

Leveling the Field: Addressing Health Disparities Through Diabetes Disease Management

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Objectives: To examine the relationships among patient characteristics, labor inputs, and improvement in glycosylated hemoglobin (A1C) level in a successful primary care-based diabetes disease management program (DDMP).

Study Design: We performed subanalyses to examine the relationships among patient characteristics, labor inputs, and improvement in A1C level within a randomized controlled trial. Control patients received usual care, while intervention patients received usual care plus a comprehensive DDMP.

Methods: The primary outcome was improvement in A1C level over 12 months stratified by intervention status and patient characteristics. Process outcomes included the number of actions or contacts with patients, time spent with patients, and number of glucose medication titrations or additions.

Results: One hundred ninety-three of 217 enrolled patients (88.9%) had complete 12-month follow-up data. Patients in the intervention group had significantly greater improvement in A1C level than the control group (−2.1% vs −1.2%, $P = .007$). In multivariate analysis, no significant differences were observed in improvement in A1C level when stratified by age, race/ethnicity, income, or insurance status, and no interaction effect was observed between any covariate and intervention status. Among intervention patients, we observed similar labor inputs regardless of age, race/ethnicity, sex, education, or whether goal A1C level was achieved.

Conclusions: Among intervention patients in a successful DDMP, improvement in A1C level was achieved regardless of age, race/ethnicity, sex, income, education, or insurance status. Labor inputs were similar regardless of age, race/ethnicity, sex, or education and may reflect the nondiscriminatory nature of providing algorithm-based disease management care.

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More than 20 years ago, the US Department of Health and Human Services issued their *Report of the Secretary's Task Force on Black and Minority Health*.¹ This study documented many health disparities and sparked efforts to improve the health and healthcare of vulnerable populations and to raise awareness and concern for health disparities research.²⁻⁴ Disparate trends in care across various groups have been noted, including racial/ethnic minorities, as well as women, children, older adults, and other potentially vulnerable populations. Despite this research and advocacy, health disparities persist across a wide spectrum of disease processes, clinical settings, and populations within the United States. According to the 2007 *National Healthcare Disparities Report*,⁵ some disparate trends are improving, such as rates of cholesterol control among racial/ethnic minorities; however, many are in major need of improvement, particularly in the areas of diabetes care and chronic disease management.

The Agency for Healthcare Research and Quality (AHRQ) has identified several priority groups that serve as targets for health disparities research and quality improvement. These groups include racial/ethnic minorities, persons with low incomes, women, children, older adults, those with disabilities, and rural inhabitants.^{5,6} In general, members of these priority groups along with those who have less education and no private insurance are more likely to receive poorer quality of care and to experience greater barriers in terms of access to care compared with their respective counterparts.⁵ For example, compared with white patients,⁷ Hispanic and lower-income patients with diabetes mellitus are less likely to receive the recommended services for diabetes care such as timely measurement of lipid levels and glycosylated hemoglobin (A1C) levels, and black patients have higher rates of many of the complications of diabetes such as admissions for lower extremity amputations.⁸ Although studies performed by Trivedi et al⁹ and by Chin et al¹⁰ have demonstrated that quality improvement measures can lead to reduced disparities in some diabetes-related processes of care, it has been more difficult to influence outcome measures such as attainment of goal blood glucose control (as measured by A1C level).¹¹ Findings from recent studies^{9,12} have also suggested that disparities in diabetes care may be related to patient characteristics, provider characteristics, or system-level factors.

Disease management programs have been shown to be successful in improving care for patients with diabetes,¹³⁻¹⁷ and there is growing interest in the usefulness of such

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models in addressing healthcare disparities.^{12,18,19} However, little is known about the specific effect of disease management programs on disparate trends and particularly on their ability to provide unbiased care and to improve patient outcomes equally across priority groups. Results of a successful primary care–delivered algorithm-based diabetes disease management program (DDMP) have been previously reported.¹⁶ Evaluation of this program within a randomized controlled trial demonstrated significant improvements in A1C level, blood pressure, aspirin use, patient satisfaction, and other measures.¹⁶ The program was also found to require modest labor inputs.^{16,20,21} In the present study, we performed a subanalysis of this program to examine the relationships among patient characteristics, labor inputs, and improvement in A1C level, with a particular focus on evaluating the potential usefulness of programs such as this to influence the care and outcomes for patients considered to be within an AHRQ-defined priority group and for patients with less education or no private insurance.

METHODS

We performed a randomized controlled trial of a DDMP among 217 patients with type 2 diabetes mellitus and poor glucose control (A1C level $\geq 8\%$) in an academic primary care practice. Details of the trial have been previously published.^{16,20,21} Patients in the intervention group received care from their primary care provider supplemented by a DDMP. The program included intensive management from clinical pharmacists and from a diabetes care coordinator who provided diabetes education, applied algorithms for treating glucose level abnormalities and decreasing cardiovascular risk, used an electronic registry to proactively identify patients in need of additional care, and addressed barriers to care. Treatment algorithms provided guidance on when to contact patients and information about titration or addition of new medications for glucose control and cardiovascular risk reduction. Control patients received a one-time disease management session from pharmacists, followed by usual care from their primary care provider. The primary outcome was improvement in A1C level over 12 months. The study was performed and subsequently analyzed with approval from the University of North Carolina at Chapel Hill and Vanderbilt University institutional review boards. Written consent was obtained from all study participants.

To estimate resources required for the DDMP, the study team documented process measures for all intervention pa-

Take-Away Points

Incorporation of a diabetes disease management program (DDMP) into the primary care setting can aid in addressing diabetes care disparities, reflecting the nondiscriminatory nature of algorithm-based care.

- Agency for Healthcare Research and Quality–defined priority populations experience worse quality and access to care than their respective reference groups.
- Little is known about the ability of DDMPs to deliver unbiased care.
- Our DDMP demonstrated significant reduction in glycosylated hemoglobin (A1C) level among participants regardless of race/ethnicity, sex, education, or insurance status.
- Labor inputs were similar regardless of age, race/ethnicity, sex, education, or whether goal A1C level was achieved.

tients. These “labor inputs” included the following: (1) minutes spent by the disease management team in direct contact with a patient or in activities related to patient care, (2) number of contacts with a patient, and (3) number of patient-specific glucose medication titrations or additions. These measures captured the labor of the DDMP and did not include any actions taken by the patient’s primary care providers.

All analyses were performed using commercially available statistical software (Stata 8.0; StataCorp LP, College Station, TX), and a 2-sided significance level of 5% was used for statistical inference. Baseline differences between intervention and control groups were determined using Wilcoxon rank sum test for continuous outcome variables and χ^2 test for categorical outcome variables. We examined the relationship between patient characteristics and improvement in the median A1C level using multivariate quantile regression analysis. Quantile regression modeling was chosen for this subanalysis because we report the median changes for each outcome of interest. The median reporting was required because of additional data stratification and subsequent changes in sample sizes. This should be contrasted with how the program was evaluated in previous publications.^{16,21} For each patient characteristic (age, race/ethnicity, sex, education, income, and insurance status), we performed a separate model that included the study status, the patient characteristic in question, and an interaction term to evaluate the potential modifying effect of intervention status and the patient characteristic in question on change in A1C level. Patient characteristics were dichotomized based on priority criteria of the *2007 National Healthcare Disparities Report*⁵ (with age dichotomized at 65 years [older adults], race/ethnicity as white vs nonwhite, and household annual income at \$10,000). Education was dichotomized at less than high school and insurance as private versus nonprivate. We used Wilcoxon rank sum test to examine the relationship between each of the labor inputs (median time spent with patients, median number of actions or contacts with patients, or median number of glucose medication additions or titrations) and each of the aforementioned patient characteristics. We also used Wilcoxon rank sum test to analyze the relationship be-

■ **Table 1.** Baseline Patient Characteristics

Characteristic	Control (n = 105)	Intervention (n = 112)
Age, median (IQR), y	58 (50-64)	53 (45-61) ^a
Older adult ≥65 y, No. (%)	21 (20.0)	17 (15.2)
Nonwhite race/ethnicity, No. (%)	63 (60.0)	81 (72.3)
Female sex, No. (%)	59 (56.2)	63 (56.3)
Household annual income <\$10,000, No. (%)	54 (51.4)	47 (42.0)
<High school education, No. (%)	46 (43.8)	40 (35.7)
No private insurance, No. (%)	77 (73.3) ^a	66 (58.9)
Covered by Medicaid or Medicare, No. (%)	50 (47.6)	43 (38.4)
Baseline glycosylated hemoglobin level, median (IQR), %	10.1 (9.1-11.5)	10.5 (9.1-12.2)
Duration of diabetes, median (IQR), y	6 (1.25-12.50)	5 (1.63-11.00)
Presence of neuropathy, No. (%)	43 (41.0)	41 (36.6)
Use of insulin at enrollment, No. (%)	40 (38.1)	45 (40.2)

IQR indicates interquartile range.
^a $P < .05$ ($P \geq .05$ for all other comparisons).

tween each of 3 labor inputs and attainment of goal A1C level ($\leq 7\%$) at 12 months of follow-up. Finally, we examined the relationship between each of 3 labor inputs and improvement in the median A1C level using multivariate quantile regression models for each labor input, with each model adjusting for the aforementioned patient characteristics.

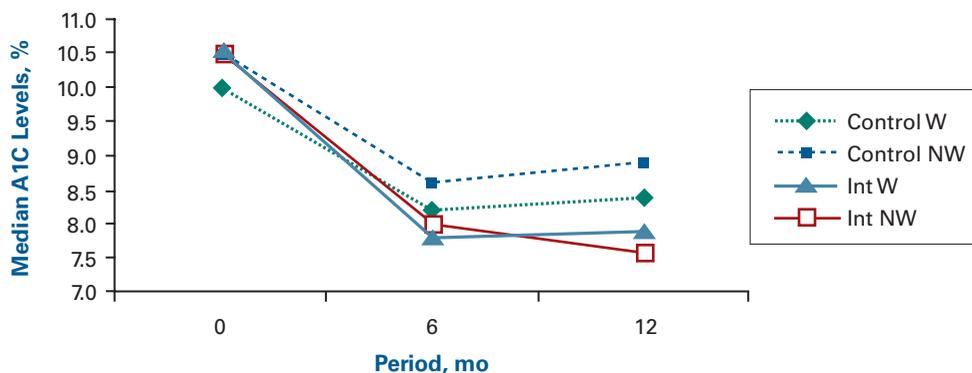
RESULTS

From February 2001 to April 2002, 217 patients were enrolled. Complete follow-up data were available for 193 patients (88.9%) at 12 months. Baseline demographics revealed diversity, with substantial sociodemographically vulnerable participants having poor diabetes control. Most nonwhite participants were African American. Intervention and control patients generally had similar characteristics (Table 1). The A1C levels improved significantly more for intervention

than control patients during the trial (Figure). From baseline to 12 months, control patients had a median 1.2% decrease in A1C level, whereas intervention patients had a median 2.1% decrease (difference, 0.9%; 95% confidence interval, 0.6%-1.3%; $P = .007$).

There was no significant difference in improvement in the median A1C level when stratified by age, race/ethnicity, sex, income, or insurance status (Figure and Table 2). There was slightly greater improvement in the median A1C level among women compared with men (-1.2% vs -0.5%) and among those with less than a high school education compared with those with at least a high school education (-1.1% vs -0.8%). Results of multivariate quantile regression analysis did not reveal any significant interaction effect on improvement in A1C level between participants' intervention status and each of the respective patient characteristics of interest.

■ **Figure.** Improvement in Glycosylated Hemoglobin (A1C) Level Stratified by Intervention Status and by Race/Ethnicity



Int indicates intervention; W, white; NW, nonwhite.

■ **Table 2.** Median Change in Glycosylated Hemoglobin (A1C) Level From Baseline to 12 Months

Variable	Change in A1C Level, %		P ^a	P for Interaction Effect ^b
	Control	Intervention		
Age			.12	.85
Older adult ≥65 y	-1.2 (n = 20)	-1.7 (n = 16)		
Non-older adult	-1.2 (n = 75)	-2.2 (n = 82)		
Race/ethnicity			.1	.89
White	-1.3 (n = 34)	-2.1 (n = 27)		
Nonwhite	-1.2 (n = 61)	-2.1 (n = 71)		
Sex			.049	.32
Female	-1.0 (n = 54)	-2.2 (n = 57)		
Male	-1.5 (n = 41)	-2.0 (n = 41)		
Education			.02	.61
<High school	-1.2 (n = 42)	-2.3 (n = 34)		
≥High school	-1.2 (n = 52)	-2.0 (n = 64)		
Household annual income, \$.17	.62
<10,000	-1.2 (n = 47)	-1.8 (n = 41)		
≥10,000	-1.3 (n = 46)	-2.3 (n = 57)		
Private insurance			.08	.89
Yes	-1.8 (n = 28)	-2.4 (n = 39)		
No	-1.2 (n = 67)	-1.9 (n = 59)		
Covered by Medicaid or Medicare			.06	.88
Yes	-1.2 (n = 48)	-2.1 (n = 61)		
No	-1.2 (n = 47)	-2.2 (n = 37)		

^aFor difference of the 4 medians.
^bBetween the variable in question and intervention status.

Among intervention patients, there were no differences in labor inputs (median time spent with patients, median number of actions or contacts with patients, or median number of glucose medication titrations or additions) when stratified by age, race/ethnicity, sex, or education (Table 3). The disease management team had significantly more contacts and spent more time with patients having a household annual income less than \$10,000 or no private insurance. There were no observed differences in each of 3 labor inputs when stratified by patients obtaining the goal A1C level of 7% or less at the end of the trial. In multivariate analysis, there was no significant relationship between each of 3 labor inputs and improvement in the median A1C level when adjusted for age, race/ethnicity, sex, education, income, and insurance status.

DISCUSSION

In this subanalysis of our DDMP, a successful reduction in blood glucose (A1C) level was achieved irrespective of race/

ethnicity and other important sociodemographic factors. Our findings were not influenced by the observed differences at baseline in terms of age and insurance status between the control and intervention groups. Also, none of the priority sociodemographic factors analyzed had a significant modifying effect with DDMP participation on improvement in A1C level. The time spent by the disease management team for intervention patients was provided similarly regardless of age, race/ethnicity, sex, or education. Improvement in A1C level did not require additional labor inputs compared with patients who did not show significant improvement when adjusted for patient characteristics. Our findings suggest that DDMPs may serve as a tool for providing equal quality of care and for addressing the current disparate trends in care often experienced by many of the AHRQ priority groups with diabetes.

The etiology of racial/ethnic and other socioeconomic disparities in diabetes and other chronic illness care is likely multifactorial. Disparities in provider behavior may be an important component. Sequist and colleagues²² recently con-

■ **Table 3.** Process Outcomes by the Disease Management Team Among Intervention Patients

Variable ^a	Time Spent With Patients		Glucose Medication Titrations or Additions		Actions or Contacts With Patients	
	Median, min	P	Median, No.	P	Median, No.	P
Age		.70		.95		.41
Older adult ≥65 y (n = 16)	490		4		45	
Non-older adult (n = 82)	455		4		44	
Race/ethnicity		.96		.23		.59
White (n = 27)	460		5		44	
Nonwhite (n = 71)	450		3		47	
Sex		.99		.97		.88
Female (n = 57)	460		4		45	
Male (n = 41)	460		4		43	
Education		.45		.95		.29
<High school (n = 64)	475		4		43	
≥High school (n = 34)	447		4		45	
Household annual income, \$.03 ^b		.91		.01 ^b
<10,000 (n = 41)	500		3		50	
≥10,000 (n = 57)	440		4		43	
Private insurance		.01 ^b		.07		.005 ^b
No (n = 59)	475		4		50	
Yes (n = 39)	420		3		42	
Covered by Medicare or Medicaid		.13		.32		.69
No (n = 61)	450		3		47	
Yes (n = 37)	470		5		43	
Goal A1C level, %^c		.65		.3		.91
>7 (n = 67)	460		4		43	
≤7 (n = 31)	440		3		49	

A1C indicates glycosylated hemoglobin.

^aNumber of patients is 98 due to 12 patients lost to follow-up and 2 deaths experienced during the study.

^bP < .05.

^cSpearman correlation coefficients for baseline A1C levels are $r = -0.04$ ($P = .69$) for time spent with patients, $r = 0.01$ ($P = .88$) for glucose medication titrations or additions, and $r = 0.00$ ($P > .99$) for actions or contacts with patients.

ducted a provocative study in which they reported on variations in diabetes-related outcomes at the level of individual physicians. They examined a 14-site primary care group practice that used an integrated electronic medical record system and found significant within-physician variation between the percentages of white and black patients who were able to achieve recommended levels of glycemic, blood pressure, and lipid control. Patient sociodemographic factors accounted for a relative range of 13% to 38% of the observed racial/ethnic differences, whereas within-physician effects (ie, racial/ethnic disparities observed within the same physician panel) accounted for 68% to 75% of the observed differences. A study by Schulman and colleagues²³ that surveyed 720 physicians eliciting recommendations regarding cardiac catheterization

found that sex and race/ethnicity independently influenced how physicians managed their patients, with many physicians surveyed being less likely to recommend needed catheterizations among women or nonwhite patients.

One reason for the success of our program in improving care regardless of socioeconomic status may be the ability of disease management to eliminate potential disparities in provider-level behavior. The nondiscriminatory nature of providing algorithm-based care may serve as a means by which health systems could ensure delivery of effective and unbiased care, while accounting for and addressing the frequent special needs that arise when caring for traditionally vulnerable patient populations. As we observed in our program, this could be achieved through management practices

that allowed for patient-centered approaches to care as individualized needs become evident (described herein). The use of a team approach to care with midlevel providers and a care coordinator working together with primary care physicians may also help to prevent provider-level disparities.

Our disease management team spent slightly more time among patients with lower income or no private insurance. This additional time may have been related to addressing economic barriers to attaining medications and other clinical care. More research is needed to better understand the resources required to achieve successful outcomes across all priority groups. In the present analysis, we also found that women and participants with less education showed slightly greater benefit from the intervention. Greater improvement in glycemic control among patients with less education and among women is more likely to reflect differences by intervention status rather than by education or sex. This was supported by the absence of an interaction effect between these variables and patient status with A1C level and should be contrasted with the previously reported analysis showing that patients having lower literacy had significantly more improvement in glucose control compared with those having higher literacy.²⁰ Significant improvement in glycemic control based on literacy level may have been related to the fact that our intervention included several approaches to address literacy, including the use of simplified communication, the “teach back technique” for confirming patient understanding, lower-literacy materials, and a care coordinator who confronted many social barriers.²⁰ An approach in which individualized physician care of patients with diabetes is supplemented with an adequately tailored and focused chronic DDMP may be an important approach in eliminating disparate trends.

Several limitations were inherent in our study. Our sample size was small, and we may have lacked adequate power to detect differences based on patient characteristics alone. In addition, our documented labor inputs characterize time spent with patients by the disease management team and do not include time spent by primary care providers or the patients or utilization of clinical services or other resources. Furthermore, the time spent by the management team included some actions that were considered “outside” of the algorithm, such as discussion of certain medication changes with providers. As previously reported,²¹ discussion with providers was required for 112 of 500 drug titrations and for 233 of 348 new drug additions. The time required by such actions would be difficult to predict if our program was repeated. The generalizability of our findings is also reduced by the fact that our study was conducted at a single-site academic institution and did not have adequate representation of several racial/ethnic minorities such as Latinos. Furthermore, our participants at en-

try had poorly controlled diabetes, and it is arguable that the magnitude of our findings would be lessened if repeated in a population with better baseline control. Finally, although we believe that the algorithm-based care was a major factor contributing to the balanced improvement in A1C level across the priority groups, it remains a possibility that our findings were influenced by regression toward the mean or by the fact that our study did not find many clinically significant racial/ethnic disparities on baseline evaluation of our study population. One may argue that, if such disparities were in fact observed, our results may have differed in their magnitude. There may be other factors associated with the intervention that could have contributed to the similar improvements. For example, we focused on patient self-management skills and provided assistance with obtaining medications. These efforts combined with aggressive treatment using algorithm-based care might have had synergistic effects among certain individuals.

We do not go so far as to suggest that our program has eliminated racial/ethnic disparities but are confident that none were created among participants who received our intervention. A disease management program integrated into primary care can be a successful model for improving care among vulnerable patients with significant barriers. Emphasis on algorithm-based treatment and on team approaches to care can result in improvements regardless of race/ethnicity, sex, education, or other characteristics and represents an important tool for addressing healthcare disparities. Future research about the role of disease management to address health disparities in diabetes and other chronic illnesses is clearly indicated.

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