Addressing Literacy and Numeracy to Improve Diabetes Care

Two randomized controlled trials

KERRI CAVANAUGH, MD, MHS,[1,2]
KENNETH A. WALLSTON, PHD[3]
TEBEB GEBRETSADIK, MPH[4]
AYUMI SHINTANI, PHD, MPH[4]
MARY MARGARET HUIZINGA, MD, MPH[5]
DIANNE DAVIS, RD, CDE[2]

REBECCA PRATT GREGORY, RD, CDE[2]
ROBB MALONE, PHARMD, CDE[6,7]
MICHAEL PIGNONE, MD, MPH[6]
DARREN DEWALT, MD, MPH[6]
TOM A. ELASY, MD, MPH[2,8]
RUSSELL L. ROTHMAN, MD, MPP[2,8,9]

OBJECTIVE — Diabetic patients with lower literacy or numeracy skills are at greater risk for poor diabetes outcomes. This study evaluated the impact of providing literacy- and numeracy-sensitive diabetes care within an enhanced diabetes care program on A1C and other diabetes outcomes.

RESEARCH DESIGN AND METHODS — In two randomized controlled trials, we enrolled 198 adult diabetic patients with most recent A1C $\geq 7.0\%$, referred for participation in an enhanced diabetes care program. For 3 months, control patients received care from existing enhanced diabetes care programs, whereas intervention patients received enhanced programs that also addressed literacy and numeracy at each institution. Intervention providers received health communication training and used the interactive Diabetes Literacy and Numeracy Education Toolkit with patients. A1C was measured at 3 and 6 months follow-up. Secondary outcomes included self-efficacy, self-management behaviors, and treatment satisfaction.

RESULTS — At 3 months, both intervention and control patients had significant improvements in A1C from baseline (intervention -1.50 [95% CI -1.80 to -1.02]; control -0.80 [-1.10 to -0.30]). In adjusted analysis, there was greater improvement in A1C in the intervention group than in the control group ($P = 0.03$). At 6 months, there were no differences in A1C between intervention and control groups. Self-efficacy improved from baseline for both groups. No significant differences were found for self-management behaviors or satisfaction.

CONCLUSIONS — A literacy- and numeracy-focused diabetes care program modestly improved self-efficacy and glycemic control compared with standard enhanced diabetes care, but the difference attenuated after conclusion of the intervention.

Diabetes Care 32:2149–2155, 2009

Patients, particularly those with poorer literacy or numeracy skills, may have difficulty interpreting and acting on abstract or complex health information related to chronic illness care (1). Approximately 90 million adults in the U.S. have basic or below basic literacy skills and >110 million have limited numeracy skills (2). Low literacy is common among patients with diabetes and has been associated with less knowledge about diabetes and worse glycemic control (3–5). In a randomized trial of a multifaceted diabetes disease management program that included literacy-sensitive interventions, we found that patients' literacy status was an independent predictor of improvement in glycemic control. Patients with lower literacy showed a greater improvement in glycemic control than patients with higher literacy, suggesting that applying literacy-sensitive communication methods could lead to improved diabetes outcomes (6). However, there have been few additional studies (7) and no randomized trials specifically examining the role of a literacy- and numeracy-sensitive intervention for patients with diabetes.

Numeracy, or the ability to use numbers in daily life, is an important but understudied component of literacy (8). Health-related numeracy includes understanding measurement, estimation, time, risk interpretation, and multistep operations and the ability to identify which math skills need to be applied to solve problems (8,9). Numeracy has been associated with asthma control, nutrition label comprehension, and obesity (10–12). Numeracy may play an integral role in successful diabetes self-management because quantitative skills are often required for tasks such as blood glucose monitoring, carbohydrate counting, and medication administration. In a cross-sectional study, we found a significant association between diabetes-related numeracy skills and glycemic control (3). However, to date, the role of providing numeracy-sensitive interventions in diabetes care has not been evaluated.

The objective of this study was to assess the impact of addressing both literacy and numeracy as part of an enhanced multidisciplinary diabetes care program, compared with usual delivery of that program. Outcome measures included glycemic control, patient-reported self-efficacy, self-management behaviors, and treatment satisfaction. We hypothesized that intervention participants who received the literacy- and numeracy-sensitive program would lower their A1C significantly more than control group participants.

RESEARCH DESIGN AND METHODS

This study included two coordinated randomized controlled trials performed at two academic medical centers from April 2006 until June 2008. The institutional review boards from Vanderbilt University Medical Center (VUMC) and the University of North Carolina (UNC) Chapel Hill approved the trials, and written consent was obtained from all participants.

Eligible patients were aged 18–80 years, English-speaking, with type 1 or type 2 diabetes, and most recent A1C ≥7.0% and were referred by their physician for participation in their local enhanced diabetes care program. Exclusion criteria were a preexisting diagnosis of severe cognitive impairment or corrected visual acuity of <20/50 using a Rosenbaum Screener (Prestige Medical, Northridge, CA). Subjects received $50 for participation.

Randomization

Among patients referred to the enhanced diabetes care program at each trial site, those who consented were then randomly assigned to the control or intervention condition. Random assignment was concealed, computer-generated, and performed at each site using random blocks of four, six, and eight assignments. Although research assistants collecting patient measures were not notified of a patient's assignment, this was not a masked study because only specified providers were trained to deliver the intervention.

Control and intervention conditions

Patients assigned to the control condition were referred to "usual care" in the local enhanced diabetes care program (supplementary Table A1, available in an online appendix at http://care.diabetesjournals. org/cgi/content/full/dc09-0563/DC1). This included one to six face-to-face visits in a diabetes care program over a period of 3 months. At VUMC, this program included visits with a diabetes nurse practitioner (>80% also were certified diabetes educators [CDEs]) and a registered dietitian CDE within the Eskind Diabetes Center. At UNC, this program included visits with a nurse practitioner CDE and a registered dietitian within the General Medicine Clinic. To avoid contamination issues, control patients were assigned to receive care only from these program staff, and these staff did not provide care to any intervention patients.

Patients assigned to the intervention condition were also referred to the local enhanced diabetes care program. Program staff delivering the intervention each received one to two didactic training sessions (1–2 h each) about health literacy, numeracy, and clear communication techniques (13) before the start of the trial. Intervention staff also used the Diabetes Literacy and Numeracy Education Toolkit (DLNET) (14) to facilitate literacy and numeracy-sensitive diabetes education and management. The DLNET (available at http://www.mc.vanderbilt.edu/ diabetes/drtc/preventionandcontrol/tools. php) is a customizable toolkit of 24 instructive modules about diabetes self-management activities, including blood glucose monitoring, nutrition management, foot care, and administration of medications including insulin. The toolkit was designed using clear communication principles, such as simple sentences with text at a sixth-grade reading level, bulleting for key points, color coding, pictures, and step-by-step instructions. The intervention was delivered in two to six sessions over a 3-month period. At VUMC, the intervention was delivered by an advanced diabetes management nurse practitioner and CDE registered dietitians, whereas at UNC the intervention was delivered by a CDE pharmacist and a dietitian. To avoid contamination issues, intervention patients were assigned to receive care only from these program staff, and intervention staff did not provide care to any control patients. Throughout the study, all control and intervention patients continued to receive usual care from their primary care or diabetes specialty providers.
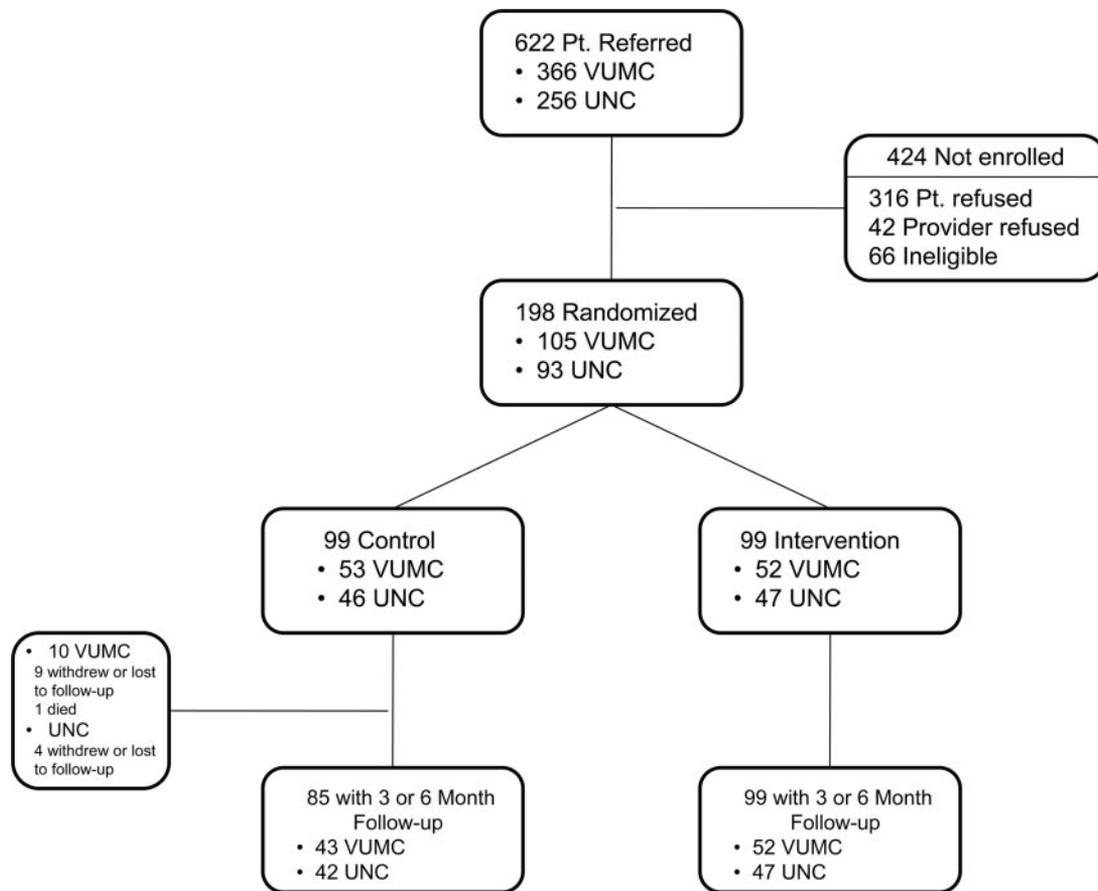
Measures

A1C was collected at baseline, at 3 months (at the conclusion of the intervention), and at 6 months (3 months after completion of the intervention). A1C measurements were performed at the laboratories of the respective institutions, which were not aware of the patients' study status. Literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM), a well-validated measure of reading ability that correlates with reading comprehension (15). If the patient scored less than a sixth-grade reading level by REALM, then the remainder of the instruments were administered orally to ensure that the survey questions were understood by the patient. All subjects were given the option of oral administration if desired. Diabetes-related numeracy skills were measured with the validated Diabetes Numeracy Test (DNT) at VUMC and the shortened DNT-15 at UNC (available at http://www.mc.vanderbilt. edu/diabetes/drtc/preventionandcontrol/ tools.php) (16). Diabetes self-management activities were assessed by patient self-report and with the validated Summary of Diabetes Self-Care Activities scale (17). Patient-perceived self-efficacy of diabetes self-management behaviors was assessed using the validated Perceived Diabetes Self-Management Scale (18) and satisfaction with the validated Diabetes Treatment Satisfaction Questionnaire (19). Diabetes-related numeracy, diabetes self-care behaviors, self-efficacy, and satisfaction were assessed at baseline and at the 6-month interval.

Statistical analyses

Descriptive statistics were calculated as median (interquartile range) or frequency and percentage for categorical variables. We compared patient characteristics by intervention status at baseline using Wilcoxon's rank-sum tests for continuous variables and Pearson's χ^2 tests for categorical variables. For all analyses we present the results for each trial site separately and then also for the two sites combined. All randomly assigned participants were included in the intention-to-treat analyses.

For our primary outcome, we used Wilcoxon's rank-sum tests to compare change in A1C between intervention and control groups from baseline to 3 months (after the completion of the enhanced diabetes education and management program) and also from baseline to 6 months (to assess additional effects on glycemic control 3 months after the intervention had been completed). Secondary analyses included comparison between intervention and control groups of patient diabetes care self-efficacy, self-management behaviors and satisfaction with diabetes care from enrollment to 6-month follow-

Figure 1—*Study flow diagram.*

up, using Wilcoxon's rank-sum test. Within each group, changes in measures from baseline to 3 or 6 months follow-up were also examined using Wilcoxon's signed-rank test. Nonparametric 95% confidence limits are presented with the median improvement measures for A1C, self-efficacy, and satisfaction.

We also performed multivariable models to assess the independent effect of the intervention on A1C at 3 and 6 months follow-up. Adjustment variables determined a priori included age, sex, race, study site, diabetes type, income status, baseline diabetes numeracy score, and baseline A1C. To assess the change in A1C by group status, using all available data, we performed a multivariable model using an ordinary least squares regression method with correction for intrasubject correlation among repeated measures of A1C via a bootstrap estimation method (20,21). Because of the high number of referring physicians (36 at VUMC and 57 at UNC), clustering by primary physician was also accounted for by nonparametric bootstrap methods. We included the interval of evaluation time (3 and 6 months)

as a factor covariate along with a cross-product term with the study group status (control or intervention) to assess whether change in A1C from baseline to 3 months or to 6 months differed between the two study arms. Patients with no measure of A1C after baseline were excluded from the analyses ($n = 14$). As a sensitivity analysis, multiple imputation methods were used to impute missing A1C data points at 3 and 6 months with available baseline covariates, and these calculations generated similar results (21).

For each study site, we estimated that a sample size of 86 patients (43 control and 43 intervention) were needed based upon 80% power with two-tailed α of 0.05, and SD of 1.5, to detect a 1 percentage point greater improvement in A1C in the intervention group than in the control group. The final sample size was inflated to include a dropout rate of 15–20%. We have studied multiple end points of interest in these studies. We report both negative and positive results, and no adjustments were made for multiple tests. Statistical analyses were performed using R 2.7.2 (http://www.r-project.org), STATA

(version 9.2; StataCorp, College Station, TX), and SAS (version 9.1; SAS Institute, Cary, NC).

RESULTS — Of the 622 patients referred, 514 were eligible and a total of 198 enrolled in the two trials. Complete data were available for evaluation for 184 (93%). Details of enrollment by study site are shown in Fig. 1. Overall, patients were a median of 52 (interquartile range 42–59) years old, 36% were male, and 43% were African American. Almost half (49%) had a high school education or less, and almost 40% of patients had a literacy level below the ninth grade. Performance on the DNT suggested diabetes-related numeracy deficits with a median score of 59% (26–86%). The median baseline A1C was 9.1% in both intervention and control groups. Baseline patient characteristics were similar between intervention and control groups except at VUMC, where the intervention group had a higher proportion of patients with type 2 diabetes and a lower average DNT score (Table 1).

There were several differences in pa-

tient characteristics between the two sites. At UNC, the patients were more likely to be older and African American and to have lower annual income, less educational attainment, lower literacy, and lower diabetes-related numeracy scores compared with participants at VUMC. UNC participants also had a longer duration of diabetes and were more likely to use insulin and to have a higher baseline A1C.

There was no significant difference between control and intervention groups in the average number of patient visits during the 3-month enhanced-care program period within each site (VUMC mean 3.8 [95% CI 3.5–4.1]; UNC 2.6 [2.3–2.9]), although VUMC participants overall had significantly more encounters than UNC participants in both intervention ($P < 0.001$) and control ($P < 0.001$) groups. For intervention participants, visits with the dietitian were longer than those with the nurse practitioner or pharmacist (mean 49 [46–52] and 40 [38–42] minutes, respectively; $P < 0.001$). For intervention participants, the most commonly used sections of the DLNET included general information about diabetes including glucose testing (88%), exercise (83%), general nutrition (77%), and foot care (63%). Specific nutritional guidelines, such as use of the plate method (35%) or carbohydrate counting (16%), were also delivered. Approximately 80% of participants were instructed on the use of the DLNET logbooks to track self-care medication and dietary management. After completion of the intervention and 3 additional months of observation, there was no difference between the control and intervention groups in the mean number of provider visits at VUMC (1.0 [0.8–1.2]); however, at UNC, control patients had slightly more provider visits than did intervention patients (1.1 [0.8–1.5] vs. 0.1 [0.03–0.2]; $P < 0.001$).

Glycemic control

At the completion of the 3-month enhanced diabetes care program, the intervention and control groups at each site had significant decreases in their A1C compared with baseline values (VUMC, intervention median −1.60 [95% CI −2.07 to −1.00], control −1.00 [−1.81 to −0.40]; UNC, intervention −1.40 [−1.75 to −0.75], control −0.30 [−1.06 to −0.10]) (Table 2). In unadjusted analysis, improvement in A1C from baseline was greater in the intervention groups

Table 1—Baseline patient characteristics by group status and trial site

| | VUMC | | UNC | | Overall | |
	Control	Intervention	Control	Intervention	Control	Intervention
n	53	52	46	47	99	99
Age (years)	45 (31–59)	49.5 (41–57)	56 (51–60)	53 (48.5–58.5)	53 (40–59.5)	52 (45–59)
Men (%)	38	40	33	34	35	37
African American (%)	21	29	72	57	44	42
Income <$20,000/year (%)	25	33	67	72	45	52
Education ≤12th grade (%)	37	33	61	67	48	49
Private insurance (%)	74	75	26	23	52	51
Type 2 diabetes (%)	74	90*	100	100	86	95*
Years of diabetes diagnosis	6 (1–12)	6.5 (2–12.3)	9 (5–14.8)	8 (4.5–16)	8 (3–13)	8 (3–15)
Monitor blood glucose ≤1 time/day (%)	25	35	49	39	36	37
Insulin use (%)	60	50	78	70	69	59
Insulin >2 times/day	32 (69)	26 (77)	36 (42)	35 (40)	68 (54)	61 (55)
Adjusts insulin for blood glucose	30 (70)	26 (73)	35 (17)	36 (22)	65 (42)	62 (44)
Adjusts insulin for carbohydrates	30 (43)	26 (31)	34 (0)	35 (0)	64 (20)	61 (13)
Yes, hypoglycemic episodes in the prior month (%)	30	25	0	6	16	16
Previous diabetes education (%)	62	69	76	74	69	71
Tobacco use (%)	21	27	26	28	23	27
BMI (kg/m^2)	34.4 (27.2–40.1)	34.4 (30.1–39.1)	35.6 (31.7–41.3)	36.9 (29.9–40.6)	35.5 (30.2–41.3)	35.2 (29.9–40.0)
Systolic blood pressure (mmHg)	138 (126–144)	133 (119–142)	131 (121–150)	142 (126–150)	136 (123–146)	136 (121–146)
Diastolic blood pressure (mmHg)	79 (72–84)	76 (70–85)	72.5 (68–82)	77 (69–84)	76 (69–83)	76 (69.5–84.5)
REALM score [0–66]	65 (62–66)	64 (62–65)	59 (44–65)	54 (39–64)	63 (57–66)	63 (46–65)
REALM score <9th grade level (%)	19	18	54	62	35	39
Diabetes numeracy test score (%)	83 (65–90)	69 (44–84)†	33 (13–51)	33 (13–70)	60 (36–86)	55 (21.5–81)
Self-efficacy: PDSMS (8–40)	24.0 (22.0–27.0)	24.5 (20.3–28.8)	26.0 (23.0–33.0)	24.0 (19.5–30.0)	25.0 (22.0–29.5)	24.0 (20.0–29.0)
Satisfaction: DTSQ (0–36)	27.5 (21.0–32.0)	29.0 (26.0–33.0)	31.5 (26.0–34.8)	30.0 (26.0–32.5)	29.0 (23.3–34.0)	29.5 (26.0–33.0)
A1C (%) baseline	8.6 (7.3–9.7)	8.5 (7.5–10.7)	9.8 (8.5–10.3)	9.2 (8.6–10.9)	9.1 (7.6–10.2)	9.1 (7.8–10.8)

Data are %, n (%), or median (interquartile range). *$P < 0.05$ comparing intervention vs. control by either χ^2 or Wilcoxon rank-sum tests, as appropriate. DTSQ, Diabetes Treatment Satisfaction Questionnaire; PDSMS, Perceived Diabetes Self-Management Scale.

than in the respective control groups at each site (VUMC −0.5 [−1.20 to 0.20]; UNC −0.8 [−1.50 to −0.20]), although only values for the UNC site were statistically significant (P = 0.014). Overall, when all patients from both sites were combined, there was greater improvement in A1C in the intervention group than in the control group (median difference in A1C −0.70 [95% CI −1.10 to −0.20]; P = 0.005). In analyses combining all patients and adjusting for previously described variables, the intervention group continued to demonstrate a significantly greater improvement in A1C than the control group at the 3-month time period (P = 0.03) (Table 2).

At 6 months follow-up, which was 3 months after completion of the enhanced care programs, patients continued to demonstrate significant improvements in A1C compared with baseline. However, neither unadjusted nor adjusted analyses showed statistically significant differences in improvement of A1C between intervention and control groups at 6 months (Table 2).

Self-efficacy, self-management behaviors, and satisfaction

At 6 months, self-efficacy of diabetes self-management scores showed significant improvements from baseline in all groups except for the UNC control group (Table 2). There was a statistically significant improvement in Perceived Diabetes Self-Management Scale scores between intervention and control groups for the UNC site (P = 0.029) and for the combined sites (P = 0.018). However, in analyses adjusted for age, sex, race, diabetes type, income, diabetes-related numeracy, and baseline A1C, the differences did not remain statistically significant.

Patient-reported self-management behaviors did not show any significant change from baseline nor were there any statistically significant differences found between intervention and control groups at either site or overall. Satisfaction with diabetes care was high in all groups at baseline, and small improvements were seen from baseline to the 6-month follow-up but did not differ between intervention and control groups (Table 2).

CONCLUSIONS — This study demonstrates that a literacy and numeracy-focused diabetes intervention may contribute to improving glycemic control and diabetes self-management self-

Table 2—Change in A1C, self-efficacy, and satisfaction by study group from baseline

	VUMC			UNC			Combined		
	Intervention	Control	P*	Intervention	Control	P*	Intervention	Control	P*
Change in A1C									
Baseline to 3 months	−1.60 (−2.07 to −1.00)†	−1.00 (−1.81 to −0.40)†	0.121‡	−1.40 (−1.75 to −0.75)†	−0.30 (−1.06 to −0.10)†	0.014	−1.50 (−1.80 to −1.02)†	−0.80 (−1.10 to −0.30)†	0.005§
Baseline to 6 months	−1.15 (−1.43 to −0.77)†	−1.20 (−2.22 to −0.70)†	0.657	−0.75 (−1.40 to −0.20)†	−0.55 (−1.30 to −0.29)†	0.732	−1.05 (−1.30 to −0.70)†	−0.90 (−1.30 to −0.53)†	1.0
Change in self-efficacy (PDSMS)									
Baseline to 6 months	+8.0 (3.0 to 8.5)†	+4.0 (1.0 to 7.2)†	0.324	+5.0 (2.0 to 6.0)†	+1.0 (−1.7 to 2.7)	0.030	+5.0 (3.0 to 7.0)†	+2.0 (1.0 to 4.0)†	0.018
Change in satisfaction (DTSQ)									
Baseline to 6 months	+2.0 (1.0 to 5.0)†	+3.0 (2.0 to 6.4)†	0.584	+2.0 (0.4 to 3.0)†	+0.5 (0.0 to 1.7)	0.474	+2.0 (1.0 to 3.0)†	+2.0 (1.0 to 3.0)†	0.836

Data are median (95% CI). *P value determined by Wilcoxon rank-sum test comparing intervention and control. †P < 0.05 for paired comparison of 3- or 6-month value with baseline value using Wilcoxon signed-rank test. ‡P = 0.056 for comparison of intervention vs. control in a repeated-measures model using all available 3- and 6-month data, adjusted for age, sex, race, type of diabetes, income, baseline Diabetes Numeracy Test score, and baseline A1C level, including accounting for physician cluster and examination of an interaction term with time. §P = 0.030 for comparison of intervention vs. control in a repeated-measures model using all available 3- and 6-month data, adjusted for age, sex, race, type of diabetes, income, baseline A1C level, including accounting for physician cluster and examination of an interaction term with time. DTSQ, Diabetes Treatment Satisfaction Questionnaire; PDSMS, Perceived Diabetes Self-Management Scale.

efficacy. However, the impact of the literacy- and numeracy-focused program on glycemic control was modest compared with that of an already strong enhanced diabetes care program control group. In addition, although patients continued to have improved glycemic control compared with baseline values, the intervention was not able to show sustained benefits above the control setting 3 months after completion of the program.

Training diabetes providers in improved health communication skills may help to improve patient understanding of health information and self-management behavior. The DLNET used in this study provides a useful comprehensive customizable resource to facilitate diabetes education and management. Patients often desire diabetes materials developed for low literacy skills (22). The DLNET uses text at the sixth-grade literacy level, as opposed to much of the existing health information including materials specific to diabetes, which are often at a higher reading level (23), and also incorporates many other principles of clear communication (24). The DLNET can be used as a core element for both initial and on-going diabetic patient education programs aimed to counsel patients of all skill levels.

Although we found that intervention group participants had an improvement in their glycemic control during the period of intervention delivery, this differential improvement was not sustained after the program concluded. One explanation may be the level of patient interaction with the health care system during the enhanced diabetes care program and the subsequent observation period. Although the total number of visits did not differ between intervention and control groups during the entire 6 months, patients in both groups did see a health provider more often during the 3 months of the intervention compared with the observation period after the intervention period. This result suggests that successful reduction in A1C may require a persistent level of intervention over time and also may suggest that our program performs better as a disease management program than as a self-care training program.

Other explanations for why there was no difference seen between intervention and control groups at the 6-month interval, as well as the modest difference at the 3-month interval, are differential loss to follow-up and the highly active control arms in this study. Patients in the control group were less likely to complete the study, and those who did not complete it may have had worse glycemic control. In addition, patients in the control arms participated in an enhanced diabetes care program that provided additional diabetes management above what is usually provided by diabetes physicians. This included multiple visits with other providers experienced in addressing physiological and social factors associated with glycemic control. In addition, the effectiveness of the intervention differed between the two study sites. Study participants in the control arm at UNC had much less improvement in A1C than that for all other study groups. This difference may be explained, in part, by different measured and unmeasured patient characteristics or by differing provider management practices at each study site.

Patient self-efficacy of diabetes self-management and satisfaction improved for all groups. Because nearly all patients reported an improvement, we were unable to demonstrate a significant difference between the intervention and control groups in this study. Participation in the trial itself may have contributed to the improvement in both self-efficacy and satisfaction for control group patients.

There are several limitations to this study. First, this study was performed and initially powered as two separate, yet coordinated, randomized trials; however, because of the similar hypotheses and design, the decision to analyze combined results of the two trials was made before the completion of data collection at either site. Second, at one of the two sites (VUMC), there were significant differences between intervention and control groups in several patient characteristics. This unequal randomization could result in residual confounding. To address this possibility we performed analyses adjusting for potential confounding variables, and the findings were consistent with the unadjusted results. Third, there were patients ($n = 30$; 15%) who did not complete evaluation of the primary outcome at one of the two designated time intervals. Although this limits cross-sectional evaluations at those times, we used ordinary least squares regression models with multiple imputations to use all data points for participants in the study and minimize the potential bias of missing information. Fourth, many patients declined participation. This may limit the generalizability of our findings, as they may not fully represent all patients with diabetes. Finally, this trial was not adequately powered to evaluate differences in the effect of the intervention by patient literacy or numeracy status.

Among patients with diabetes, literacy and numeracy are important characteristics that have been associated with glycemic control and may play a significant role in the optimization of diabetes care. Use of materials designed to facilitate diabetes education and empower patients to effectively self-manage their condition within an environment by applying clear communication principles is a fundamental component of comprehensive diabetes care. Strategies to enhance effective communication between patients and providers transferring health literacy and numeracy-sensitive information need to be further studied to identify ways to improve care for patients with diabetes.

References
1. Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association. Health literacy: report of the Council on Scientific Affairs. JAMA 1999;281:552–557
2. Kutner M, Greenberg E, Baer J. A first look

at the literacy of america's adults in the 21st century. Washington, DC, National Center for Education Statistics, U.S. Department of Education, 2005

3. Cavanaugh K, Huizinga MM, Wallston KA, Gebretsadik T, Shintani A, Davis D, Gregory RP, Fuchs L, Malone R, Cherrington A, Pignone M, DeWalt DA, Elasy TA, Rothman RL. Association of numeracy and diabetes control. Ann Intern Med 2008;148:737–746

4. Gazmararian JA, Williams MV, Peel J, Baker DW. Health literacy and knowledge of chronic disease. Patient Educ Couns 2003;51:267–275

5. Schillinger D, Grumbach K, Piette J, Wang F, Osmond D, Daher C, Palacios J, Sullivan GD, Bindman AB. Association of health literacy with diabetes outcomes. JAMA 2002;288:475–482

6. Rothman RL, DeWalt DA, Malone R, Bryant B, Shintani A, Crigler B, Weinberger M, Pignone M. Influence of patient literacy on the effectiveness of a primary care-based diabetes disease management program. JAMA 2004;292:1711–1716

7. Wallace AS, Seligman HK, Davis TC, Schillinger D, Arnold CL, Bryant-Shilliday B, Freburger JK, Dewalt DA. Literacy-appropriate educational materials and brief counseling improve diabetes self-management. Patient Educ Couns 2009; 75:328–333

8. Rothman RL, Montori VM, Cherrington A, Pignone MP. Perspective: the role of numeracy in health care. J Health Commun 2008;13:583–595

9. Golbeck AL, Ahlers-Schmidt CR, Paschal AM, Dismuke SE. A definition and operational framework for health numeracy. Am J Prev Med 2005;29:375–376

10. Apter AJ, Cheng J, Small D, Bennett IM, Albert C, Fein DG, George M, Van Horne S. Asthma numeracy skill and health literacy. J Asthma 2006;43:705–710

11. Huizinga MM, Beech BM, Cavanaugh KL, Elasy TA, Rothman RL. Low numeracy skills are associated with higher BMI. Obesity (Silver Spring) 2008;16:1966-1968

12. Rothman RL, Housam R, Weiss H, Davis D, Gregory R, Gebretsadik T, Shintani A, Elasy TA. Patient understanding of food labels: the role of literacy and numeracy. Am J Prev Med 2006;31:391–398

13. Kripalani S, Weiss BD. Teaching about health literacy and clear communication. J Gen Intern Med 2006;21:888–890

14. Wolff K, Cavanaugh K, Malone R, Hawk V, Gregory BP, Davis D, Wallston K, Rothman RL. The Diabetes Literacy and Numeracy Education Toolkit (DLNET): materials to facilitate diabetes education and management in patients with low literacy and numeracy skills. Diabetes Educ 35:233–236, 238–241, 244–245

15. Davis TC, Long SW, Jackson RH, Mayeux EJ, George RB, Murphy PW, Crouch MA. Rapid estimate of adult literacy in medicine: a shortened screening instrument. Fam Med 1993;25:391–395

16. Huizinga MM, Elasy TA, Wallston KA, Cavanaugh K, Davis D, Gregory RP, Fuchs LS, Malone R, Cherrington A, Dewalt DA, Buse J, Pignone M, Rothman RL. Development and validation of the Diabetes Numeracy Test (DNT). BMC Health Serv Res 2008;8:96

17. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care 2000;23:943-950

18. Wallston KA, Rothman RL, Cherrington A. Psychometric properties of the Perceived Diabetes Self-Management Scale (PDSMS). J Behav Med 2007;30:395–401

19. Bradley C. Diabetes treatment satisfaction questionnaire. In *Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice*. Chur, Switzerland, Harwood Academic, 1994, p. 111–132

20. Feng Z, McLerran D, Grizzle J. A comparison of statistical methods for clustered data analysis with Gaussian error. Stat Med 1996;15:1793–1806

21. Harrell FE. *Regression Modeling Strategies: With Applications to Linear Models, Logistic Regression and Survival Analysis.* New York, Springer, 2001

22. Hill-Briggs F, Renosky R, Lazo M, Bone L, Hill M, Levine D, Brancati FL, Peyrot M. Development and pilot evaluation of literacy-adapted diabetes and CVD education in urban, diabetic African Americans. J Gen Intern Med 2008;23: 1491–1494

23. Hill-Briggs F, Smith AS. Evaluation of diabetes and cardiovascular disease print patient education materials for use with low-health literate populations. Diabetes Care 2008;31:667–671

24. Doak CC, Doak LG, Root JH. *Teaching Patients with Low Literacy Skills.* Philadelphia, JB Lippincott, 1996