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

THE CALIFORNIA MEDI-CAL TYPE 2 DIABETES STUDY GROUP*

OBJECTIVE — Disparities exist in the diabetes health status of ethnic minority and/or low-income populations relative to other groups. A primary objective of diabetes management is to improve glycemic control. The feasibility of implementing intensive diabetes case management in disparate populations remains largely untested.

RESEARCH DESIGN AND METHODS — Clinical sites in three southern California counties serving low-income, ethnic minority populations participated in our study. We randomized 362 Medicaid (called Medi-Cal in California) recipients with type 2 diabetes for at least 1 year to intervention (diabetes case management) or control (traditional primary care treatment) groups. Fifty-five percent of participants were minorities. Participants with HbA_{1c} levels less than 7.5%, serious diabetes-related complications, or other serious medical conditions were excluded. We assessed the effect of the intervention (ongoing diabetes case management added to primary care) on glycemic control using serial HbA_{1c} measurements over several years.

RESULTS — The mean duration of follow-up was 25.3 months. HbA_{1c} decreased substantially in both groups from an average of 9.54–7.66% (a reduction of 1.88%) in the intervention group and from an average of 9.66–8.53% (a reduction of 1.13%) in the control group. This improvement was sustained throughout the study. The reduction in HbA_{1c} was consistently greater in the intervention group at each time point ($P < 0.001$), ranging between 0.65 at 6 months and 0.87 at study end.

CONCLUSIONS — Diabetes case management, added to primary care, substantially improved glycemic control compared with the control group. Diabetes case management can help reduce disparities in diabetes health status among low-income ethnic populations.

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Accumulating evidence (1,2) has demonstrated that achievement of near-normal glycemic control in diabetes care reduces the development and progression of microvascular and macrovascular complications and, furthermore, that this approach is cost effective compared with other treatments (3). As a result, the American Diabetes Association has recommended that all individuals with diabetes attempt to achieve near normalization of blood glucose levels and has advocated measurement of HbA_{1c} and daily self-monitoring of blood glucose as important components of care (4). However, these recommendations are not routinely followed in medical practice (5), with reports showing that over 80% of participants with diabetes are in poor glycemic control (6). Also, less than 18% of physicians reported that they ordered HbA_{1c} determinations, and less than 10% of participants with type 2 diabetes were monitoring their blood glucose at least once a day (7,8).

It appears that multiple mechanisms are likely responsible for poor adherence to American Diabetes Association recommendations, including both provider behaviors and participant responses. In particular, multiple barriers to care have been identified that explain the low adherence rates to intensive diabetes management protocols. The list of barriers includes the high cost of glucose monitoring strips, lack of language skills and cultural sensitivity of the health care providers (9), high cost of medicines, and difficulty filling prescriptions.

Poor diabetes control and suboptimal self-management have also been observed more frequently in racial and ethnic minorities (10) and are associated with a lower frequency of self-monitoring of blood glucose (11) in adults with diabetes. This disparity is of particular concern because of the increased prevalence of diabetes and its complications among minority groups. In California, Latino and African-American women over the age of 55 years have double the prevalence of diabetes compared with white women in the same age-group (Diabetes Data for California, California Department of Health Services, March, 1997). Diabetes age-adjusted mortality rates (per 100,000) in California for the year 1998 were 59.9 for Latinos and 97.6 for African Americans compared with 37.9 for non-Hispanic whites. These disparities may be the result of multiple factors. However, regardless of the cause of these disparities, appropriate and effective measures should be undertaken to reduce them. The studies that provide the basis for the modern approach to intensive diabetes care (1,2) have not included low-income eth-

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A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

nic and racial minority groups and thus do not deal with barriers to care in these populations.

Case management has been used as a method for implementing recommended diabetes standards (7,8,12), especially in type 2 diabetes populations. Most attempts thus far appear to have been reasonably successful (13–15). These studies have typically evaluated relatively small numbers of participants over short periods of time within managed care settings. In addition, the populations in which intensive therapy has been studied have generally not had representation of minority and/or indigent populations (16). Thus, the question remains: will the lessons of the Diabetes Control and Complications Trial (17) and the U.K. Prospective Diabetes Study (2) be applicable to medically underserved populations that have historically benefited the least from advances in health care? We therefore undertook this study to determine if intensive diabetes case management using specific, population-directed, case management strategies could improve glycemic control in a southern California Medicaid (called Medi-Cal in California) population of participants with type 2 diabetes in which minorities are overrepresented.

Table 1—*Comparison of baseline characteristics in the intervention and control groups

	Intervention		Control	
Variables	Mean ± SE	%	Mean ± SE	%
n	186		172	
Age (years)	57.0 ± 0.9		56.9 ± 1.0	
Sex: female (%)		72.6		70.9
Education				
Beyond 12th grade (%)		20.8		19.4
12th grade (%)		16.3		23.6
9–11th grade (%)		21.9		17.6
8th grade or less (%)		41.0		39.4
Ethnicity				
African American (%)		16.1		15.7
Hispanic (%)		39.2		38.4
White (%)		34.9		36.0
Other (%)		9.7		9.9
Smoking (%)		14.8		13.0
Duration of diabetes (years)	10.3 ± 0.8		12.0 ± 0.8	
HbA_{1c} (%)	9.6 ± 0.1		9.7 ± 0.1	
Weight (kg)	87.4 ± 2.2		84.1 ± 2.0	
BMI (kg/m^2)	33.1 ± 0.8		31.5 ± 0.8	
Blood pressure: systolic (mmHg)	136 ± 2		134 ± 1	
Blood pressure: diastolic (mmHg)	81 ± 4		76 ± 1	
Cholesterol (mg/dl)	210.0 ± 3.3		212.1 ± 3.7	
Triglyceride (mg/dl)	209.3 ± 11.6		220.3 ± 13.6	
Lipid: HDL (mg/dl)	41.9 ± 1.0		43.0 ± 1.1	
Lipid: LDL (mg/dl)	129.8 ± 3.2		130.1 ± 3.6	

*There is no statistically significant difference in the baseline variables between the intervention and control groups.

RESEARCH DESIGN AND METHODS

— Between 1 July 1995 and 30 June 1999, we conducted a randomized, controlled study of individuals ≥18 years who had type 2 diabetes of at least 1 year duration. Individuals with type 2 diabetes were recruited at clinical sites in three counties (Santa Barbara, Los Angeles, and San Diego) serving racial/ethnic minority, low-income Medi-Cal populations. The three clinical sites were selected to participate in the study via a competitive award process. One study site was a community-based program within a county-wide managed care plan for Medi-Cal recipients. The other two study sites were university-based centers. One of these recruited fee-for-service Medi-Cal recipients from within and outside its health care system. The other university-based site recruited participants from both the fee-for-service and managed care plans within hospital-based and outlying clinics served by its health care system.

Informed consent was obtained from all prospective participants using Institutional Review Board–approved forms.

Participants with HbA_{1c} levels greater than 7.5% were recruited to assess the effectiveness of case management intervention on participants with suboptimal glycemic control (Table 1); 188 were randomized to the intervention group and 174 individuals were randomized to the control group (Fig. 1). Intensive diabetes case management was provided to the intervention group in addition to primary care (Table 2). Individuals randomized to the control group continued to receive usual care from their primary health care provider. Study staff met with the participant at study entry and exit to assess overall health status, glycemic control, diabetes self-care behaviors, and presence of diabetes-related complications. Blood for HbA_{1c} was collected at 6-month intervals in the control group, and interim contact between study staff and participants was generally limited to that needed to assure collection of HbA_{1c} samples. Primary care providers responsible for the care of control participants were, in many cases, also responsible for the care of intervention participants within the same clinical setting.

Case management

The study staff at each site, consisting of registered nurses and registered dietitians working in close collaboration with an endocrinologist, provided diabetes case management to the intervention group only. Evidence-based practice guidelines and algorithms for medication and insulin initiation and/or adjustment were used in a collaborative practice model with the primary care provider (18) (Table 2). Potential barriers to care were identified, often influenced by the demographics, and socioeconomic status of the participant population and individualized treatment and education strategies was designed to address as many of these barriers as possible (19–21).

The study protocol included basic guidelines for glucose and medication management. American Diabetes Association goals for treatment of diabetes, hypertension, and dyslipidemia served as

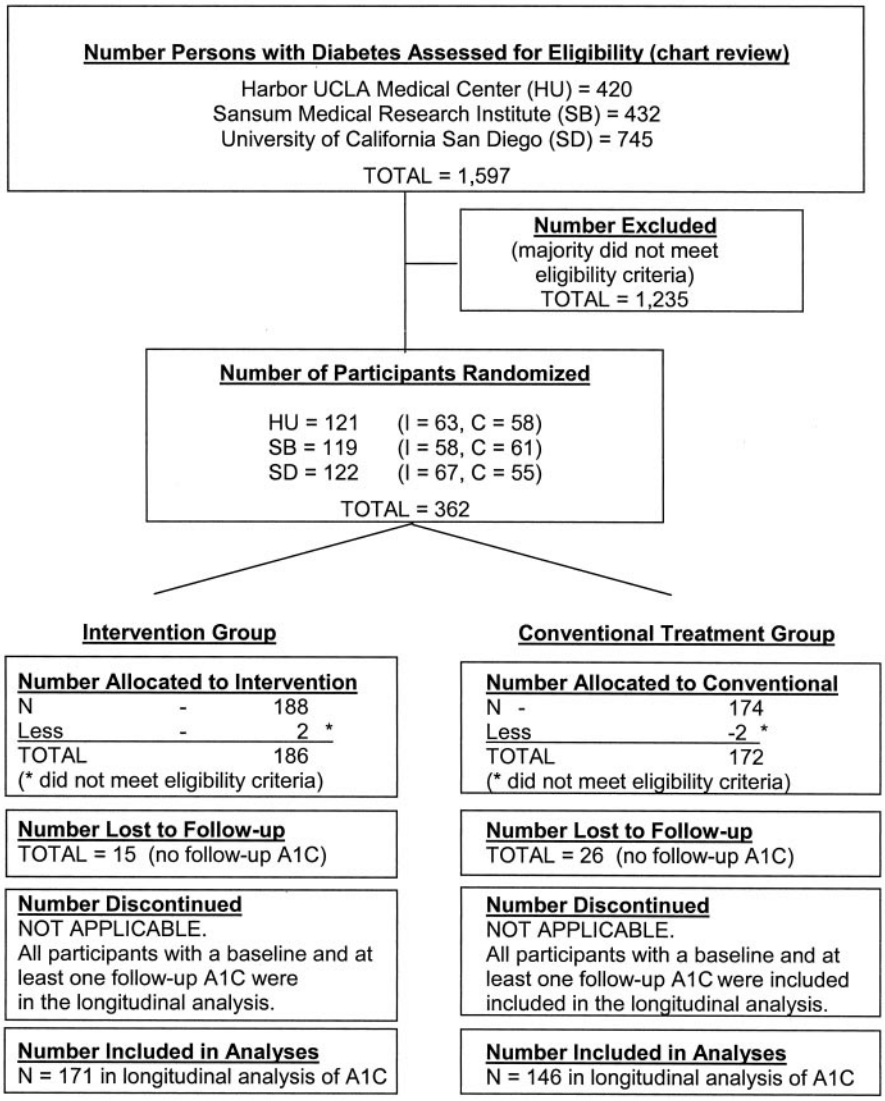

Figure 1—*Recruitment and randomization flow diagram.*

the basis for the development of protocol guidelines. Treatment goals and targets for therapy were uniform across sites. However, each clinical center had flexibility to use individualized treatment algorithms and strategies for glucose and medication management. All participants in the intervention group were provided with the same glucose meter and received individualized education regarding use and data recording. In addition, diet, exercise, and self-care behaviors were assessed by diabetes educators, and strategies to improve self-care education and management were used throughout the study in the intervention group. These strategies considered participant's level of education, literacy and functional understanding, treatment goals, general health status, cultural beliefs, and support network. Interactions between the participant and study staff occurred in person at the clinic site and via telephone between visits as needed.

Diabetes care appointments were scheduled and completion monitored; missed appointments were rescheduled. Transportation issues were addressed to improve visit completion. The need for ancillary medical evaluations and/or services (for example, ophthalmologic, podiatry, home health) was identified with subsequent follow-up to ensure receipt of services, results retrieval, and communication of results to the primary care provider.

Primary outcome measures

Level of glycemic control, as measured by serial HbA_{1c} measurements, was the primary outcome measure. HbA_{1c} levels were obtained on a quarterly basis in the intervention group and every 6 months in the control group. HbA_{1c} was assessed by high-pressure liquid chromatography method in the laboratories used by the three centers. The normal range for these laboratories was 4.9–6.1% (percent coefficient of variation less than 3%) and was calibrated to the Diabetes Control and Complications Trial standard (22).

Statistical analysis

The sample sizes for the two comparison groups were chosen to detect an anticipated HbA_{1c} reduction in the intervention group that exceeded the corresponding change in the control group by 1.0%. Allowing for a 30% drop-out rate within the planned initial sample size of 150 in each group yielded 105 for analysis; this resulted in a power of slightly greater than 95% with a two-sided significance level of 0.05, assuming a standard deviation for HbA_{1c} change of 2.0%. Potential gains in power from use of longitudinal analysis, which could accommodate participants with incomplete follow-up, were not considered in the sample size planning.

The study biostatistician prepared a separate computer-generated time-blocked allocation sequence for each of the three clinical centers. Each center's sequence was provided in individual sealed envelopes sequentially labeled with participant study codes and containing randomization assignment. Treatment group assignment was unknown until the day of randomization.

Neither participants nor caregivers were masked to HbA_{1c} measurements or other laboratory results. HbA_{1c} values were used by study staff to guide treatment decisions in the intervention group.

A longitudinal analysis was used to assess changes in HbA_{1c}. The trend of mean HbA_{1c} over time for each group was estimated using a normal linear mixed model with the robust standard error option. The dependence between the participants' repeated HbA_{1c} measurements was modeled using the group-specific compound symmetry covariance model. This analysis was implemented with PROC MIXED in SAS 8.1 (23). This approach allowed for inclusion of varying numbers and times of follow-up assess-

Table 2—*Case management interventions*

Blood glucose management	• Self-monitoring of blood glucose (SMBG): individual education and ongoing assessment to reach individually defined targets. • Testing frequency: as needed to meet treatment goals, generally at least two times per day. • Glucose records: maintained by participant; results reviewed each visit and compared with meter memory. • Data review: SMBG trends/patterns identified; collaboration with primary care provider to modify treatment. • Treatment: strategies individualized to meet goals.
Nutrition education and management	• Weight: measured at every visit. • Treatment: individualized meal plans to meet nutrition and weight-management goals. • Routine assessment: content, quantity, and timing of food intake; adjustments as needed.
Exercise	• Assessment of physical activity: at least quarterly. • Exercise stress testing: when advisable/available. • Exercise plan: incorporation of current activity preference and level; increased as tolerated.
Foot care	• Visual inspection/examination at least quarterly. • Education: daily self-inspection and preventive care. • Referrals for specialty care: as needed.
Monitoring of participant progress and retention	• Record sheets: developed to promote ongoing participant assessment and provider communication (monitor appointments, physical measurements, laboratory values, SMBG results, active problems, treatment, etc.). • Retention strategies: *1*) interim visit telephone contact; *2*) appointment reminders/tracking/rescheduling; *3*) group education/social activities; *4*) holiday/special greeting cards. • Written record of participant interactions: shared with primary care providers to ensure continuity and quality of care. • Community support: family/significant others encouraged to attend appointments and events. • Communication: bilingual study staff and native language print materials used when possible. • Interpretation services: telephone company interpretation service; bilingual clinic staff assistance. • Staff reassignment: as needed to optimize participant interactions, care, and retention. • Ongoing self-management assessment: provide or refer for diabetes education, nutrition, and/or exercise guidance, psychosocial support, or community assistance resources.
Retinopathy prevention/ treatment	• Retinal examinations and/or retinal photographs: at least yearly. • Ophthalmologic follow-up: direct referral to an ophthalmologist; results obtained and forwarded to primary care provider.
Nephropathy prevention/ treatment	• Microalbumin: assessed at least yearly. • Results: abnormal results flagged, primary care provider notified. • Prevention/treatment: optimize blood glucose and blood pressure control; initiation of ACE inhibitors.
Hypertension management	• Blood pressure measurements: at every visit. • Target: ≤135/85 mmHg; more frequent monitoring and treatment if target exceeded. • Treatment: diet and exercise modifications, weight management, pharmacological therapy.
Dyslipidemia management	• Fasting assessment: at least yearly. • Target: total cholesterol <200 mg/dl, LDL <130 mg/dl, triglycerides <150 mg/dl. • Treatment: dietary and exercise modifications; pharmacological therapy as indicated.
Cardiovascular disease prevention/treatment	• Risk factor assessment: at least yearly. • Smoking cessation: encouraged; referral to community programs. • Weight management: encouraged; referral to community-based dietary counseling or programs. • Aspirin and hormonal replacement therapy: initiated when appropriate.

Disenrollment from the study	• Criteria for early termination:
	  • withdrawal of consent;
	  • inability to keep appointments or respond to oral/written contact for 6 consecutive months;
	  • loss of Medi-Cal beneficiary status;
	  • geographic relocation;
	  • death.

ments. Thus, participants having at least one HbA_{1c} value beyond baseline were included in the analyses. Because an initial sharp decrease in the HbA_{1c} followed by a linear decline at a slower rate was observed in both groups, a piecewise linear model (also known as a "hockey stick" model) (24) was used to model the trend in mean HbA_{1c} over time. Because individuals with HbA_{1c} <7.5% were not eligible for participation, the sharp initial drop in both groups is partly due to regression to the mean, which should be comparable in both groups. The breakpoint for the fitted piecewise linear model was determined using the Akaike Information Criterion (25) to choose from a spectrum of breakpoint options. For

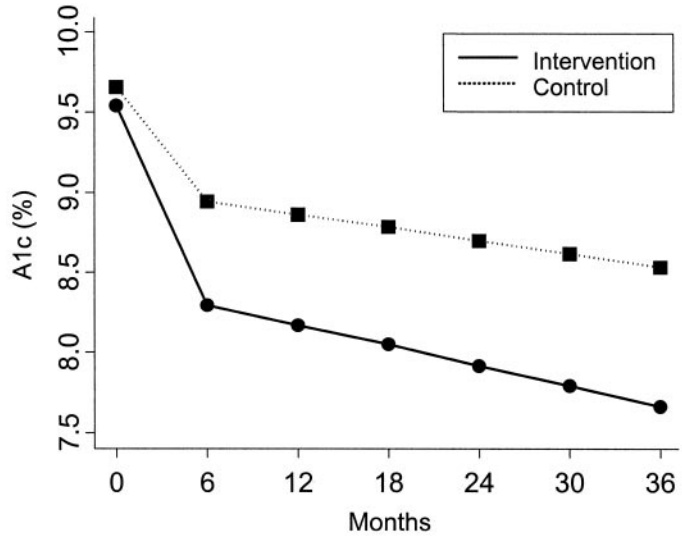

Figure 2—*Comparison of mean HbA_{1c} in the intervention and control groups using mixed effects analysis. For more detailed results and statistical significance, see Table 3.*

graphic and tabular presentation in Fig. 2 and Table 3, estimated mean HbA_{1c} values with standard errors from baseline to 36 months by 6-month intervals were obtained from the fitted model.

We analyzed the percentage of participants who achieved specified HbA_{1c} goals (<6.5, <7.0, or <7.5%) on at least one occasion during the study. Figure 3 shows that the percent of HbA_{1c} values that achieved target was consistently greater in the intensive group compared with the control group at the level of ≤6.5, ≤7.0, and <7.5%. By design, the frequency of HbA_{1c} tests for participants in the intervention group was higher than in the control group (once every 3 months for the intervention versus once every 6 months for the control). On average, there were 6.1 HbA_{1c} tests per participant in the intervention groups vs. 4.4 in the control group. An HbA_{1c} test schedule with higher frequency might result in a higher percentage of participants appearing to achieve HbA_{1c} goals. To compare the difference between the two groups without any bias contributed by the HbA_{1c} test schedule, we estimated the percentages achieving targets for the intervention group by using the bootstrap method. This method randomly chooses a number of subjects and tests in the intervention group that is set to be identical with the control group. This procedure was repeated 100 times in the intervention group to provide an HbA_{1c} test schedule that simulates the HbA_{1c} schedule of the control group (26).

Demographic characteristics were obtained in the intervention and control group (Table 1). For continuous characteristics, groups were compared using means and standard errors. However, because some variables were not normally distributed, the nonparametric Wilcoxon's rank-sum test method was used to assess significance of observed differences between groups. For categorical variables, descriptive comparisons were based on proportions in each category, and statistical significance was tested with χ^2 tests. Analysis of baseline data included 186 intervention and 172 control participants. For the longitudinal analysis, all participants with baseline and at least one follow-up HbA_{1c} were included. Thus, the cohort for HbA_{1c} analysis included 171 and 146 participants in the intervention and control groups, respectively. All analyses were performed using the intent-to-treat model.

Changes in secondary outcome variables (e.g., weight, BMI, blood pressure, and lipid parameters) were analyzed using the Generalized Linear Model with SAS PROC GLM (23). Participants included in the analysis for a secondary outcome variable needed a baseline and an ending value with corresponding measurement dates associated with the outcome variable. In the case of missing ending measurements, the participant was excluded from that analysis. This method of exclusion resulted in different numbers being analyzed for each of the secondary outcome variables and medications.

RESULTS

Baseline data

There were no statistically significant differences in mean age, duration of diabetes, HbA_{1c}, weight, BMI, blood pressure, or fasting lipid parameters between groups at baseline (Table 1). The presence of diabetes-related complications after randomization was similar in both groups. Other demographic and socioeconomic indicators were similar between the two groups. The majority of participants represented ethnic/racial minorities. Approximately 40% had 8 years or less of formal education and ~80% of this population did not have any education beyond the twelfth grade in high school. Level of education and literacy were not included as eligibility criteria.

Management of glycemic control

The major study end point was glycemic control, as measured by HbA_{1c} change from baseline. Results of the analysis us-

Table 3—*Mean HbA_{1c} and difference as determined by mixed effects analysis*

Time	Intervention (%)	Control (%)	Difference	*P* value*
n	171	146		
Baseline	9.54 ± 0.12	9.66 ± 0.13	−0.12	0.51
6 months	8.29 ± 0.12	8.94 ± 0.15	−0.65	<0.01
12 months	8.17 ± 0.11	8.86 ± 0.14	−0.69	<0.01
18 months	8.11 ± 0.11	8.82 ± 0.13	−0.71	<0.01
24 months	7.92 ± 0.13	8.70 ± 0.15	−0.78	<0.01
30 months	7.85 ± 0.14	8.66 ± 0.15	−0.80	<0.01
36 months	7.66 ± 0.17	8.53 ± 0.20†	−0.87	<0.01

**P* values are applied to HbA_{1c} differences between the intervention and control groups. †The respective drops in the 36-month HbA_{1c} compared with the baseline HbA_{1c} in both the intervention group and the control group of 1.88 and 1.13% are statistically significant.

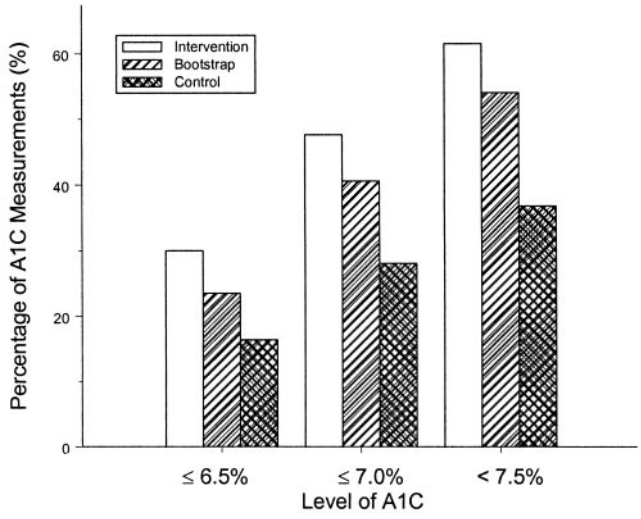

Figure 3—*Percentage of HbA_{1c} measurements that achieved goals in intervention and control groups. The "bootstrap" group in the legend refers to the adjusted frequency obtained for the intervention group, estimated using the bootstrap method (see RESEARCH DESIGN AND METHODS) to provide an HbA_{1c} test schedule that simulates the schedule of the control group. The difference of the percentages between intervention and control groups and bootstrap and control groups were statistically significant* ($P < 0.01$).

ing the mixed effects model showed that the intervention group had a significant improvement in HbA_{1c} compared with the control group (Table 3). The intervention and control groups had similar mean HbA_{1c} values at baseline, 9.54 ± 0.12 and 9.65 ± 0.13%, respectively ($P = 0.58$). A progressive reduction in HbA_{1c} over the study period was seen in both groups, from 9.54 to 7.66% (a reduction of 1.88%) in the intervention group and from 9.66 to 8.53% (a reduction of 1.13%) in the control group. However, the reduction in the intervention group was significantly greater at each time period ($P < 0.01$). The difference between the estimated HbA_{1c} means was greater in the intervention group than in the control group by at least 0.65 at all time periods and progressively enlarged to 0.87 by study end (Fig. 2). We found no relationship between duration of diabetes and HbA_{1c} changes from baseline to the end of the study or between duration of diabetes and end HbA_{1c} in either the intervention or control groups.

Percentage of participants achieving HbA_{1c} goals

We analyzed the percentage of participants who achieved specified HbA_{1c} goals (≤6.5, ≤7.0, or ≤7.5%) on at least one occasion during the study. Figure 3 shows that the percent of HbA_{1c} values that achieved target was consistently greater in the intensive group compared with the control group at the level of ≤6.5, ≤7.0, and ≤7.5%. The differences in percent of values achieving target between groups were significant at all three levels of HbA_{1c} ($P < 0.01$).

Medication usage

Diabetes medication usage was quantified using a simple scoring system, assigning one point for each medication used and dividing medications into oral agents or insulin. As shown in Table 4, the greater reduction in HbA_{1c} observed throughout the study in the intervention group was accompanied by an increased use of oral hypoglycemic agents without any significant change in the number of subjects using insulin. In contrast, no significant change in medication use occurred in the control group.

Secondary outcome variables

Measures of weight, blood pressure, and lipid status were also analyzed in the intervention and control groups (Table 5). In the intervention group, there were significant changes from baseline to the end of the study with decreases in diastolic blood pressure ($P = 0.012$), LDL cholesterol ($P < 0.001$), and total cholesterol ($P = 0.018$) and an increase in HDL cholesterol ($P = 0.012$) that were associated with case management. In the control group, there were similar but nonsignificant decrements in diastolic blood pressure, LDL cholesterol, and total cholesterol; however, the increase in HDL cholesterol was statistically significant ($P = 0.04$). Despite the differences observed between baseline and end of study (up to 36 months of observation) within the intervention group, when the results at the end of the study from the intervention and control groups were compared

Table 4—*Analysis of medication usage**

	Intervention	Control	Intervention versus control	*P* value†
n	176	117		
All medications				
Baseline	1.64 ± 0.10	1.49 ± 0.11	0.16 ± 0.15	0.297
Ending	2.05 ± 0.11	1.50 ± 0.11	0.56 ± 0.16	<0.001
Change (ending to baseline)	0.41 ± 0.15	0.01 ± 0.16	0.40 ± 0.22	0.064
P value for change	<0.001	0.957	0.064	—
Oral agent				
Baseline	0.97 ± 0.07	0.88 ± 0.09	0.09 ± 0.11	0.454
Ending	1.40 ± 0.09	0.93 ± 0.09	0.47 ± 0.13	<0.001
Change (ending to baseline)	0.43 ± 0.12	0.05 ± 0.12	0.38 ± 0.17	0.026
P value for change	<0.001	0.680	0.026	—
Insulin				
Baseline	0.67 ± 0.06	0.61 ± 0.07	0.07 ± 0.10	0.466
Ending	0.65 ± 0.06	0.56 ± 0.07	0.09 ± 0.09	0.334
Change (ending to baseline)	−0.02 ± 0.09	−0.04 ± 0.10	0.02 ± 0.13	0.880
P value for change	0.794	0.669	0.880	—

Data are means ± SE. *Medication usage is quantified using an arbitrary medication score (one unit is assigned for each medication used); see RESEARCH DESIGN AND METHODS. †The *P* value for the difference between the intervention and control groups.

Table 5—*Effect of diabetes case management upon secondary outcome variables*

Variable	Desired level	*n* (Int/Con)		Intervention	Control
Weight (kg)	NA	182/172	Baseline	89.39	85.00
			Ending	89.28	83.85
			P value*	0.971	0.685
BMI (kg/m^2)	<25	182/165	Baseline	34.04	32.79
			Ending	34.02	32.45
			P value	0.980	0.732
Blood pressure: systolic (mmHg)	<130	182/172	Baseline	136.25	134.04
			Ending	133.42	134.62
			P value	0.184	0.789
Blood pressure: diastolic (mmHg)	<80	182/172	Baseline	77.24	76.40
			Ending	74.38	75.52
			P value	**0.012**	0.453
LDL (mg/dl)	<100	129/107	Baseline	129.88	127.25
			Ending	115.61	121.03
			P value	**<0.001**	0.186
HDL (mg/dl)	>55 F	139/121	Baseline	42.53	42.84
	>45 M		Ending	46.51	46.32
			P value	**0.012**	**0.040**
Cholesterol (mg/dl)	<200	176/156	Baseline	209.41	211.84
			Ending	198.32	205.59
			P value	**0.018**	0.209
Triglyceride (mg/dl)	<200	174/154	Baseline	205.14	215.89
			Ending	186.72	200.71
			P value	0.236	0.358

**P* value compares end values with baseline within each group. Significant values are in bold print.

with each other, there were no significant differences between the two groups for change in weight, BMI, systolic blood pressure, or triglyceride levels.

Effects of case management on rates of hypoglycemia

Frequency of severe hypoglycemia was assessed. Severe hypoglycemia was defined as requiring the assistance of another person, which is comparable with that used in the Diabetes Control and Complications Trial (1). The number of severe hypoglycemic events was small and frequency similar across study sites. The incidence of severe hypoglycemia was greater in the intervention group compared with the conventional group (6.95 vs. 3.55%); however, this difference was not statistically significant (P = 0.28). Likewise, the difference in the rate of hypoglycemic events per 100 patient-years in the intervention and conventional groups was not significant (P = 0.22).

CONCLUSIONS — The goals of the case management intervention used during this study focused on improving diabetes care and associated outcomes, with glycemic control being the major outcome measure. Interventions were designed to enhance individual participant self-management efforts, improve access to needed supplies and services, identify and address associated risk factors, minimize participant loss to follow-up, and facilitate access to needed community resources. The study protocol included basic guidelines for glucose and medication management, as well as goals for treatment of hypertension and dyslipidemia. Treatment goals and targets for therapy were uniform across sites. However, each clinical center had flexibility to use individualized treatment algorithms and strategies to achieve these goals. Participant interactions were designed to address glycemic control, lifestyle adjustments, learning deficiencies and needs, and overall adaptation to self-management. Ongoing collaboration with the primary care provider was crucial to the participant's care.

This study provides evidence that diabetes case management is feasible and can substantially improve glycemic control in a racial/ethnic minority and/or low-income Medi-Cal population. A progressive reduction in HbA_{1c} over the study period was seen in both groups, from 9.54 to 7.66% (a reduction of 1.88%) in the intervention group and from 9.66 to 8.53% (a reduction of 1.13%) in the control group. The difference between the HbA_{1c} means as estimated by the mixed effects model was greater in the intervention group than in the control group by at least 0.65% at all time periods and progressively enlarged to 0.87% by the study end. This improvement in HbA_{1c} in the intervention group was most likely due to the addition of the case-management strategy and not just medication induced.

Both the intervention group and the control group achieved a sizeable drop in HbA_{1c} levels during this study. However, we had not expected the extent of the improvement seen in the control group. Factors that may have influenced the change in this group include the following: *1*) primary care providers responsible for the management of intervention participants also provided care for control group participants and may have altered their intervention strategies based upon observations of unmasked outcomes in the intervention group; *2*) control participants were required to have HbA_{1c} testing every 6 months, and the frequency and results of these data may have had an effect on improving glycemic control; and *3*) regression toward the mean in participants with elevated HbA_{1c} levels at baseline may explain part of the drop in HbA_{1c} observed in both treatment groups.

The secondary outcome variables showed a response to case management intervention that was similar but less dramatic than the HbA_{1c} response. In the intervention group, improvement in most risk factors was observed when compared with baseline; this included significant decreases in diastolic blood pressure, LDL, and total cholesterol, accompanied by a significant increase in HDL cholesterol. As with HbA_{1c}, the control group showed improvements from baseline that were similar but smaller than the intervention group. However, when the improvements observed within each group were compared between intervention and control groups, no significant advantage to being in the case management group was found. This is likely due to the fact that improvement occurred in both groups although it was not generally significant

in the control group. We conclude that with respect to our secondary outcome variables, case management was successful but did not manage to create an improvement greater than the modest effect achieved by the combination of improved standards of care and new, more powerful pharmaceuticals in the control group. Also, as with the HbA_{1c} effect discussed earlier, the design of the study may also have influenced diabetes care practices in the control group as a result of the provider education that accompanied intervention practices, diminishing the differences between the two groups.

In our present study, baseline parameters tested were not predictive of glycemic control outcomes. It is of interest to note that there was a positive correlation between the frequency of HbA_{1c} testing and the reduction in HbA_{1c} levels in the intervention group. This issue warrants further study. The observed glycemic control improvement was sustained over the 36 months of the study. This improvement persisted without weight gain or a significant increase in the frequency of severe hypoglycemia, two barriers that often interfere with participant willingness to strive for tight glycemic control (7,9,10).

Eliminating disparities that exist in health status among minority groups has become a national priority (20). Our study has demonstrated that diabetes case management is a feasible treatment approach that can substantially improve glycemic control in disadvantaged populations. The U.K. Prospective Diabetes Study demonstrated that improving glycemic control reduces the risk of the microvascular complications of type 2 diabetes (2). The Center for Disease Control Diabetes Cost-Effectiveness Group has shown that the costs per quality-adjusted life-year for intensive glycemic control are comparable with other commonly funded interventions, especially for individuals age <65 years (3). If disparities in the diabetes health status among racial/ethnic minority and low-income populations are to be reduced or eliminated, this study provides a basis to suggest that additional resources should be invested in providing systematic diabetes case management for these populations (27,28).

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APPENDIX

The California Medi-Cal Type 2 Diabetes Study Group

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