

Improved Outcomes in Diabetes Care for Rural African Americans

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ABSTRACT

PURPOSE Rural low-income African American patients with diabetes have traditionally poorer clinical outcomes and limited access to state-of-the-art diabetes care. We determined the effectiveness of a redesigned primary care model on patients' glycemic, blood pressure, and lipid level control.

METHODS In 3 purposively selected, rural, fee-for-service, primary care practices, African American patients with type 2 diabetes received point-of-care education, coaching, and medication intensification from a diabetes care management team made up of a nurse, pharmacist, and dietitian. In 5 randomly selected control practices matched for practice and patient characteristics, African American patients received usual care. Using univariate and multivariate adjusted models, we evaluated the effects of the intervention on intermediate (median 18 months) and long-term (median 36 months) changes in glycated hemoglobin (hemoglobin A_{1c}) levels, blood pressure, and lipid levels, as well as the proportion of patients meeting target values.

RESULTS Among 727 randomly selected rural African American diabetic patients (368 intervention, 359 control), intervention patients had a significantly greater reduction in mean hemoglobin A_{1c} levels at intermediate (−0.5% vs −0.2%; $P < .05$) and long-term (−0.5% vs −0.10%; $P < .005$) follow-up in univariate and multivariate models. The proportion of patients achieving a hemoglobin A_{1c} level of less than 7.5% (68% vs 59%, $P < .01$) and/or a systolic blood pressure of less than 140 mm Hg (69% vs 57%, $P < .01$) was also significantly greater in intervention practices in multivariate models.

CONCLUSION Redesigning care strategies in rural fee-for-service primary care practices for African American patients with established diabetes results in significantly improved glycemic control relative to usual care.

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INTRODUCTION

Data from the United Kingdom Prospective Diabetes Study (UKPDS) study has shown that improving glycemic and blood pressure control in patients with diabetes results in significant reductions in morbidity and mortality.¹ Many patients, particularly rural minority patients, however, do not achieve these recommended levels of care. Dansky et al² found that rural Medicare beneficiaries with diabetes mellitus reported fewer physician visits than urban patients, whereas others have shown that low-income, rural patients with diabetes are more likely to receive care from a primary care physician than from a specialist.^{3,4} In studies in the United States^{3,5,6} and Canada,⁷ diabetes care in rural areas has been found to be inadequate relative to the standards described by the American Diabetes Association (ADA) and often is of lower quality than in urban settings. In a study by Coon et al,⁸ as well as in studies of rural populations by Porterfield and Kinsinger⁹ and Bell et al,¹⁰ hyperglycemia was also less well controlled. Moreover, in unpublished data from 233 diabetic patients from the rural region of this study, African Americans were 1.7

times more likely than whites to have hemoglobin A_{1c} levels greater than 8.0%, even when controlling for age, education level, body mass index, and health insurance. These outcomes are confounded by poverty, which is also associated with patients not reaching goals.¹¹

Numerous interventions have been explored that address the challenges of inadequate control. In a Cochrane Collaboration systematic review of 41 studies involving 48,000 patients, the authors describe the effectiveness of health professionals–directed interventions, organizational change interventions, and patient-focused interventions.¹² In a recent assessment of system redesign using the Chronic Care Model,¹³ patients' hemoglobin A_{1c} levels decreased significantly with a redesigned practice but not in the usual care settings. Most studies, however, have occurred in urban prepaid or managed care settings involving mostly white patients. The system redesign techniques recommended in the Chronic Care Model for adoption in primary care¹⁴ have had limited evaluation in rural, fee-for-service, primary care practices that have substantial minority and low-income populations.¹⁵ Finally, most studies have examined only short-term outcomes, and more research on long-term outcomes is needed. We therefore implemented in fee-for-service, primary care practices a model of redesigned care that offered inter-professional care management for African American patients with type 2 diabetes to determine its effectiveness on their intermediate- and long-term glycemic, blood pressure, and lipid levels compared with patients receiving usual care in similar control practices.

METHODS

This quasi-experimental study assessed the effectiveness of a primary care practice redesign that included a care management intervention, piloted by the investigators,¹⁶ similar to the health-coaching requirements described for patient-centered medical homes.¹⁷ There are 6 key elements to the intervention design: education with behavioral coaching, treatment intensification, point-of-care management, expanded roles of clinic staff to facilitate management, a team-care approach, and physician leadership. Full details regarding the program's design, including a detailed description of clinic staff and leadership training, patient flow protocols, implementation details, start-up budgets, staff roles, and education protocols can be found at <http://www.ecarediabetes.org/>, the ECARE-DIABETES Web site.

All study practices were located in rural counties as defined by the US Census Bureau (ie, non-metropolitan statistical areas and with a population density of less than 1,000 persons per square mile). For the

intervention group, we purposively selected 3 rural, fee-for-service, primary care practices in which African Americans have traditionally poor clinical outcome as described above. All African American adult patients with type 2 diabetes received point-of-care diabetes care management involving education, self-management coaching, and medication adjustment from a team made up of a nurse case manager, pharmacist, and dietitian. The intervention clinics were purposefully selected because of local funding requirements and staff willingness to participate in diabetes quality improvement training and because senior leadership committed time and resources to improve clinical outcomes.

A nurse, pharmacist, and dietitian care manager traveled to the 3 different intervention practice sites on different days and provided proactive, individualized, office-based care management and follow-up as part of the usual office visit for adult patients with type 2 diabetes mellitus. Patients with new-onset type 2 diabetes mellitus or who had a hemoglobin A_{1c} level of greater than 7.5% were scheduled to be seen by one of the care managers. The clinical targets in the intervention practices included reducing elevated hemoglobin A_{1c} levels to 7.5%, blood pressure to less than 140/90 mm Hg, and low-density lipoprotein (LDL) cholesterol levels to less than 100 mg/dL. These pragmatic targets were selected because many of these patients were older, had multiple comorbidities, and had a long duration of diabetes, and because data have shown that African American patients have higher hemoglobin A_{1c} values than white populations.^{18,19}

The redesign model encouraged that diabetic patients in intervention practices be scheduled on specific days when the additional care manager was in the practice. Each patient was seen on average 4 times over a 12-month period by the nurse, pharmacist, or dietitian care manager for 30 to 60 minutes as part of and in addition to the traditional physician visit (ie, point of care). Subsequently the patient was seen every 3 to 6 months by the care manager as part of the physician visit for an additional 2 years. During these visits the care managers used a behaviorally centered coaching strategy that was tailored to overcome psychosocial and environmental barriers to behavioral change through a strong, culturally relevant focus on emotional, cultural, and social factors related to eating, activity, and medications. When a patient's hemoglobin A_{1c} level was above 7.5%, the pharmacist and nurse care managers, in collaboration with the primary care physician, increased the patient's medication regimen, including the dosage of current medications and the initiation of new oral medications or insulin.

A comparison group of patients was made up of African American adults with type 2 diabetes receiving

usual care from their regular physicians in 5 rural control practices. The practices were selected by stratified randomization (ie, stratified by practice financing to match the rural health clinic and community health center funding status in the intervention practices) from a sampling frame of similar regional practices (eg, similar practice financing and payer mix) and patient characteristics (eg, race, age). Usual care provided in the control clinics was a billable clinic visit to a physician, nurse practitioner, or physician assistant, but these clinicians did not provide point-of-care self-management coaching or a health coach-educator, and there was no team-based medication adjustment. Usual care visits lasted an average of 15 minutes and included standard measurement of hemoglobin A_{1c} levels, blood pressure, and lipid levels. Medications including insulin were prescribed and adjusted based on the sole clinical judgment of the physician. Diabetes educational handouts were frequently offered. In 2 control practice communities, a health educator was available at local health departments through referral.

To assess the impact of the intervention or usual care in each of the 8 practices, a biostatistician, using a review of billing and electronic health records, assigned a unique numerical identifier to African American patients with type 2 diabetes, and a sample of patients was obtained using a computer-based random number generator. The following patient data were then collected by unblinded staff at baseline, 18 months (intermediate), and 36 months (long term): demographic characteristics (age, sex, insurance, duration of diabetes); height, weight, and blood pressure using standard procedures; and blood specimens obtained by venipuncture and measured in the hospital laboratory using standard laboratory procedures for total, LDL, and high-density lipoprotein (HDL) cholesterol, and glycemic control (hemoglobin A_{1c}). The study was approved by the institutional review board, and each patient provided informed consent.

Descriptive statistics (means and *t* tests for continuous variables; proportions and χ^2 statistics for categorical variables) were used to characterize the study patients' demographic characteristics and diabetes-specific outcome measures at baseline. The study design used an intention-to-treat analysis; for patients who did not complete the study in both arms, the investigators carried the last observation forward for data analysis. Using baseline, 18-month (intermediate), and 36-month (long-term) follow-up values, we calculated the mean change in hemoglobin A_{1c} levels; systolic blood pressure; and total, LDL, and HDL cholesterol levels. Intervention and control outcome means were compared in univariate analyses using independent samples *t* tests. We also calculated the number and percentage

of patients who met target goals (defined above) at baseline and at the intermediate and final evaluations, each of which were compared by χ^2 analysis.

The data for hemoglobin A_{1c} levels were further analyzed using a linear mixed-modeling strategy to examine the overall impact of the composite intervention on change in hemoglobin A_{1c} levels in intervention practice patients relative to that in control practice patients using baseline values as a covariate. Specifically, these linear mixed models were constructed to assess the multivariate relationship between the continuous dependent variable (eg, change in hemoglobin A_{1c} level) and a variety of continuous and categorical variables, including age, sex, duration of diabetes, health insurance, practice attended (intervention vs control practice), and number of office visits in the last year. Likewise, the data on the proportion of patients achieving target values (eg, hemoglobin A_{1c} level of less than 7.5%) in intervention and control practices were analyzed using multivariable logistic regression that incorporated the same additional variables. All fitted models included correlation structures to accommodate clustering of patients in practices, and appropriateness of models was examined using residual analysis and model diagnostics. All analyses were performed using SAS 9 (SAS Institute).

Finally, although a full economic analysis is beyond the scope of this article, we briefly present a summary of total and per-patient program costs (primarily personnel costs for year 1 start-up and year 2 and 3) in comparison with the total 3-year patient panel served. A fuller description of costs and revenue, as well as potential business plans, are presented on the ECARE-DIABETES Web site (<http://www.ecarediabetes.org>).

RESULTS

Patients

Seven hundred twenty-seven randomly selected African American patients with established type 2 diabetes mellitus signed a statement of informed consent and were enrolled in this study, including 368 intervention practice patients, and 359 control practice patients. Approximately 5% of patients approached declined to participate in the study. A total of 25 patients in the intervention practices and 26 patients in the control practices did not complete the study. Dropouts were primarily due to patients moving from the area.

There were no statistically significant differences between patients in the intervention and control practices in demographic characteristics or in mean clinical parameters at baseline. The mean age was 59.5 years (SD = 12.0 years) for intervention and 60.6 years (SD = 12.4 years) for control patients, 66% of the inter-

Table 1. Comparison of Baseline Values and Intermediate and Long-Term Changes in Clinical Outcome Measures in Intervention and Control Practice Patients

Clinical Parameters	Control Practice (n = 359 Patients)			Intervention Practice (n = 368 Patients)		
	Baseline	18 Mo	36 Mo	Baseline	18 Mo	36 Mo
HbA _{1c} , mean (SD), %	7.9 (2.2)	7.7 (1.9)	7.8 (2.0)	7.9 (2.1)	7.4 (1.6) ^a	7.4 (1.9) ^b
≤7.5 %, No. (%)	134 (56)	170 (60)	165 (59)	164 (55)	189 (66)	146 (68) ^c
>7.5%, No. (%)	106 (44)	114 (40)	117 (41)	132 (45)	96 (34)	69 (32) ^c
Systolic/diastolic blood pressure, mean (SD), mm Hg	138 (18)/81 (10)	139 (16)/80 (9)	140 (17)/79 (10)	135 (16)/79 (8)	135 (14)/78 (9)	135 (16)/78 (9)
≤40 mm Hg, No. (%)	208 (64)	198 (59)	178 (57)	257 (71)	222 (69) ^c	171 (69) ^c
>140 mm Hg, No. (%)	116 (36)	140 (41)	134 (43)	107 (29)	101 (31) ^c	76 (31) ^c
LDL cholesterol, mean (SD), mg/dL	101 (36)	99 (38)	97 (32)	105 (33)	95 (32)	99 (36) ^a
≤100 mg/dL, No. (%)	64 (52)	141 (57)	136 (59)	94 (46)	128 (61)	91 (57)
>100 mg/dL, No. (%)	60 (48)	106 (43)	94 (41)	109 (54)	81 (39)	68 (43)
HDL cholesterol, mean (SD), mg/dL	50 (13.3)	51 (13.4)	50 (13.3)	50 (12.7)	50 (13.6)	52 (13.9) ^a
Total cholesterol, mean (SD), mg/dL	176 (39.7)	177 (42.5)	170 (38.1)	182 (38.1)	171 (37.7)	176 (39.1)

HbA_{1c} = glycated hemoglobin; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

^a $P < .05$ in univariate comparison of change.

^b $P = .005$ in multivariate model comparison.

^c $P < .01$ in univariate comparison.

vention and 63% of the control patients were female, and the mean duration of diabetes for the intervention patients was 13 years (SD = 6.4 years) and for the control patients was 11 years (SD = 7.2 years). Baseline characteristics, as well as mean changes in hemoglobin A_{1c}, blood pressure, and lipid values from baseline to intermediate (median 18 months) and to long-term follow-up (median 3.3 years) are given in Table 1. Mean values for hemoglobin A_{1c} in each group were similar at baseline and above target values recommended by the American Diabetes Association.²⁰

Clinical Outcomes

As shown in Table 1, mean hemoglobin A_{1c} levels decreased significantly more from baseline to the 18-month (−0.5% vs −0.2%; $P < .05$) and the 36-month follow-up (−0.5% vs −0.1%; $P < .005$) among intervention practice patients than among control practice patients. The mean change in LDL and HDL cholesterol values in intervention practice patients was significantly greater than in control practice patients in univariate comparisons. Improvements in the proportion of patients reaching clinical targets are also displayed in Table 1. A significantly greater percentage of patients in the intervention practices achieved a hemoglobin A_{1c} value near

7% at the final assessments (68% vs 59% $P < .01$). The proportion achieving a systolic blood pressure of less than 140 mm Hg was also substantially greater in the intervention practices at 18 and 36 months. There were no significant differences in clinical outcomes by sex.

In multivariate linear modeling, the mean decrease in hemoglobin A_{1c} levels from baseline to final follow-up for intervention practice patients was significantly greater when compared with control practice patients ($F_{(1,16)} = 17.97$; $P = .005$), even when controlling for other variables (Table 2). Older age and higher baseline hemoglobin A_{1c} values were also significant independent predictors of greater long-term change in hemoglobin A_{1c} levels. A longer duration of diabetes was significantly and inversely related to the long-term change in hemoglobin A_{1c} levels in the multivariate model (Table

Table 2. Multivariate Model of Change in Hemoglobin A_{1c} Level From Baseline to Final (Median 3.3 Years) Follow-up

Variable	Multivariate Linear Model Mean Change		Multivariate Logistic Regression Model Change in Percentage With HbA _{1c} ≤7.5%	
	Model Parameter (SE)	Effect P Value	OR	95% CI
Age	0.022 (0.006)	<.001	1.041	1.007-1.075
Sex	0.184 (0.138)	NS	0.804	0.356-1.818
Duration of diabetes	−0.026 (0.010)	.009	0.998	0.955-1.043
No. of visits per year	0.008 (0.029)	NS	1.080	0.898-1.30
Baseline HbA _{1c} level	0.606 (0.030)	<.001	0.417	0.308-0.564
Intervention vs control clinic effect ^a		.005	0.393	0.156-0.988

HbA_{1c} = glycated hemoglobin; NS = nonsignificant; OR = odds ratio; SE = standard error.

^a $F_{(1,16)} = 17.97$.

2). There was no significant independent effect of the individual clinic within the intervention or control strata. Results of the logistic regression model examining change from baseline to final follow-up in the odds of patients meeting the target hemoglobin A_{1c} level ($\leq 7.5\%$) are also given in Table 2. In this analysis, control practice patients were significantly less likely (OR = 0.39; 95% CI, 0.16-0.98) to achieve the target hemoglobin A_{1c} levels even when controlling for other variables. As in the linear model, age and baseline hemoglobin A_{1c} level were also independent predictors of change in the odds of meeting the target hemoglobin A_{1c} level.

The cost of implementing the intervention was as follows: annual personnel costs for the 3-year project were \$86,800 for 1 full-time equivalent registered nurse, \$12,000 for 0.1 full-time equivalent clinical pharmacist, and \$43,400 for 0.5 full-time equivalent dietitian; \$5,000 were spent on supplies and miscellaneous start-up costs. The 1.6 full-time equivalent coach-educators covered an annual diabetes panel of 1,280 patients. The cost per patient per year was approximately \$115.

DISCUSSION

In a study of primary care practices based in rural communities with high rates of poverty and with high-risk African Americans who have well-established type 2 diabetes and traditionally poor outcomes, we found that redesigning diabetes care to incorporate interprofessional care management results in significantly greater intermediate and long-term improvement in glycemic control. These findings are consistent with those of Glazier et al²¹ and Pimouguet et al.^{22,24} Reductions in hemoglobin A_{1c} levels were modest but approach those observed in the UKPDS study¹ and suggest the potential for improved long-term microvascular and macrovascular outcomes^{2,3}

We also observed modest improvements in the proportion of patients with a systolic blood pressure of less than 140 mm Hg and small but significant changes in mean LDL and HDL cholesterol levels. These outcomes are similar to those of the multifactorial intervention in the Steno-2 study, which was associated with significant reductions in mortality, as well as microvascular and macrovascular outcomes.²⁵ Further, because visit frequency was not a significant independent predictor, the improvement in clinical outcomes may be related to improvements in the intensity and quality of the visit, specifically at the point of care—which has important implications for health care reform.

This study involved only rural African American patients, a group previously shown to have important challenges in access to care and poor clinical outcomes.^{10,11} The busy practices serving these large

patient populations represent fragile care environments, as they are often the only sources of care and have limited clinical staff. Our redesign study shows that diabetes care can be effectively managed even in environments with limited resources.

Parchman et al²⁶ and Stange²⁷ described how busy primary care physicians struggle with the challenge of competing demands when attempting to address elevated hemoglobin A_{1c} levels. Our strategy suggests that a portion of chronic diabetes management can be accomplished with an interprofessional team, potentially making the clinicians more available for acute problems. Our findings should be viewed as early evidence suggesting the effectiveness of an interprofessional environment similar to a patient-centered medical home.¹⁷

In conventional care, diabetic patients are referred for a separate diabetes education visit, often located apart from the practice and often on a different day. Our findings illustrate the advantage of concurrent diabetes care management integrated into the primary care visit. Interprofessional diabetes care team management on a part-time but consistent basis appears to significantly improve long-term glycemic control and benefit blood pressure and lipid level outcomes.²⁸ Because the interprofessional care team is shared across 3 practices, personnel costs might be allocated across multiple funding sources.

This study has several limitations. Some improved outcomes may have resulted from purposefully selecting intervention sites that required quality improvement training and a leadership commitment. These elements, however, may be a prerequisite for successful team-based care management initiatives. Further, the control sites were chosen randomly from practices with similar patient and practice characteristics and from the same regional environment, which included systemic efforts driven by national and state initiatives to improve diabetes care among federally funded centers and clinics. Other limitations are our lack of information on medication adherence or treatment intensification and patient satisfaction, and how those factors affected the intervention. In our study, we incorporated a complex, multicomponent intervention, and the study was not designed, powered, or funded to tease apart the relative contributions of various components. Even so, our findings were similar to those of other investigators who used interventions centered on care management²² and suggest that the redesign strategy is beneficial.

Although this study was not designed to include cost-effectiveness analysis, if the study results were hypothetically applied to an annual caseload of 1,280 patients for 1.6 full-time equivalent educator-coaches, the cost to reach target hemoglobin A_{1c} levels at 18

months is \$1,044 per patient. These costs might be covered by a combination of insurance reimbursement and health system investment. Program costs and strategies for cost recovery are discussed on the program's Web site (<http://www.ecarediabetes.org>).

We present evidence of the effectiveness of a redesigned primary care delivery system with expanded care management similar to a patient-centered medical home. Although our findings illustrate important progress, more research is required to identify program modifications to facilitate more patients meeting clinical goals.

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Key words: diabetes; improved outcomes; African Americans; delivery redesign; rural; patient-centered medical homes

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