Addressing Literacy and Numeracy to Improve Diabetes Care: Two Randomized Controlled Trials

Running Title: Trials of Numeracy-sensitive Diabetes Education

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**Objective:** Diabetes 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 diabetes patients with most recent A1C ≥ 7.0%, referred for participation in an enhanced diabetes care program. For 3 months, control patients received care from existing enhanced diabetes care programs, while 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 (DLNET) 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, -1.02]; Control: -0.80 [95% CI: -1.10, -0.30]). In adjusted analysis, there was greater improvement in A1C in the intervention group compared to 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.

**Conclusion:** A literacy and numeracy focused diabetes care program modestly improved self-efficacy and glycemic control compared to standard enhanced diabetes care, but the difference attenuated after conclusion of the intervention.
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 United States have basic or below basic literacy skills and more than 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, multi-step 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 to usual delivery of an enhanced multidisciplinary diabetes care 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**

**Setting and Study Participants.** This study included two coordinated randomized controlled trials performed at two academic medical centers [NCT00469105 and NCT00311922] 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 age 18 to 80 years, English-speaking, with type 1 or type 2 diabetes mellitus, most recent A1C ≥ 7.0%, and were referred by their physician for participation in their local enhanced diabetes care program. Exclusion criteria included those who had a pre-existing diagnosis of severe cognitive impairment, or with corrected visual acuity of less than 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 randomized to the control or intervention condition. Randomization was concealed, computer generated, and performed at each site using random blocks of 4, 6 and 8 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 1A in the online appendix which is available at http://care.diabetesjournals.org). This included 1 to 6 face-to-face visits in a diabetes care program over a period of three months. At VUMC this program included visits with a diabetes nurse practitioner (>80% also were certified diabetes educators (CDE)) and a registered dietitian (RD) CDE within the Eskind Diabetes Center. At UNC, this included visits with a nurse practitioner (NP) CDE and an RD 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 1-2 didactic training sessions (1-2 hours each) about health literacy, numeracy and clear communication techniques(13) prior to 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 6th grade reading level, bulleted for key points, color coding, pictures, and step-by-step instructions. The intervention was delivered in 2-6 sessions over a three-month period. At VUMC the intervention was delivered by an advanced diabetes management nurse practitioner and CDE registered dietitians, while 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, 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 6th grade reading level by the REALM, then the remainder of the instruments were administered orally to ensure 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/prevention
andcontrol/tools.php) (16). Diabetes self-management activities were assessed by patient self-report, and with the validated Summary of Diabetes Self-Care Activities (SDSCA) 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 (DTSQ) (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 [IQR]) or frequency and percent for categorical variables. We compared patient characteristics by intervention status at baseline using Wilcoxon rank-sum tests for continuous variables and Pearson’s $\chi^2$ 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 randomized participants were included in the intention to treat analyses.

For our primary outcome, we used Wilcoxon 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-up, using Wilcoxon rank-sum test. Within each group, change in measures from baseline to 3 or 6-month follow-up were also examined using the Wilcoxon signed-rank test. Non-parametric 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, gender, 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 square regression method with correction for intra-subject correlation among repeated measures of A1C via a bootstrap estimation method (20; 21). Due to the high number of referring physicians (36 at VUMC and 57 at UNC), clustering by primary physician was also accounted for by non-parametric bootstrap methods. We included the interval of evaluation time (3 months 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 performed to impute missing A1C data points at 3 months and 6 months using available baseline covariates and this 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 alpha of 0.05, and standard deviation of 1.5, to detect a 1%-point greater improvement in A1C in the intervention compared to the control group. The final sample size was inflated to include a drop-out rate of 15-20%. We have studied multiple endpoints of interest in these studies. We report both negative as well as 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 Inc.; 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 Figure 1. Overall, patients were a median of 52 [IQR: 42 – 59] years old, 36% were male, and 43% African American. Almost half (49%) had a high school education or less, and almost 40% of patients had a literacy level below the 9th grade. Performance on the Diabetes Numeracy Test (DNT) suggested diabetes-related numeracy deficits with a median score of 59% [IQR: 26%-86%]. The median baseline A1C was 9.1% in both intervention and control groups. Baseline patient characteristics were similar between intervention and control except for 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 patient characteristics between the two sites. At UNC, the patients were more likely to be older, African American, have lower annual income, less educational attainment, lower literacy, and lower diabetes-related numeracy scores compared to participants at VUMC. UNC participants also had a longer duration of diabetes, 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 [95% CI]: 3.8 [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 dietician were longer than those with the nurse practitioner or pharmacist (mean [95%CI]: 49 [46 – 52] minutes 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 three 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-months enhanced diabetes care program, the intervention and control groups at each site had significant decreases in their A1C compared to baseline values (median [95% CI]: VUMC, Intervention -1.60 [-2.07, -1.00], Control -1.00 [-1.81, -0.40]; UNC, Intervention -1.40 [-1.75, -0.75], Control -0.30 [-1.06, -0.10]) (Table 2). In unadjusted analysis, improvement in A1C from baseline was greater in the intervention groups compared to the respective control groups at each site (VUMC: Median -0.5 [95% CI -1.20, 0.20]; UNC: -0.8 [95% CI -1.50, -0.20]), although only the UNC site was statistically significant (p=0.014). Overall, when combining all patients from both sites, there was greater improvement in A1C in the
intervention group compared to the control group (Median Difference in A1C: -0.70 [95% CI -1.10, -0.20]; p=0.005). In analyses combining all patients and adjusting for previously described variables, the intervention continued to demonstrate a significantly greater improvement in A1C compared to control at the 3-month time period (p=0.03) (Table 2).

At 6-months follow-up, which was 3-months after the completion of the enhanced care programs, patients continued to demonstrate significant improvements in A1C compared to 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 PDSMS scores between intervention and control for the UNC site (p=0.029), as well as for the combined sites (p=0.018). However, in analyses adjusted for age, gender, 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 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 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-efficacy. However, the impact of the literacy and numeracy-focused program on glycemic control was modest when compared to an already strong enhanced diabetes care program control group. In addition, although patients continued to have improved glycemic control compared to baseline values, the intervention was not able to show sustained benefits above the control setting three 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 Diabetes Literacy and Numeracy Education Toolkit (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 6th grade literacy level, as opposed to much of the existing health information, including materials specific to diabetes, which is often at a higher reading level (23) and also incorporates many other principles of clear communication. The DLNET can be used as a core element for both initial and on-going diabetes 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. While the total number of visits did not differ between intervention and control during the entire six months, patients in both groups did see a health provider more often during the three months of the intervention.
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compared to the observation period after the intervention period. This suggests that successful reduction in A1C may require a persistent level of intervention over time. This also may suggest that our program performs better as a disease management program rather than as a self-care training program.

Other explanations of why there was no difference seen between intervention and control group at the 6-month interval, as well as the modest difference at the 3-month interval, may be due to 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 that 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 physiologic and social factors associated with glycemic control. Also, the effectiveness of the intervention differed between the two study sites. Study participants in the control arm at UNC had much less of an improvement in A1C compared to 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, due to the similar hypotheses and design the decision to analyze the combined results of the two trials was made prior to 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. While this limits cross-sectional evaluations at those times, we used ordinary least squared regression models with multiple imputations to utilize 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 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 needs to be further studied to identify any and
all ways to improve care for patients with diabetes.

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Previous presentation of information in manuscript: Portions of this research have been previously reported in abstract form at the national meeting of the American Diabetes Association, 2008 and the national meeting of the Society of General Internal Medicine, 2008.

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REFERENCES

**Table 1. Baseline patient characteristics by group status and trial site**

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<th>Control</th>
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<td>24.5 [20.3, 28.8]</td>
<td>26.0 [23.0, 33.0]</td>
<td>24.0 [19.5, 30.0]</td>
<td>25.0 [22.0, 29.5]</td>
<td>24.0 [20.0, 29.0]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction: DTSQ [0-36] *</td>
<td>27.5 [21.0, 32.0]</td>
<td>29.0 [26.0, 33.0]</td>
<td>31.5 [26.0, 34.8]</td>
<td>30.0 [26.0, 32.5]</td>
<td>29.0 [23.3, 34.0]</td>
<td>29.5 [26.0, 33.0]</td>
<td></td>
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</tr>
</tbody>
</table>

*Median (Interquartile range); VUMC=Vanderbilt University Medical Center; UNC=University of North Carolina; REALM=Rapid Estimate of Adult Literacy in Medicine; PDSMS=Perceived Diabetes Self-Management Scale; DTSQ=Diabetes Treatment Satisfaction Questionnaire

† p<0.05 comparing intervention versus control by either Chi-squared or Wilcoxon-rank sum tests, as appropriate
Table 2. Change in A1C, self-efficacy, and satisfaction by study group from baseline

<table>
<thead>
<tr>
<th></th>
<th>Vanderbilt University Medical Center</th>
<th>University of North Carolina</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>P*</td>
</tr>
<tr>
<td><strong>Change in A1C</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median [95% CI]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to 3-months</td>
<td>-1.60 [-2.07, -1.00] §</td>
<td>-1.00 [-1.81, -0.40] §</td>
<td>0.121 †</td>
</tr>
<tr>
<td>Baseline to 6-months</td>
<td>-1.15 [-1.43, -0.77] §</td>
<td>-1.20 [-2.22, -0.70] §</td>
<td>0.657</td>
</tr>
<tr>
<td><strong>Change in Self-efficacy (PDSMS)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median [95% CI]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to 6-months</td>
<td>+ 8.0 [3.0, 8.5] §</td>
<td>+ 4.0 [1.0, 7.2] §</td>
<td>0.324</td>
</tr>
<tr>
<td><strong>Change in Satisfaction (DTSQ)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median [95% CI]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline to 6-months</td>
<td>+ 2.0 [1.0, 5.0] §</td>
<td>+ 3.0 [2.0, 6.4] §</td>
<td>0.584</td>
</tr>
</tbody>
</table>

CI=Median non-parametric 95% Confidence Interval; PDSMS=Perceived Diabetes Self-Management Scale; DTSQ=Diabetes Treatment Satisfaction Questionnaire

* P-value determined by Wilcoxon rank sum test comparing intervention and control.

§ P<0.05 for paired comparison of 3-month or 6-month value to 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, gender, race, type of diabetes, income, baseline Diabetes Numeracy Test score, baseline A1C level, accounted for physician cluster, and examined 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, gender, race, type of diabetes, income, baseline Diabetes Numeracy Test score, baseline A1C level, accounted for physician cluster, and examined an interaction term with time.
Trials of Numeracy-sensitive Diabetes Education

Figure

- 622 Pt. Referred
  - 366 VUMC
  - 256 UNC
- 424 Not enrolled
  - 316 Pt. refused
  - 42 Provider refused
  - 66 Ineligible
- 198 Randomized
  - 105 VUMC
  - 93 UNC
- 99 Control
  - 53 VUMC
  - 46 UNC
  - 10 VUMC
  - 9 withdrew or lost to follow-up
  - 1 died
  - UNC
  - 4 withdrew or lost to follow-up
- 99 Intervention
  - 52 VUMC
  - 47 UNC
- 85 with 3 or 6 Month Follow-up
  - 43 VUMC
  - 42 UNC
- 99 with 3 or 6 Month Follow-up
  - 52 VUMC
  - 47 UNC

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