

# Clinical and Behavioral Correlates of Achieving and Maintaining Glycemic Targets in an Underserved Population With Type 2 Diabetes

VALERIE RUELAS, MSW<sup>1</sup>  
G. MICHAEL ROYBAL, MD, MPH<sup>2</sup>  
YANG LU, MPHIL<sup>3</sup>

DANA GOLDMAN, PHD<sup>3</sup>  
ANNE PETERS, MD<sup>1</sup>

**OBJECTIVE** — In an underserved Latino area, we established a disease-management program and proved its effectiveness. However, many patients still remained above target. This study was designed to evaluate which factors are associated with reaching program goals.

**RESEARCH DESIGN AND METHODS** — This was a randomized, prospective, observational study in which patients enrolled in our program were followed for 2 years with outcomes, measures, and questionnaires assessed at baseline and at 6, 12, and 24 months.

**RESULTS** — Overall, A1C fell by 1%. Adherence to medication was the strongest predictor of reaching the target A1C of <8%; baseline A1C was also predictive. Knowledge scores increased in those who reached target, but the measures of self-efficacy and empowerment did not change for either group.

**CONCLUSIONS** — Diabetes management is effective in a lower-income Latino population. However, adherence was suboptimal even when medications were provided on-site for free. Further research into barriers associated with medication adherence is needed.

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In the U.S., Latino individuals have a high prevalence of diabetes and are often poor and uninsured (1). Research needs to be done to develop cost-effective, ethnically appropriate diabetes programs for these vulnerable individuals. We implemented a diabetes-management program in a comprehensive health center serving low-income, Latino patients in east Los Angeles. A previous study indicated that our program improves short-term outcomes but that the improvement is often not sustained (2). This study was conducted to identify the correlates of success in our program.

## RESEARCH DESIGN AND METHODS

This study was a 2-year one-center randomized comparative trial.

Consenting patients entering our program were randomized to either an episodic model of care or a continuous model of care. Each patient completed an Institutional Review Board–approved informed consent form. All subjects underwent the same first 6 months of care in accordance with our protocols. After 6 months, those in the episodic group were to be discharged and returned annually for an evaluation. Those in the continuous model were seen at least every 3 months for the duration of 2 years. Patients were randomized and frequency matched based on age, diabetes duration, sex, BMI, and A1C.

Routine diabetes clinical and laboratory measurements and questionnaires

(Diabetes Knowledge Test [3], the Summary of Diabetes Self-Care Activities questionnaire [4], Diabetes Empowerment Scale [5], and the Problem Areas in Diabetes questionnaire [6]) were completed at baseline and at 6, 12, and 24 months. Adherence to prescribed drugs was measured as a medication possession ratio (MPR), which represents the proportion of days on which the patient had the medication available (7).

The design of our program has previously been described (2). Most patients have no health insurance and live below the federal poverty level. Care managers (nurses and nurse practitioners) provide care following protocols and are supervised by a diabetologist. The program attempts global risk reduction in a culturally appropriate context. Our A1C target is <8%, with recommendations for reducing the A1C further in primary care. Initially, we followed patients indefinitely, but resources mandated shortening the programs duration to 6 months, with a possible extension based on the judgment of the care manager.

## Statistical analysis

Data are presented as means  $\pm$  SEM. Changes in each variable from baseline at each follow-up time were compared between the two groups using a two-way Student's *t* test. For all behavioral response measures, the scores of responses for each questionnaire were compared between the two groups at baseline and each visit using Wilcoxon's rank-sum test. Data were analyzed using GraphPad InStat 3, version 3.0b.

We conducted a multivariate logistic regression analysis on patients treated with metformin (the most frequently used medication) to determine the factors associated with a patient's probability of achieving an A1C <8% at the last follow-up evaluation. The key regressor, adherence to metformin, was defined as the fraction of time metformin was available to the patient. Other covariates included a set of demographics (sex, age, education,

From the <sup>1</sup>University of Southern California Keck School of Medicine, Los Angeles, California; the <sup>2</sup>Los Angeles County Department of Health Services, Los Angeles, California; and the <sup>3</sup>Research and Development (RAND) Corporation, Santa Monica, California.

Corresponding author: Anne Peters, momofmax@mac.com.

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**Table 1—Factors associated with achieving an A1C level of <8% at the last follow-up (n = 107)**

	Odds ratio	95% CI	P
Adherence to metformin	19.31	2.16–172.60	0.01
A1C at baseline	0.51	0.36–0.73	0.00
Country of origin (Mexico)	1.23	0.30–5.09	0.78
Sex (female)	0.28	0.05–1.55	0.15
Age	1.07	0.99–1.15	0.09
Years of education	1.00	0.85–1.19	0.96
No formal education	0.82	0.07–9.88	0.87
Years with diabetes at baseline	0.91	0.83–1.01	0.09
On insulin therapy at baseline	0.86	0.25–2.94	0.80
Taking metformin at baseline	0.97	0.22–4.21	0.97
No. of drugs taken at baseline	0.90	0.61–1.33	0.61
Attendance at last month's follow-up	1.01	0.92–1.11	0.86

and country of origin) and pretreatment conditions (duration of diabetes at baseline, baseline A1C, and drug treatment at baseline). The model was analyzed using Stata Statistical Software, version 10.1.

**RESULTS**— Of 211 eligible patients, 162 were enrolled, with 79 in the control group and 83 in the episodic group. In the first year, 129 patients (79.7%) completed the program, and 100 (61.7%) had data available during the second year. Baseline mean A1C values were  $7.9 \pm 1.8\%$  (control) and  $7.7 \pm 1.6\%$  (episodic) and fell by  $\sim 1\%$  at 6 and 12 months in both groups. However, the total number of visits was the same in the control and episodic groups, erasing the separation between the models. No relationship was found between the number of visits and change in A1C.

Subsequent analyses compared those who reached the A1C target of <8% with those who did not. Ninety-six subjects (62%) achieved the target of <8%, and 59 (38%) were above the target. Patients in the group with <8% A1C showed significant improvements on the Summary of Diabetes Self-Care Activities questionnaire in diet and foot care as well as improvements on the Diabetes Knowledge Test. These variables did not improve in the  $\geq 8\%$  A1C group. No significant changes were seen on the Diabetes Empowerment Scale or the Problem Areas in Diabetes questionnaire in either group.

Regression results are presented in Table 1. Factors that are statistically significant include adherence to metformin and A1C at baseline with odds ratios of 19.31 (95% CI 2.16–172.60;  $P = 0.01$ )

and 0.51 (0.36–0.73;  $P = 0.00$ ), respectively. The results suggest that the probability of reaching the <8% A1C target increases with higher adherence to metformin and lower baseline A1C levels.

Based on both pharmacy data and patient self-report, rates of self-monitoring of blood glucose did not differ between groups ( $\sim 30$  strips obtained and reportedly used per month). No differences were seen in visits to walk-in clinics or the emergency department or in rates of inpatient hospitalization.

**CONCLUSIONS**— This study showed a 1% sustained reduction in A1C through diabetes management. Adherence is a statistically significant ( $P = 0.01$ ) and robust predictor for the <8% target at follow-up. Other studies have found a similar relationship between medication adherence and outcomes in individuals treated for diabetes (8,9). Unlike most diabetic patients in most settings, however, our patients are able to obtain their prescriptions for free in the same building where they are seen for their diabetes care.

Limitations to our study include the failure of the initial episodic model to be implemented, the use of medication attainment as a measure for medication adherence (less accurate than actual pill counts but more accurate than patient self-report) (10), and a high dropout rate in the second year.

The surveys used did not capture the psychosocial stressors of our patients. The need for study of barriers to self-management has been discussed by others (11). Additionally, many of our patients experience food insecurity (12) and

lack access to the recommended healthy foods (13). These considerations make more traditional questions about lifestyle and stress more difficult to interpret.

In conclusion, medication adherence was a strong predictor of maintaining an A1C level below target. Incorporating new approaches to enhance adherence (14,15) might help improve outcomes.

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