Confronting Disparities in Diabetes Care: The Clinical Effectiveness of Redesigning Care Management for Minority Patients in Rural Primary Care Practices

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ABSTRACT: ***Context:*** *Diabetes mellitus and its complications disproportionately affect minority citizens in rural communities, many of whom have limited access to comprehensive diabetes management services.* ***Purpose:*** *To explore the efficacy of combining care management and interdisciplinary group visits for rural African American patients with diabetes mellitus.* ***Methods:*** *In the intervention practice, an advanced practice nurse visited the practice weekly for 12 months and facilitated diabetes education, patient flow, and management. Patients participated in a 4-session group visit education/support program led by a nurse, a physician, a pharmacist, and a nutritionist. The control patients in a separate practice received usual care.* ***Findings:*** *Median hemoglobin A1c (Hb_{A1c}) was not significantly different at baseline in the intervention and control groups but was significantly different at the end of the 12-month follow-up period ($P<.05$). In the intervention group, median Hb_{A1c} at baseline was 8.2 ± 2.6%, and median Hb_{A1c} at an average follow-up of 11.3 months was 7.1 ± 2.3%, ($P<.0001$). In the control group, median Hb_{A1c} increased from 8.3 ± 2.0% to 8.6 ± 2.4% ($P<.05$) over the same time period. In the intervention group, 61% of patients had a reduction in Hb_{A1c}, and the percentage of patients with a Hb_{A1c} of less than 7% improved from 32% to 45% ($P<.05$).* ***Conclusions:*** *These findings suggest that a redesigned care management model that combines nurse-led case management with structured group education visits can be successfully incorporated into rural primary care practices and can significantly improve glycemic control.*

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Recent evidence documents that the prevalence of diabetes mellitus in the United States has increased by more than 60% since 1990.[1] African Americans had the highest diabetes prevalence of any racial group, approximately 1.6 times the rate in Euro-Americans, and African Americans are also more likely to develop the microvascular complications of diabetes, including end-stage renal disease,[2] retinopathy,[3] and peripheral vascular disease that often results in lower extremity amputations.[4] Authors have hypothesized that African Americans may have diminished access to comprehensive diabetes management services,[5] resulting in poorer health outcomes. However, a controlled trial of lifestyle intervention and glucose control in the Diabetes Prevention Program demonstrated similar outcomes regardless of race.[6] This and other trials suggest that if comparable health services achieving similar degrees of glycemic control are provided to African Americans with diabetes mellitus, good clinical outcomes and reduced complications can be achieved. Beyond

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The authors would like to acknowledge the following contributions: Dipes Ray and the staff of the Roanoke-Chowan Medical Clinic, Murfreesboro, N.C., for their program support and cooperation in the collection of this data; Curtis Dickson, Stephanie Pihl, and the staff of the Herford-Gates District Health Department for their support in the design and implementation of the project; Susan Lassiter, President Roanoke-Chowan Hospital, for her support and guidance. We also thank the Kate B. Reynolds Charitable Trust, The Roanoke-Chowan Foundation, and The Duke Endowment for ongoing support.
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treatment outcomes, other studies reveal that African Americans may be less likely to receive screening and evaluation processes for diabetic complications.[7,8] This may be particularly true in rural areas, where access to comprehensive diabetes care management services is limited. These important racial disparities in health services delivery and health outcomes are increasingly recognized, and new methods for the prevention, evaluation, and treatment of diabetes mellitus and its complications in disadvantaged populations are being investigated.

Efforts to provide comparable services and to achieve similar outcomes are based on several landmark studies that have demonstrated that maintaining blood glucose as close to normal as possible can result in significant reductions in the incidence of microvascular and neuropathic complications.[9,10] Although this has led the American Diabetes Association to recommend that blood glucose be maintained as close to normal as possible, the reality is that this standard is not routinely achieved in medical practice.[11] This creates a situation in which health care outcomes for patients with diabetes mellitus, especially minority patients, could be improved. New systems of care as well as new systems of patient and provider education must be devised to facilitate this. As a result, attempts have been made to restructure care by intervening with providers,[12,13] system processes,[14-16] and patients.[16-18] The restructuring of care has usually included 1 or more of the following: new medical record/reminder systems,[14] patient recall systems,[15] care management by nurses and/or other providers,[19] and group visits.[16] Evidence suggests that the medical record reminder systems have been successful in improving measures of the process of care[14,15] but appeared to have only limited effect on glycemic control. Care management generally refers to a structured system of planned visits and planned education that is provided by a prepared practice team, usually nurses or other nonphysicians. In studies that included a nurse to follow-up and manage patients, clinical outcomes were improved.[19,20] This demonstrates that care management by nonphysician providers can be an important component of system redesign.

A more recent system redesign method uses a collective or group visit format for patients with diabetes.[16] The group visit concept represents an attempt to provide group education and mutual support through the evaluation and training of patients with similar conditions in group settings. Early evidence regarding the effectiveness of group visits in improving both care processes and patient outcomes suggests a clear benefit.[16] Sadur et al[16] studied a group visit structure for providing care management to adults with diabetes in an HMO setting in northern California. These authors describe a decline of 1.1% in the hemoglobin A1c (Hb_{A1c}) in the intervention subjects relative to controls after 6 months of follow-up, although no data are provided at later time points. They also report high patient satisfaction and a significantly lower utilization of health system resources (eg, hospitalization) as a result of the intervention. Aubert et al[19] described the efficacy of nurse-led case management for diabetic patients in an HMO setting. These authors also describe a similar decline in Hb_{A1c} of 1.1% relative to usual care.

Most of the studies with system redesign efforts have been conducted in structured managed care settings. By contrast, many rural settings do not have the collective resources, funding, and infrastructure to implement a comprehensive redesign of diabetes care management processes. Similarly, many system redesign efforts have not focused on the unique needs of minority patients in order to minimize disparate health outcomes. Consequently, no studies to date have evaluated the effectiveness of combining nurse-led care management with a group visit structure for minority diabetic patients in primary care practice settings in rural communities. The extent to which these system redesign efforts can be specifically targeted to improve racial disparities in diabetes care in rural settings is unclear. The present study focuses on the patient outcomes from a demonstration project designed to investigate the feasibility of restructuring care for rural, primarily minority, patients with type 2 diabetes mellitus.

Methods

Practice/Patients. A convenience sample of adult patients with an established diagnosis of type 2 diabetes mellitus from 2 primary care practices in 2 adjacent rural counties in eastern North Carolina was recruited. One of the counties is designated as a federal health professions shortage area. Both practices were hospital-owned at the time of this study. The practices have been in existence for approximately 30 years, each in a community of approximately 3500 people, and each has a total active patient population of approximately 2000 to 3000 people. These practices were selected because they represent rural fee-for-service practices that provide primary care for predominantly African American patient populations with type 2 diabetes mellitus.

Patient selection for participation identified adult diabetics at high risk for suboptimal patient outcomes. In the intervention practice, all patients with diabetes were verbally informed about the study

and were asked to participate. The patients in the intervention practice who were specifically recruited were those with type 2 diabetes mellitus in which any of the following conditions were met on the day of the visit: $Hb_{A1c} > 7.0\%$, blood pressure > 135/85 mm Hg, or physical examination or laboratory evidence of a high risk of end-organ disease including diabetic retinopathy, nephropathy, or neuropathy. Most patients who were recruited agreed to participate. All patients who participated in the intervention were included in the analysis. In the control practice, patients were randomly selected from a printout of all patients in the practice with a billable diagnosis (ie, 250.xx, ICD-9 code) of type 2 diabetes mellitus. The charts of these control patients were then reviewed to identify those with the same conditions mentioned above regarding glycemic control, blood pressure control, or chart-documented evidence of end-organ damage. Data were abstracted from their medical records for the time period of this study (October 2000 to October 2001).

Care Management Intervention. In the intervention practice, the care of the diabetic patients was redesigned in an effort to optimize patient outcomes and to provide patients with access to a full range of diabetic management services. This care redesign process included nurse-led planned care visits using evidence-based clinical management, patient education and support for self-management through a group visit structure, making decision support tools available for providers, and providing a new clinical information system in the form of a patient registry. Evidence-based clinical management and patient education were informed by the recommendations of the American Diabetes Association.[21] Intervention design and content including teaching points, group visit materials, encouragement of patient-to-patient interaction, and educational handouts were selected and tailored to meet the unique needs of the target population, primarily rural African Americans.

A major initiative in this redesign was nurse-led care management. This certified nurse specialist (CNS) was not an employee of the intervention clinic but was employed by the academic medical center in the region and was incorporated into the practice as a consulting care provider. Under the oversight of the supervising physician, the nurse-led care management protocol was integrated into the practice. Each patient at the intervention site was initially evaluated by the CNS, who identified diabetes-relevant problems and developed specific action plans. The initial problems were then reviewed with the physician provider, and action plans agreed on. Each action plan included scheduling the patient to attend the group visit process described below. Clinic staff and the CNS implemented a new procedure to remind patients of their office visits and to recall those who missed appointments. The CNS returned to the intervention practice on the day that the patient was scheduled and evaluated the patient's progress in implementing agreed-on changes.

Most visits for intervention patients were redesigned to include a group visit structure. Specifically, patients were assigned to a group of 3 to 12 patients who met for a series of four 2-hour group sessions over approximately 6 months. During each session, intervention patients were checked in by an office staff member (vital signs and fingerstick glucose), were evaluated initially by the CNS, completed 1 of a series of 4 educational sessions, and were evaluated by the physician provider. The 4 educational sessions were led by an interdisciplinary team of regional providers and focused on an overview of diabetes, nutrition, medication, and self-management/goal-setting. Following the educational sessions, each patient in the intervention practice saw the physician for a brief visit, after which the care plan was reviewed, laboratory tests were obtained, and the patient scheduled for a subsequent visit.

The care redesign was supplemented by making available the standards for type 2 diabetes medical care of the American Diabetes Association and by implementing an electronic patient care registry system called CVDEMS that was being used in some federally qualified health centers. For the present study, data including weight, blood pressure, and Hb_{A1c} values from before enrollment in the system redesign and from approximately 12 months after enrollment were abstracted from patient records in the CVDEMS system at the intervention practice. Data on demographics and glycemic control only were collected in the control practice. Demographic and clinical data were then entered into a statistical database (SPSS 11.5, SPSS Inc, Chicago, Ill) and analyzed as follows: median Hb_{A1c} in the intervention and control groups was compared at baseline and again at approximately 12 months of follow-up using a Mann-Whitney *U* test. Median Hb_{A1c}, weight, and blood pressure values from baseline and approximately 12 months of follow-up were compared within group (ie, within each of the intervention and control groups but across time) using a Wilcoxon rank sum test. The percentage of patients in each group with an Hb_{A1c} below 7% and the percentage with a reduction in Hb_{A1c} were calculated at both baseline and at follow-up and compared using a Wilcoxon rank sum test.

Clinical Outcomes in Diabetic Patients in Intervention and Control Practices

Parameter	Control (n = 48)	Intervention (n = 112)
Baseline median Hb_{A1c} (%)	8.3 ± 2.0	8.2 ± 2.6
Follow-up median Hb_{A1c} (%)	8.6 ± 2.4	7.1 ± 2.3

Results

Patients. One hundred sixty (n = 160) diabetic patients were enrolled in the study, including 112 patients in the intervention practice and 48 patients in the control practice who received usual care. The mean age was not significantly different in the intervention and control groups (60 ± 13 years vs 58 ± 17 years, respectively); over 90% of patients in both intervention and control practices were African American. The proportion of patients in the intervention and control practices who were female (57% and 52% respectively) was not significantly different. Most patients had health insurance through Medicare (66%) or Medicaid (17%).

Clinical Outcomes. Median Hb_{A1c} was not significantly different at baseline in the intervention and control groups but was significantly different when compared at the end of the follow-up period ($P<.05$) (see Table). In the intervention group, median Hb_{A1c} at baseline was 8.2 ± 2.6%, and median Hb_{A1c} at an average follow-up of 11.3 ± 5.7 months was 7.1 ± 2.3%, ($P<.0001$). In the control group, median Hb_{A1c} increased from 8.3 ± 2.0% to 8.6 ± 2.4% ($P<.05$) over the same time period. In the intervention group, 61% of patients had a reduction in Hb_{A1c}, whereas only 37% of control patients had a reduction ($P<.01$). The percentage of patients who had a Hb_{A1c} of less than 7% increased significantly in the intervention group from baseline to follow-up (32% to 45%, $P<.01$) but not in the control group (23% vs 29%). There were no significant differences in mean weight or blood pressure measurements between baseline and follow-up in the intervention group (see Table). In a small sample of 10 randomly selected patients from the intervention group, the average diabetes visit frequency/year appeared to increase to a level consistent with published recommendations for patients with higher Hb_{A1c} levels (from 1.1 to 4.7 visits/year). Although a formal cost analysis is outside the scope of this paper, the increased costs of the intervention may be partially offset by this increased patient volume in the office.

Discussion

These findings suggest that a revised care management system that includes nurse-led visits and a group visit structure can be successfully incorporated into a rural primary care practice seeing predominantly African Americans and appears to produce improved clinical outcomes compared to usual care. These findings support the work of previous investigators who have employed similar strategies with other patient groups. As noted above, Sadur et al[16] and Aubert et al[19] demonstrated improved Hb_{A1c} through group visits and nurse-led case management, respectively. Similar to our findings, there were no significant differences in weight or blood pressure.

The present intervention adds to this body of evidence by demonstrating that similar results can be achieved in rural settings with predominantly African American patients. The importance of this finding relates to the logistic challenges of providing comprehensive multidisciplinary care in remote rural settings. In most of the previous studies, the professionals who were conducting the intervention were usually employees and were on site most of the time. In our study it was necessary to employ a "circuit rider" concept in which regional professionals necessary to the care-improvement process rotated to the rural site to provide needed education and care.

Also of importance are the clinical implications of improved glycemic control. Prior research has clearly shown in both type 1 and type 2 diabetes that decreases in Hb_{A1c} of approximately 1% to 2% are associated with a 21% to 76% reduction in the incidence of retinopathy, a 34% to 56% reduction in the incidence of nephropathy, and a 25% to 60% reduction in the incidence of peripheral neuropathy.[9,10] Thus, innovative strategies to improve glycemic control such as the one described in this study have the potential to profoundly influence the morbidity associated with diabetes mellitus. Importantly, we found that more than 60% of the patients in the intervention group responded with some reduction in their Hb_{A1c}. Further, improvements in Hb_{A1c} were evident in all age groups and in both men and women. This suggests the broad applicability of these interventions for patients with diabetes mellitus, including predominantly minority patients in remote rural communities. We also noted that the percentage of patients who achieved a goal Hb_{A1c} of less than 7% increased from 32% to 45%.

The limitations to this study include it being a predominantly African American study group in a rural primary care setting so that these findings cannot be extrapolated to a different population or setting. However, as we have noted, our findings are quite

similar to those described by other investigators in more urban settings and those with more managed care. Our study is limited by the small sample size, the use of only 2 practice sites, and the potential for selection bias in recruitment. However, patients were chosen for this study predominantly because of a significant pattern or history of poor glycemic control, and the effect of the intervention in them was carefully measured and compared to that in a separate control practice receiving usual care. We believe these sites to be representative of rural practices providing care to minority patients with diabetes. The study is also limited by the combining of several interventions (care management, group visits, patient recall system, and the CVDEMS diabetes registry/database) into a single study so that the identification of factors most associated with improvement in glycemic control cannot be teased apart. However, these individual factors have already been shown to be of benefit but their combined use in a rural primary care setting had not previously been demonstrated.

Our findings suggest that care for adult African American patients with diabetes mellitus in rural primary care settings can be substantially redesigned by utilizing nurse-led case management in conjunction with a structured group visit process. Further, this redesigned care management process can result in important improvements in glycemic control.

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