

# Nurse-Run, Telephone-Based Outreach to Improve Lipids in People With Diabetes

Henry H. Fischer, MD; Sheri L. Eisert, PhD; Rachel M. Everhart, MS; Michael J. Durfee, MSPH; Susan L. Moore, MSPH; Stanley Soria, RN; Diana I. Stell, RN; Cecilia M. Rice-Peterson, RN, BSN; Thomas D. MacKenzie, MD, MSPH; and Raymond O. Estacio, MD

**D**iabetes is a disease growing in epidemic portions worldwide with associated costs that significantly impact healthcare systems. In the United States more than 20 million persons have been diagnosed with diabetes, a number which at the current rate will increase to more than 30 million by the year 2030.<sup>1,2</sup> Estimates of diabetes costs rose from \$130 billion in 2002 to \$174 billion in 2007, and are projected to reach \$192 billion by 2020.<sup>1,3,4</sup>

In our safety-net institution, Denver Health Medical Center (DHMC), the majority of patients with diabetes are of Latino ethnicity (59%) with a substantial minority being of African American race (21%). Most of the patients enrolled in our system have either no or inadequate insurance coverage. Consistent with national trends, the majority of our patients with diabetes do not meet the targets of care recommended by the American Diabetes Association (ADA) and National Cholesterol Education Program (NCEP) guidelines.<sup>5</sup> These guidelines are based on numerous prospective interventional studies which demonstrated the delay or prevention of the microvascular and macrovascular complications associated with this disease.<sup>6,7</sup>

The reasons for suboptimal performance on diabetes outcomes are complex and involve the patient, the provider, the systems of healthcare delivery, the ability to track and assist patient populations, and societal-level factors.<sup>4</sup> Potentially modifiable patient-level factors include lack of diabetes education, resources, and motivation. Competing demands in the 20-minute visit limit the provider's ability to identify barriers and educate and motivate patients.<sup>8,9</sup>

Nurse-run case management programs may overcome some of these chronic disease management barriers through frequent patient contact, tracking of patients, and the use of motivational interviewing and self-management techniques. Recent reviews of diabetes disease-management programs point to mounting evidence for the benefits of nurse-run case management and targeted interventions in the clinic.<sup>10,11</sup> There is a growing but insufficient study of telephone-based case management in diabetes. Telephone-based diabetes interventions have often focused on glycemic control, targeting the veteran population as well as elderly, ethnically diverse patients,<sup>12-15</sup> and often focus on glycemic control. To

date, however, we are not aware of any study of a nurse-run, telephone-based intervention to improve lipid control in a population with diabetes com-

**Background:** There is a need for randomized, prospective trials of case management interventions with resource utilization analyses.

**Objectives:** To determine whether algorithm-driven telephone care by nurses improves lipid control in patients with diabetes.

**Design:** Prospective, randomized, controlled trial.

**Participants:** Adults with diabetes at a federally funded community health center were randomly assigned to intervention (n = 381) or usual-care (n = 381) groups.

**Interventions:** Nurses independently initiated and titrated lipid therapy and promoted behavioral change through motivational interviewing and self-management techniques. Other parameters of diabetes care were addressed based on time constraints.

**Main Measures:** The primary outcome was the proportion of patients with a low-density lipoprotein (LDL) less than 100 mg/dL. Secondary outcomes included the number of hospital admissions, total hospital charges per patient, and the proportion of patients meeting other lipid, glycemic, and blood pressure guidelines.

**Key Results:** The percent of patients with an LDL <100 mg/dL increased from 52.0% to 58.5% in the intervention group and decreased from 55.6% to 46.7% in the control group ( $P < .01$ ). Average cost per patient to the healthcare system was less for the intervention group (\$6600 vs \$9033,  $P = .03$ ). Intervention patients trended toward fewer hospital admissions ( $P = .06$ ). The intervention did not affect glycemic and blood pressure outcomes.

**Conclusions:** Nurses can improve lipid control in patients with diabetes in a primarily indigent population through telephone care using moderately complex algorithms, but a more targeted approach is warranted. Telephone-based outreach may decrease resource utilization, but more study is needed.

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**In this article**  
Take-Away Points / p78  
[www.ajmc.com](http://www.ajmc.com)  
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**For author information and disclosures, see end of text.**



### Take-Away Points

Nurses can improve lipid control in patients with diabetes in a primarily indigent population through telephone care using moderately complex algorithms, but a more targeted approach is warranted. Telephone-based outreach may decrease resource utilization, but more study is needed.

- The percent of patients with a low-density lipoprotein <100 mg/dL increased from 52.0% to 58.5% in the intervention group as compared with decreasing from 55.6% to 46.7% in the control group.
- Average cost per patient to the healthcare system was less for the intervention group (\$6600) than for the control group (\$9033).
- Intervention patients trended toward fewer hospital admissions.

education side effects and a 6-week follow-up call to recheck lipids after medication changes.<sup>16</sup> The nurses were also trained in motivational interviewing techniques and facilitation of patient self-management. Additionally, the nurses used algorithms addressing other aspects of diabetes care which included glycemic and blood pressure control, update on vaccinations, and facilitation of primary care provider (PCP) and subspecialty appointments based on time constraints. The nurses used pre-printed prescriptions signed by a physician champion who offered educational and management support.

posed mainly of minorities with no or inadequate insurance coverage. Also, there is a call for large, prospective diabetes case-management interventions with resource utilization analyses.<sup>11</sup>

## METHODS

### Design, Setting and Participants, and Randomization

The design, setting and participants, and randomization flow are described in a previous publication.<sup>16</sup> Briefly, this randomized, controlled trial was conducted at Denver Health's Westside Family Health Center (Westside Clinic), a federally funded community health center which serves a primarily indigent, Latino population. We included only adult patients (aged >17 years) in our diabetes registry who were actively utilizing Westside Clinic for their primary care (at least 2 visits in the past year) and who spoke either English or Spanish. We sought to maximize the generalizability of the study and therefore had only minimal exclusion criteria: pregnant or lactating women, patients with end-stage renal disease (creatinine >3.0 mg/dL), and/or a comorbid illness with life expectancy less than 12 months (eg, terminal cancer or Child's-Pugh Class C hepatic cirrhosis).

### Intervention

The details of this intervention have been previously published.<sup>16</sup> Briefly, this telephone outreach program lasted 20 months, ending in May 2007, and was considered an adjunct to usual care. At the time of this intervention, usual care consisted of largely primary care provider-driven diabetes care with most providers recommending clinic visits every 1 to 3 months for patients not at diabetes goal, and every 6 months for those at goal. The study nurses focused on lipid management, using algorithms based on published guidelines from the most current NCEP and ADA recommendations.<sup>17,18</sup> The nurses independently checked labs and initiated and titrated lipid-lowering medications over the telephone with a 2-week follow-up call to assess for medi-

### Baseline Data

Relevant demographic and laboratory data were extracted from an integrated electronic health record for all patients. Comorbidities were determined based on all historical diagnosis codes that existed for the patients in our integrated system. Medication use was determined based on outpatient pharmacy records for prescriptions that were filled within our system in the 3 months leading up to study initiation.

### Outcomes and Measures

The primary outcome is the proportion of patients (both with and without cardiovascular disease [CVD]) with a low-density lipoprotein (LDL) less than 100 mg/dL, secondary outcomes include: 1) average hospital charges per patient including inpatient, outpatient, emergency department, and intervention costs; 2) total number of inpatient admissions; 3) proportion of patients with CVD with an LDL less than 70 mg/dL per NCEP guidelines<sup>17</sup>; 4) percentage of patients with last blood pressure less than 130/80 mm Hg as recommended by The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure<sup>19</sup> percentage of patients with glycated hemoglobin (A1C) less than 7 mg/dL per ADA guidelines.<sup>18</sup>

### Statistical Analysis

#### Sample Size Calculations

We performed a conservative sample size estimate by assuming that 50% of control patients at study end would achieve the target LDL of less than 100 mg/dL (no improvement) as compared with 70% in the intervention group. Utilizing an alpha = 0.05, power of 90%, we estimated that we needed 129 patients in each randomization group. However, we expanded the sample size to 381 patients in each group since previous chronic disease management at DHMC suggested nurses could handle a panel of this size and allowed for cost analyses.



### Clinical Outcomes Analyses

Differences in lipid, glycemic, and blood pressure outcomes were compared pre- and post-intervention for both the control and treatment groups using an intention-to-treat analysis. Patients without a lab value during the designated time period were counted as not being at goal for that time period. Multivariate logistic regression controlled for baseline lipid performance, age, gender, insurance, and ethnicity for the primary lipid outcomes. Statistical analyses were performed using SAS (version 9.1, SAS Institute Inc, Cary, North Carolina) software.

### Measuring Healthcare Utilization and Costs

Nine separate multiple linear regression models were used to compare treatment and control groups over time according to the following utilization and cost measures: number of inpatient admissions; number of outpatient visits; number of emergency visits; total inpatient costs; total outpatient costs; total emergency costs; sum of all costs; and total cost per patient enrolled.

The linear models were adjusted to account for differences in age, race/ethnicity, gender, baseline levels for each outcome variable, and degree of illness, and included generalized estimated equations (GEEs) to account for the within-subject correlation of repeated measures by individual patients. Patients lost to follow-up, defined as no primary care visit in the year preceding the end of the study, were not assessed when comparing baseline with the intervention period, for consistency of results.

Costs were evaluated from the perspective of the healthcare system, which included case-management programmatic costs and the incremental costs associated with the change in the utilization of healthcare services. Cost-to-charge ratios were used to convert charges to the patients into costs to the healthcare system. These ratios are developed using the total costs divided by the total charges for inpatient admits, outpatient visits, and emergency visits separately. These total costs include indirect and direct costs. The cost-to-charge ratios applied were 0.43 for inpatient admits, 0.51 for outpatient visits, and 0.35 for emergency visits.

### Risk Adjustment

The Chronic Illness and Disability Payment System (CDPS) diagnostic classification model was used to risk adjust the study population. CDPS uses a diversity of *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)* codes to group and weight diagnoses for chronic and disabling diseases.<sup>20</sup> A comparison among Medicaid beneficiaries found that CDPS compared favorably with other leading diagnostic classification systems, with

moderate advantage over the Hierarchical Condition Category model and significant advantage over the Adjusted Clinical Groups model.<sup>20</sup> Given that more than 90% of the study patient population is composed of Medicaid patients and the uninsured, the CDPS model was chosen to best reflect the degree of illness among the study participants.

### Role of the Funding Source

This study was in part funded by the ADA, which played no role in patient selection, implementation of the intervention, interpretation of the data, or writing of the manuscript.

## RESULTS

### Baseline Characteristics

Overall, the randomization of participants resulted in similar baseline characteristics (**Table 1**). The intervention and usual care groups were comparable in insurance type, ethnicity, and age. There were more females in the intervention group (64.0% vs 57.2%,  $P = .05$ ). There was no significant difference in baseline laboratory values, except for a lower baseline creatinine level in the intervention group (0.87 mg/dL vs 0.94 mg/dL,  $P = .01$ ). There was no significant difference in any of the primary or secondary clinical outcomes at baseline (**Table 2**). Baseline comorbidities based on ICD-9-CM codes, including hypertension, coronary artery disease, peripheral vascular disease, congestive heart failure, and renal failure, were equivalent in the 2 groups (**Table 1**). There was a higher percentage of participants with a baseline history of cerebrovascular disease in the control group (14% vs 9%,  $P = .04$ ). Assessment of baseline risk using the CPDS risk adjustment methodology showed no difference between the intervention and usual care groups ( $P = .46$ ).

### Lipid and Secondary Clinical Outcomes

The intervention group performed significantly better than the usual-care group on our primary outcome, the percent of patients with an LDL less than 100 mg/dL in the preceding year (increased from 52.0% to 58.5% vs decreased from 55.6% to 46.7%,  $P < .01$ , **Table 2**). An “on-intervention” analysis (**Table 3**) compared lipid outcomes for the control group versus intervention patients with 3 or more contacts by the nurses during the study period. A higher percentage of the patients in this intervention subgroup were at goal at study end for the primary lipid outcome of LDL less than 100 mg/dL (69.1% vs 46.7%,  $P < .01$ ). Among those patients with cardiovascular disease, only the “on-intervention” patients achieved the goal of LDL less than 70 mg/dL more than the control patients (50.0% vs 30.4%,  $P = .02$ ). The intervention did not impact glycemic and blood pressure outcomes.

■ **Table 1.** Baseline Patient Characteristics

Demographics	Intervention (n = 381)	Control (n = 381)	P
<b>Gender (%)</b>			.05
Female	64.0	57.2	
Male	36.0	42.8	
<b>Ethnicity (%)</b>			.69
American Indian	1.3	0.8	
Asian	0.5	0.0	
African American	3.4	3.1	
Latino	81.6	81.1	
White	12.6	14.4	
Unknown	0.5	0.5	
<b>Insurance type (%)</b>			.48
Medicare or Medicaid	56.2	57.5	
Uninsured	42.5	40.2	
Private	1.3	2.4	
<b>Current smoker (%)</b>	24.0	22.6	.66
<b>Mean age (SD)</b>	58.5 (12.4)	58.3 (12.1)	.84
<b>Laboratory values, mean (SD)</b>			
Total cholesterol <sup>a</sup>	176.4 (41.4)	173.4 (46.3)	.38
LDL <sup>a</sup>	89.1 (29.9)	85.3 (33.0)	.13
HDL <sup>a</sup>	47.0 (11.4)	46.6 (11.8)	.67
Triglycerides <sup>a</sup>	213.8 (177.3)	225.9 (204.1)	.43
A1C	8.5 (2.1)	8.3 (2.1)	.24
Creatinine <sup>a</sup>	0.87 (0.32)	0.94 (0.41)	.01
Urinary albumin/creatinine ratio (%)	N = 191	N = 201	.79
Normal (<.02)	50.8	49.8	
Micro (>.02 and <0.2)	37.2	36.8	
Macro (>0.2)	12.0	13.4	
<b>Blood pressure</b>			
Systolic (mm Hg)	130.6 (19.3)	130.6 (20.1)	.96
Diastolic (mm Hg)	74.4 (10.8)	74.5 (11.3)	.86
Body mass index <sup>a</sup> mg/dL	32.9 (7.2)	33.1 (7.5)	.72
<b>Comorbidities (%)</b>			
Hypertension	85	84	.76
Coronary artery disease	19	17	.30
Cerebrovascular disease	9	14	.04
Peripheral vascular disease	5	4	.86
Congestive heart failure	14	14	1.00
Renal failure	49	53	.31
<b>Medication use (%)</b>	<b>Intervention (n = 160)</b>	<b>Control (n = 146)</b>	
Statin	45.0	47.3	.69
Fibrate	5.0	4.8	.93
Niacin	0	0	—
Sulfonylurea	50.6	36.3	.01
Thiazolidinedione	11.9	12.3	.90
Biguanide	63.1	65.8	.63
Insulin	24.4	37.7	.01
ACE inhibitor or ARB	60.0	56.9	.58
Thiazide diuretic	25.6	27.4	.73
Beta-blocker	19.4	22.6	.49
Calcium channel blocker	14.4	13.0	.73

A1C indicates glycated hemoglobin; ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SD, standard deviation.

<sup>a</sup>A patient was counted as not being at goal if he/she did not have the lab or blood pressure measured during preceding year.



■ **Table 2. Outcomes**

Outcomes <sup>a</sup>	Baseline		P	Post-Intervention		P	Adjusted OR <sup>b</sup>	95% CI
	Intervention % (n = 381)	Control % (n = 381)		Intervention % (n = 381)	Control % (n = 381)			
LDL checked in past year	78.7	78.5	.93	69.8	60.1	.01	1.57	1.16-2.14
LDL <100 mg/dL	52.0	55.6	.31	58.5	46.7	<.01	1.72	1.28-2.32
Cardiovascular disease <sup>c</sup>	26.0	26.8	.81	27.3	26.8	.87	1.17	0.72-1.91
LDL checked in past year	81.8	84.3	.64	72.1	61.8	.11	1.83	0.99-3.39
LDL <70 mg/dL	31.3	36.3	.46	39.4	30.4	.17	1.31	0.65-2.67
BP <130/80 mm Hg	48.9	44.1	.22	—	44.5	50.2	.20	—
A1C <7.0	18.1	19.7	.58	—	16.3	15.5	.77	—

A1C indicates glycated hemoglobin; BP, blood pressure; CI, confidence interval; LDL, low-density lipoprotein.

<sup>a</sup>A patient was counted as not being at goal if he/she did not have the lab or blood pressure measured during preceding year.

<sup>b</sup>Adjusted for baseline status of outcome, age, insurance, gender, and race/ethnicity.

<sup>c</sup>Based on ICD-9-CM codes indicating coronary artery disease, cerebral vascular disease, or peripheral arterial disease.

### Healthcare Utilization and Costs

**Table 4** provides a comparison between the intervention and control groups regarding utilization of healthcare services. At baseline, the control and treatment groups experienced similar rates of outpatient and emergency department (ED) visits. The control patients at baseline experienced more hospital admissions and higher associated cost per patient than the intervention patients. During the study period, the rate of inpatient admissions decreased for the intervention group whereas there was an increase for the control group that trended toward statistical significance (adjusted GEE,  $P = .06$ ).

The case management intervention was not associated with a change in the number of outpatient visits (adjusted GEE,  $P = .60$ ) or the number of emergency care visits (adjusted GEE,  $P = .19$ ). For the nurse telephone intervention group, we observed a significant decrease in total costs of \$60,802 when comparing the 18-month time period prior to randomization with the same time period post randomization. In contrast, there was an increase of \$477,467 for the same comparison in the control group (adjusted GEE,  $P = .01$ ). Similar results were demonstrated with hospitalization

costs; the intervention group was associated with a decrease of \$109,077 versus an increase of \$268,723 in the control group (adjusted GEE,  $P = .02$ ). A similar trend was seen for ED costs (decreased by \$13,702 vs increased by \$39,890 in the control group, adjusted GEE,  $P = .05$ ). There was not a significant intervention effect on outpatient costs (adjusted GEE,  $P = .47$ ). This pattern of healthcare utilization was not altered in our “on-intervention” analysis (data not shown).

The direct programmatic costs for the case management program were \$134,750 over the 20-month intervention. Incorporating programmatic costs, the average cost per patient to the healthcare system for patients enrolled in the nurse case management program was \$6600 whereas the average cost per patient for those with diabetes not enrolled in the program was \$9033. The difference in average per-patient cost between these 2 groups was \$2433 (adjusted GEE,  $P = .03$ ).

### DISCUSSION

This nurse-run, telephone-based case management program served a vulnerable, underinsured population and was associated with improved lipid control and a decrease in

■ **Table 3. On-Intervention Lipid Outcomes Analysis**

	On Intervention <sup>a</sup> (n = 217)	Control (n = 381)	P
LDL checked in past year	83.9	60.1	<.01
LDL <100 mg/dL	69.1	46.7	<.01
Cardiovascular disease <sup>b</sup>	24.0	26.8	.45
LDL checked in past year	88.5	61.8	<.01
LDL <70 mg/dL	50.0	30.4	.02

LDL indicates low-density lipoprotein.

<sup>a</sup>At least 3 contacts by nurses during the study period.

<sup>b</sup>Based on ICD-9-CM codes indicating coronary artery disease, cerebral vascular disease, or peripheral arterial disease.



■ **Table 4.** Utilization of Services and Costs

	Pre-intervention Feb 1, 2004, to Sep 30, 2005		Study Period Oct 1, 2005, to May 31, 2007		P <sup>a</sup>
	Intervention n = 352	Control n = 357	Intervention n = 352	Control n = 357	
<b>Inpatient Admissions</b>					
Total number of patients with hospital admission	79 (22.4%)	89 (24.0%)	69 (19.6%)	90 (25.2%)	
Total number of hospital admissions	133	162	112	184	.06
Total inpatient costs	\$978,612	\$1,433,959	\$869,535	\$1,702,682	.02
<b>Outpatient visits</b>					
Total number of patients with outpatient visits	352 (100.0%)	357 (100.0%)	351 (99.7%)	356 (99.7%)	
Total number of visits	6711	6717	5955	5934	.60
Total outpatient costs	\$1,175,293	\$1,212,646	\$1,237,270	\$1,381,900	.47
<b>ED visits</b>					
Total number of patients with ED visits	95 (27.0%)	91 (25.5%)	92 (26.1%)	103 (28.9%)	
Total number of ED visits	136	148	134	176	.19
Total ED costs	\$95,270	\$100,305	\$81,568	\$140,195	.05
<b>Total cost (inpatient + outpatient + ED)</b>	<b>\$2,249,174</b>	<b>\$2,746,910</b>	<b>\$2,188,372</b>	<b>\$3,224,377</b>	<b>.01</b>
Average cost per patient	\$6390	\$7694	\$6217	\$9033	

ED indicates emergency department.

<sup>a</sup>Comparison of costs utilized between intervention groups over time, adjusting for differences in demographics, baseline utilization, and degree of illness.

overall healthcare utilization. The percentage of patients achieving the LDL goal of less than 100 mg/dL increased in the intervention group and decreased in the usual-care group. The intervention was also associated with higher percentage of patients with pre-existing cardiovascular disease reaching a more rigorous target of LDL less than 70 mg/dL. Additionally, the intervention was associated with lower healthcare utilization and total costs, which was primarily attributable to less inpatient and emergency department utilization. There was no significant difference in other secondary outcomes, including glycemic control and blood pressure control.

The strength of the current study is that it was completed in a vulnerable underinsured population composed mainly of Latino patients while utilizing less than 1 full nurse full-time equivalent (FTE). This population is often difficult to reach and has historically had low rates of compliance and clinic attendance. This is certainly exemplified in our study, in which the nurse was unable to contact 65 of the 381 patients. Of the remaining 316 patients, 217 were contacted 3 or more times throughout the intervention. Despite these obstacles, the intervention demonstrated a positive effect on achieving lipid control when compared with the control group. Furthermore, there appeared to be a dose effect of the intervention. When including only patients who had at least 3 contacts with the nurse, the percentage reaching an LDL goal of less than 100 mg/dL increased to nearly 70%.

A disappointing finding, but not surprising given the nurse focus on lipids, was that the intervention did not impact blood pressure or glycemic control when compared with the control group. These results are compared with studies performed by Piette et al in 2 county health clinics<sup>21</sup> and in the Veterans Administration Healthcare System<sup>12</sup> in which automated calls combined with a nurse follow-up call resulted in improved glycemic control, fewer hypoglycemic reactions, and greater patient satisfaction with their healthcare. In both these studies, there appeared to be more patient interaction with the healthcare system when compared with our intervention. Improving blood pressure and glycemic control often requires more complex medication regimens than lipid control. For lipid control, using 1 medication, a statin, would often be sufficient to get the patient to goal. A major difference between our study and the studies of Piette et al is the method of recruitment of patients into the study. For our study, we purposely randomized patients from our diabetes registry prior to contacting them as opposed to recruiting at clinic visits. This design enabled us to evaluate the efficacy and effectiveness of the intervention across a broad sample of our diabetes population. As a result, the study nurse was unable to contact 17% of the 381 patients randomized to the intervention.

At baseline, over 20% of the intervention population was hospitalized at least once 18 months prior to randomization and more than 25% made at least 1 ED visit. During



the follow-up period of nearly 20 months, the intervention was associated with lower overall costs and a trend toward less hospitalizations. It is difficult to establish causality between the intervention and the lower healthcare utilization. One could hypothesize that the increased number of inpatient admissions in the control group related to hyper- and hypoglycemia, as well as secondary infection (pneumonia and pyelonephritis), might have been prevented with closer nurse-based monitoring. Frequent contact would allow nurses to identify worrisome clinical indicators and coordinate care to prevent worsening clinical status. Chart review revealed that of the 5 control patients with the highest charges, 3 failed to follow up as recommended by their primary care providers. One of these 3 patients was admitted with hyperglycemia and sepsis and required additional admits for secondary complications; another was admitted for hyperglycemia and osteomyelitis, which also led to subsequent admits; and the third patient developed recurrent cellulitis and urinary tract infections.

Were there baseline differences between the intervention and control groups that may have affected our results? The control and intervention groups did not differ significantly in baseline comorbidities, except for a higher baseline rate of cerebrovascular disease in the control group, a difference that was small but statistically significant (14% vs 9%,  $P = .04$ ). Also, a higher percentage of control patients were using insulin at baseline (38% vs 24%,  $P = .01$ ). In our healthcare utilization analysis, GEE equations adjusted for the higher percentage of females in the intervention group. Most strikingly, the control group had higher baseline hospitalization rates and total costs. As discussed in the methods section, the CPDS risk adjustment methodology was well suited to the DHMC patient population, which demonstrated equivalent baseline risk between the 2 groups. Although we demonstrated impressive results regarding a decrease in both hospitalizations and total costs in the intervention group while both increased in the control group, our results should be interpreted with caution given the baseline differences noted above.

How can we improve the design of this case-management intervention? As noted, we purposely designed this randomized study to evaluate the effectiveness and the “reach” of this program. This aspect of the study is important since many safety net healthcare institutions, like ours, provide care to thousands of patients with diabetes and confront similar obstacles for their patients accessing care. The major obstacle as reported by the nurses for this study was the difficulty contacting and obtaining buy-in from some patients. Unfortunately we did not include focus groups or individual interviews to clearly identify obstacles and potential solutions with the patients.

Nurses could expand their panel size in 2 ways. First, medical assistants could take the lead role in using the diabetes registry on a regular basis to identify and contact those patients due for labs or follow-up. Or, ideally, automated flagging of and outreach to at-risk patients would occur through an electronic health record through various modalities, such as text message, automated phone calls, e-mail, Skype, audio video telemedicine, patient portals, or smart phone applications, based on patient preference. Second, nurses could change their focus to starting statin medications, as opposed to up-titrating them, which is a time-consuming, lower-yield process. The nurses would need to be allotted sufficient time to also implement basic blood pressure and glycemic control algorithms, taking much of the chronic-disease management out of the PCP's hands. In this primary care delivery redesign, the physician would increasingly supervise nurses and staff. Physician visits would focus on complex patients and allow more time to respond to patient-centered agendas.<sup>22</sup> To implement this redesigned chronic-disease management, we will need to overcome important barriers, including getting buy-in from our patients, providers, staff, and institution, as well as the pressures tied to the external reporting of performance measures, such as provider productivity.

A limitation of this study is the possibility that participants may have used services in other healthcare centers, resulting in an underestimate of total costs. This is unlikely to affect the comparison of the intervention with the control patients since both groups were equally likely or unlikely to obtain outside medical care. Furthermore, our patient population had high rates of uninsurance and Medicaid coverage, making it difficult to seek care in other healthcare facilities. We did not include medication analyses or medication side effect and adherence data, given our incomplete medication database, as only our uninsured patients, making up less than half the cohort, had financial incentives to fill at DHMC pharmacies. Although the nurses tracked statin initiations, titrations, and side effects, we did not include these data, as the nurses admit to not always recording these data for every patient contact. Another limitation was that the study was performed at 1 site in which the 3 study nurses shared 0.75 FTE. Given that the nurses also interacted with control patients, contamination of the intervention was a possibility, thus diluting the effect of the intervention. Furthermore, investigators doing the analysis of the data were not blinded to control versus intervention patients. There is also an increased risk of finding differences by chance (type 1 error) when performing multiple hypotheses at a set  $P$  value,<sup>23</sup> as seen in these analyses. It should be noted that our primary end point is lipid control, and that the other secondary end points are informative, but that further analyses with sepa-

rate data sources are necessary to better assess their merit. Also, while over 90% of our diabetes population is type 2, we did not distinguish between Type 1 and Type 2 in our analysis.

This intervention took place in a safety-net health organization that serves a predominantly indigent and Latino population. The intervention was facilitated by the presence of a diabetes registry with a software interface for identifying patients not meeting recommended diabetes guidelines. The use of motivational interviewing techniques and the promotion of patient self-management were key components of this intervention. The results must be interpreted in this context and are most relevant to other community health centers that participate in diabetes collaboratives and serve primarily indigent populations.

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**Author Affiliations:** From Denver Health and Hospital Authority (HHF, SLE, RME, MJD, SLM, SS, DIS, CMR-P, TDM, ROE), Denver, CO; Colorado School of Public Health (SLE), University of Colorado Denver, Denver, CO; University of Colorado Denver School of Medicine (HHF, SLE, TDM, ROE), Denver, CO.

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**Address correspondence to:** Henry H. Fischer, MD, WFHC Adult Clinic, 1100 Federal Blvd, Denver, CO 80204. E-mail: henry.fischer@dhha.org.

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