of Participating Patients Based on Proportions of Blood Pressure Markers

	Pre	Post	% Change
Patients with <u>Target</u> BP			
Systolic < 130 mmHg	41%	49%	+ 19%*
Diastolic < 80 mmHg	39%	47%	+ 20%
Patients with <u>Very High</u> BP			
Systolic > 140 mmHg	34%	33%	- 5%
Diastolic > 90 mmHg	21%	16%	- 29%

Note: Blood pressure percentages reflect the change in proportion (pre to post) of patients whose blood pressure is on target (<130/80 mmHg) and patients with very high blood pressure (>140/90 mmHg).
* Difference of proportions from pre to post are statistically significant at p=<0.05 level based on Chi--Square statistic.
** Difference of proportions from pre to post are statistically significant at p=<0.01 level based on Chi-Square statistic.

Table 4 shows the changes in overall means of biological markers (HbA_{1c}, fasting blood sugar, lipid parameters and blood pressure) from baseline to follow-up for participating patients and control group, with significant mean reduction in HbA_{1c}, fasting blood sugar, triglyceride and diastolic blood pressure. Comparing the follow-up measures for participating patients and control group shows that control group has significantly higher HbA_{1c} than the participating patients, using one-way analysis of variance.

Table 4. Healthcare Outcomes of Participating Patients and Control Group Based on Overall Means

	Participating Patients			Control Group		
	Pre	Post	Mean Difference	Pre	Post	Mean Difference
HbA1c (healthy target < 7.0)	10.6	8.9	- 1.63**	11.18	9.77	- 1.42**
Fasting Blood Sugar	224.2	180.2	- 44.05**	183.2	176.8	- 6.44
Cholesterol – HDL (good)	41.2	42.5	+ 1.35	37.9	37.7	- 0.20
Cholesterol – LDL	118.7	114.6	- 4.10	100.1	103.7	+ 3.60
Triglycerides	158.6	143.3	- 15.24*	155.6	162.4	+ 6.76
BP – Systolic	133.81	133.41	- 0.40	138.8	139.2	+ 0.38
BP – Diastolic	80.04	78.12	- 1.92*	79.59	78.89	- 0.70

* Mean difference from pre to post is statistically significant at p=<0.05 level based on T-test statistics.
** Mean difference from pre to post is statistically significant at p=<0.01 level based on T-test statistics.

Table 5 shows changes in project's clinical outcome measures from baseline to follow-up for project patients broken down by project's targeted racial/ethnic categories (African Americans and Hispanics). African Americans have experienced greater changes in HbA_{1c} and fasting blood sugar, and Hispanics showed greater improvements in triglycerides.

Table 5. Healthcare Outcomes of Participating Patients by Race and Ethnicity

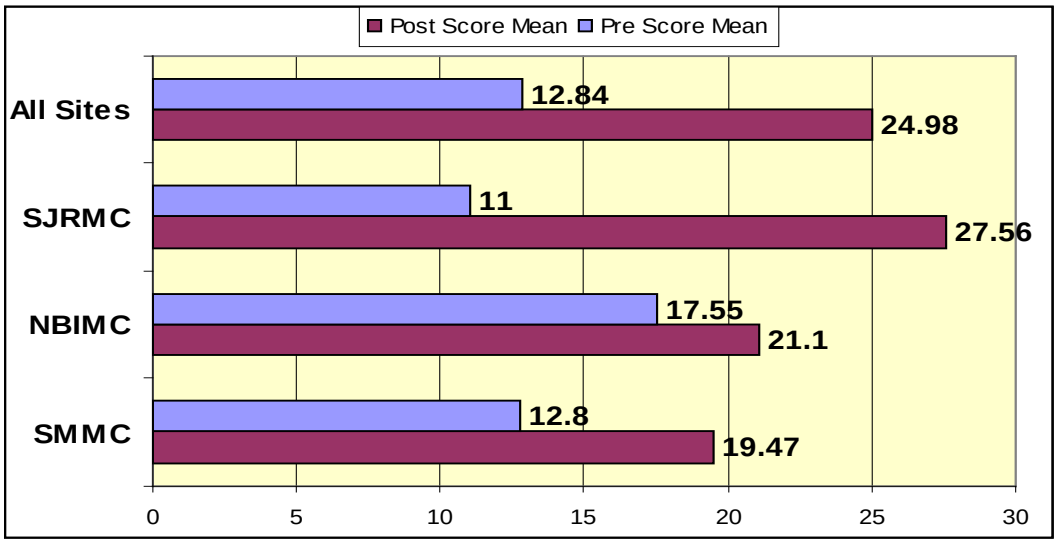
	African American/Black			Hispanic		
	Pre	Post	% Change	Pre	Post	% Change
HbA1c (healthy target < 7.0)	10.9	8.9	- 18%**	10.6	9.0	- 15%**
Fasting Blood Sugar	242.9	169.9	- 30%**	223.5	188.2	- 16%**
Cholesterol – HDL (good)	43.9	45.1	3%	39.4	41.2	5%
Cholesterol - LDL	121.8	113.2	- 7%	117.2	114.6	- 2%
Triglycerides	132.7	129.7	- 2%	174.8	154.8	- 12%
BP Systolic	139.8	140.2	0.3%	128.4	129.3	0.7%
BP Diastolic	83.1	82.7	- 0.5%	78.2	75.3	- 4%

Note: African American/Black is not exclusive of Hispanic origin. Percentages reflect the rate of change from the patient's initial visit (pre) to the last follow-up visit (post) for each measure.
* Percent change of mean results from pre to post is statistically significant at p=<0.05 level based on T-test statistic.
** Percent change of mean results pre to post is statistically significant at p=<0.01 level based on T-test statistic.

Knowledge, Beliefs and Self-Care Behaviors

A total of 126 participants out of the 165 who completed the project's education component (76%) filled both the pre and post knowledge survey. Figure 1 provides the mean of knowledge scores for all participating patients and by pilot site. The knowledge scores of total patients showed 95 percent improvement from pre to post-education intervention. The patients from the St. Joseph's pilot site experienced the greatest improvement in knowledge score (151% change).

Figure 1: Patients' Knowledge Change by Site



Note: Knowledge scores for each participant are calculated as a cumulative score for correct responses. Total possible score is 31.

Table 6 presents the scores of participating patients on four dimensions of self-care behavior. They experienced significant improvements in diet and nutrition compliance (25% change), exercise (78% change), glucose monitoring (39% change) and medications (5% change). Again, St. Joseph's pilot site showed significantly greater improvements on all dimensions. It should be noted that despite project efforts to link uninsured patients to pharmaceutical assistance programs and low-cost drugstores, medication compliance did not improve as much as anticipated.

Table 6. Patients' Behavior Improvement by Activity Dimensions & Site

	Pre Score Mean	Post Score Mean	% Change
Nutrition (Scale: 1-5)			
Site 1 – SMMC	3.20	3.97	+ 24%**
Site 2 – NBIMC	3.14	3.47	+ 11%**
Site 3 – SJRMC	2.95	3.90	+ 32%**
ALL SITES	*3.03*	*3.79*	*+ 25%***
Exercise (Scale: 0-7)			
Site 1 – SMMC	2.81	4.51	+ 61%**
Site 2 – NBIMC	2.28	3.04	+ 33%**
Site 3 – SJRMC	2.13	4.25	+ 99%**
ALL SITES	*2.24*	*3.99*	*+ 78%***
Glucose Monitoring (Scale: 1-4)			
Site 1 – SMMC	2.88	3.50	+ 22%**
Site 2 – NBIMC	2.75	3.27	+ 19%**
Site 3 – SJRMC	2.35	3.53	+ 50%**
ALL SITES	*2.50*	*3.46*	*+ 39%***
Medications (Scale: 1-4)			
Site 1 – SMMC	3.67	4.00	+ 9%*
Site 2 – NBIMC	3.60	3.73	+ 4%
Site 3 – SJRMC	3.77	3.93	+ 5%*
ALL SITES	*3.71*	*3.89*	*+ 5%***

Note: Behavior improvement scores for each participant are calculated as the mean of responses (based on a point scale) for each domain. Improvements for these indicators are measured as the percentage change in the overall mean of participants' mean scores, from pre to post. Lack of significant improvement for "Medications" could be due to barriers patients may face that the program cannot directly control of (e.g., affordability/access to medication coverage).

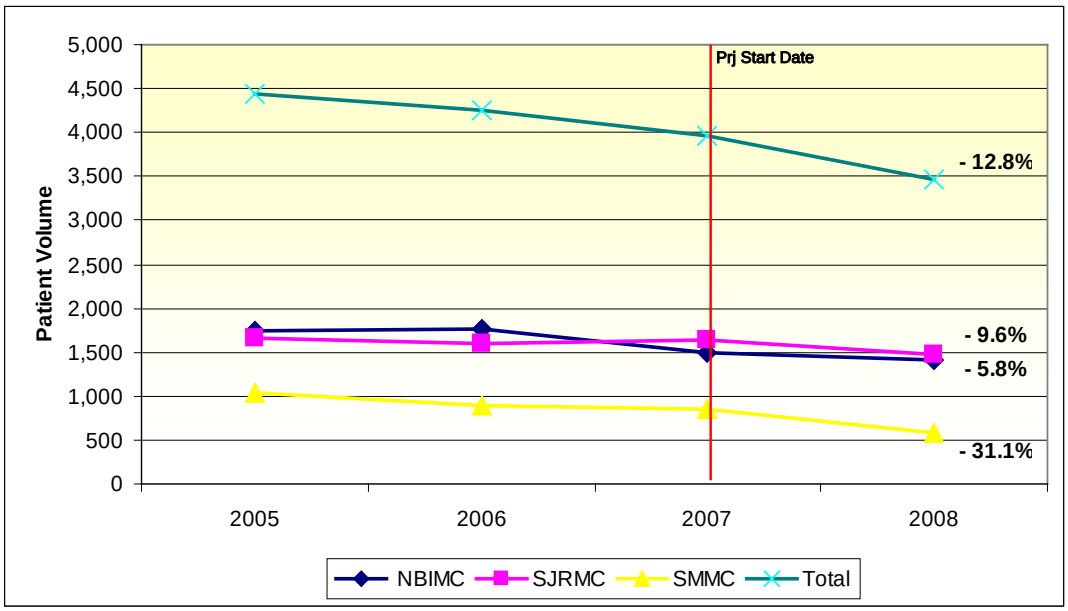
* Percent change of mean scores from pre to post is statistically significant at p=<0.05 level based on T-test statistic.

** Percent change of mean scores pre to post is statistically significant at p=<0.01 level based on T-test statistic.

Costs of Diabetes Care

The project implementation began in 2007, and community-based educational interventions were offered starting in 2008. To determine the impact of the project, data on hospital emergency department visits and admissions for conditions related to diabetes and its complications were analyzed over time (2005 - 2008). As shown in Figure 2, from 2007 to 2008, there is a significant reduction in hospital admissions for diabetes and related conditions at the pilot sites. Data on ED visits in hospital pilot sites for 2005 to 2008 were also reviewed and different from the admission patterns, the ED utilization pattern for diabetes-related conditions and overall showed an increase in volume. However, when the ratio of ED visits for diabetes-related conditions to all ED visits was examined, it demonstrated a downward trend.

Figure 2. Inpatient Admissions with a Primary Diagnosis of Diabetes or Related Complications, 2005-2008



Data on hospital ED visits and inpatient admissions for diabetes-related conditions and their associated costs have some limitations. During the project implementation period, all three hospital pilot sites faced the closures of other hospitals in their service area and had to deal with the consequences of absorbing additional patient volume, reflected in significantly increased ED visits. Caution should therefore be exercised in any interpretation of the reported utilization and cost data, and no strong conclusions should be drawn based on the available data. Additional data is needed for any meaningful assessment of the project impact on ED visits and hospital admissions, as the full impact of 2008 and 2009 educational interventions will not be observed until 2009 and 2010 data are released.

Model Implementation Challenges and Accomplishments

The Dulce New Jersey pilot sites faced and addressed several challenges in implementing the project model. One of the biggest challenges was ensuring continued participation of patients in all sessions of the diabetes education course and lowering the attrition rate. Incentives were

utilized or considered by all pilots, but many factors contributing to this problem were outside of their control. Saint Michael's Medical Center had significant difficulty with meeting the targets for enrollment and education. Saint Michael's serves a large immigrant population, which is very transient, and a number of patients moved out of state or out of the region before completing the diabetes education course. To address this issue, Saint Michael's expanded its reach for recruitment into the community, targeted more diabetes patients (lowering the HbA1c criteria for enrollment), provided additional incentives (e.g., grocery store gift certificates), offered healthy snacks during classes, hosted classes in the evenings and at Latino community sites, worked more collaboratively with the existing ADA diabetes education program and conducted a monthly blitz awareness within the clinic. Saint Michael's pilot program was also featured on the local Spanish-speaking television news broadcast on *Telemundo*. Newark Beth Israel Medical Center faced financial hardship during the 2008 economic downturn, with a significantly reduced workforce in the clinic serving the Dulce New Jersey project patients (and closure of other hospital clinics), which created some project delays in reaching the targets for enrollment and education as staff were stretched with more responsibilities per staff. With a significant number of potential participants on the waiting list for the classes, the Newark Beth team rearranged schedules to provide more clinic and class hours to move these patients through the program. St. Joseph's Regional Medical Center was the most successful in reaching the targets for enrollment and education. This pilot made adjustments to its enrollment protocols as needed and condensed the class cycles into four weeks by hosting two classes per week, reducing the attrition rate among the transient population they serve.

CONCLUSIONS

The results of this demonstration project show that underserved minority patients with diabetes who enrolled in the Dulce New Jersey project – a culturally sensitive, community-based, nurse case management and peer education diabetes care model – benefited greatly from improvements in health status, diabetes care outcomes, knowledge of diabetes and self-care empowerment. In a short period of time, many patients were able to meet the goals of significantly decreased HbA_{1c}, fasting blood sugar, lipid parameters and blood pressure. Patients enrolled in Dulce New Jersey also overcame many cultural barriers to care and developed a better understanding of the disease and their care/treatment instructions. Participants demonstrated enhanced ability to manage their own health more effectively. These findings confirm that the Dulce model is an effective method of delivering diabetes care to culturally diverse populations in New Jersey and addressing barriers to accessing healthcare services faced by minority patients, such as language, cultural beliefs, health literacy, educational level and transportation.

Initially, implementation of a program such as Dulce New Jersey requires some funding. However, this approach should be potentially cost-saving if the clinical benefits are sustained long-term and result in significant reductions in complications, improved health and healthcare outcomes and, ultimately, decreased costs of care. It is the goal of this project to continue advocating for widespread use of this model and insurance coverage of peer educator services.

In conclusion, use of the Dulce model can help in providing culturally-appropriate diabetes care to underserved and minority populations, reducing disparities and resulting in significant improvements in health status and quality of life among the most vulnerable populations.

ACKNOWLEDGMENTS

This study was funded through grants from the Healthcare Foundation of New Jersey and Novartis Pharmaceuticals Corporation and additional support from Horizon Foundation for New Jersey and Novo Nordisk Inc.

Special thanks are extended to the project partners at Newark Beth Israel Medical Center, Saint Michael's Medical Center and St. Joseph's Regional Medical Center that implemented the project model interventions.

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