An Internet-Based Diabetes Management Platform Improves Team Care and Outcomes in an Urban Latino Population

OBJECTIVE
To compare usual diabetes care (UDC) to a comprehensive diabetes care intervention condition (IC) involving an Internet-based "diabetes dashboard" management tool used by clinicians.

RESEARCH DESIGN AND METHODS
We used a parallel-groups randomized design. Diabetes nurses, diabetes dietitians, and providers used the diabetes dashboard as a clinical decision support system to deliver a five-visit, 6-month intervention to n = 199 poorly controlled (HbA$_1c$ >7.5% [58 mmol/mol]) Latino type 2 diabetic (T2D) patients (mean age 55 years, 60% female) at urban community health centers. We compared this intervention to an established, in-house UDC program (n = 200) for its impact on blood glucose control and psychosocial outcomes.

RESULTS
Recruitment and retention rates were 79.0 and 88.5%, respectively. Compared with UDC, more IC patients reached HbA$_1c$ targets of <7% (53 mmol/mol; 15.8 vs. 7.0%, respectively, $P < 0.01$) and <8% (64 mmol/mol; 45.2 vs. 25.3%, respectively, $P < 0.001$). In multiple linear regression adjusting for baseline HbA$_1c$, adjusted mean ± SE HbA$_1c$ at follow-up was significantly lower in the IC compared with the UDC group ($P < 0.001$; IC 8.4 ± 0.10%; UDC 9.2 ± 0.10%). The results showed lower diabetes distress at follow-up for IC patients (40.4 ± 2.1) as compared with UDC patients (48.3 ± 2.0) ($P < 0.01$), and also lower social distress (32.2 ± 1.3 vs. 27.2 ± 1.4, $P < 0.01$). There was a similar, statistically significant ($P < 0.01$) improvement for both groups in the proportion of patients moving from depressed status at baseline to nondepressed at follow-up (41.8 vs. 40%; no significance between groups).

CONCLUSIONS
The diabetes dashboard intervention significantly improved diabetes-related outcomes among Latinos with poorly controlled T2D compared with a similar diabetes condition without access to the diabetes dashboard.

Type 2 diabetes (T2D) is a rapidly growing epidemic in the U.S., currently affecting 29.1 million Americans (1) and projected to impact >40 million individuals by 2034 (2). National surveys show that the large majority of individuals with T2D are not at recommended treatment goals for its underlying risk factors, namely,
Diabetes Dashboard and Team Care for Latinos

providing usual diabetes care (UDC). Also, patient psychosocial factors, such as diabetes distress, social distress, and depression, that impact patient engagement and treatment adherence are not systematically managed as part of routine medical care in T2D (6,7).

The Affordable Care Act is a landmark piece of healthcare legislation that promotes more proactive and patient-centered management of T2D and other chronic diseases and, to accomplish this, promotes significant clinical care delivery and provider payment reforms. Other significant national healthcare legislation has mandated the national adoption of electronic medical records (EMRs) in clinical care to allow more efficient capture and “meaningful use” of patient clinical data across providers and clinical settings to facilitate greater patient engagement in self-care (8). For U.S. healthcare system reforms to succeed, it will be critical that providers are equipped with well-designed clinical decision support (CDS) tools that can facilitate patient-centered care and improve team communication and efficiency (9,10). CDS tools typically include clinical alerts and reminders, order sets, and drug-dose calculators that automatically prompt the clinician to implement a specific action and include care summary dashboards that provide performance feedback on important quality indicators. Although significant recent progress has been made in the creation of CDS applications for T2D (11–14), they remain at an early stage of development and evaluation.

We report here on the results of a randomized clinical trial that examined the clinical effectiveness of a comprehensive diabetes care intervention in which an Internet-based “diabetes dashboard” disease management application was used as a CDS system for team care delivered at urban poor safety net clinics. We compared the clinical benefit of the diabetes dashboard intervention with that of a control condition providing usual diabetes care (UDC).

RESEARCH DESIGN AND METHODS

We used a parallel-groups randomized design for this clinical trial. Eligible patients were randomized either to the diabetes dashboard intervention condition (IC) or to an in-house UDC program delivered without access to the diabetes dashboard. The study was conducted at two affiliated Federally Qualified Healthcare Centers (FQHCs) located in Western Massachusetts in an area where >30% of families locally live below the federal poverty line (15). The clinics are located in a medically underserved and health professional shortage area. The 29 clinic providers serve a predominantly (~80%) Latino urban poor community including >2,400 diabetic patients.

For this study, eligible T2D patients were recruited from December 2010 to December 2012. Patients were identified from a clinic diabetes registry and using referrals from an ophthalmology practice affiliated with the participating clinics. Patient inclusion criteria were as follows: age 18 years or older, self-identified Hispanic ethnicity, diagnosis of T2D, HbA1c >7.5% (58 mmol/mol), and provider approval given for patient participation. Exclusion criteria included inability to consent, pregnant or planning to become pregnant in the next year, taking glucocorticoid therapy, or having serious psychiatric or medical complications (e.g., late-stage diabetes complications, seizures, dementia, or psychiatric hospitalization) that would prevent participation in study activities. Patients were paid a stipend for completion of baseline and 6-month follow-up research assessments ($25 each). The intervention was implemented at medical offices located within the FQHCs. The protocol was approved by the Baystate Medical Center Institutional Review Board.

Diabetes Dashboard IC

The IC involved a program of five, in-person, one-on-one diabetes education visits with a diabetes nurse or diabetes dietitian, scheduled at baseline, 2 weeks, 1 month, 3 months, and 6 months post-enrollment. The initial visit was an hour long, and the remaining visits were a half hour long each. The IC was delivered by a team of four bicultural, bilingual diabetes educators (two diabetes nurses and two diabetes dietitians), with patients scheduled to see specific educators by request or based on availability (e.g., patients could request to see the same educator for repeated visits or could see all four educators over the course of their study participation).

The diabetes nurse and diabetes dietitian interventionists used an Internet-based “diabetes dashboard” disease management tool (see Supplementary Fig. 1) to structure each education visit and to share information collected during each visit with each other and with clinic providers. This dashboard, referred to during this study as the Comprehensive Diabetes Management Program, has been described previously (16,17) and combines existing clinical data obtained from paper chart-based and electronic health records (i.e., vital signs, laboratories, medications, admissions, procedures, and diagnoses) with additional patient data gathered using integrated surveys (described below) and during the course of ongoing care. Two of the diabetes educators (P.S.-K. and Z.R.) had extensive experience using the diabetes dashboard in an earlier pilot study (16).

The diabetes dashboard provides the following: 1) a system of individual clinical alerts and reminders (e.g., missing or elevated HbA1c) and a diabetes complications risk profile (five composite risks of glycemia, retinopathy, cardiac, peripheral vascular disease/periﬁer neuropathy, and nephropathy) that supports the delivery of evidence-based treatment protocols (18,19) (for example, the glycemia risk complications alert reflects the current level of HbA1c, annual frequency of testing of HbA1c, and diagnoses hypoglycemia); 2) a set of nursing, medical nutrition therapy, and physical activity treatment plan encounter forms involving drop-down menus and a structured data collection process; 3) a library of diabetes education teaching resources based on American Association of Diabetes Educator guidelines (AADE7) (20); and 4) a series of clinical reports, including a provider summary (see Supplementary Fig. 2) generated after each intervention visit that is emailed to the provider to support clinical decision making and includes recommendations for changes in medication management for hyperglycemia, hypertension, and dyslipidemia.

For the current study, each education visit with the diabetes nurse or diabetes
dietitian interventionists began with a review based on a summary of patient-reported self-management behaviors and barriers (i.e., blood glucose testing, diet, physical activity, and medication adherence) and psychosocial challenges (i.e., diabetes distress, social distress, depression, hypoglycemia, binge eating, alcohol abuse, and low social support) collected using an established survey integrated within the dashboard (i.e., the Diabetes Self-Care Profile [21]). Next, the interventionist reviewed the patient’s vital signs and laboratory data, conducted a medication review and reconciliation process and updated the medication list, reviewed clinical alerts and reminders generated by the system, and updated the nursing or dietetic treatment plan using encounter forms. Following these steps, the interventionist delivered diabetes education tailored to the patient’s individual clinical, behavioral, and psychosocial profile and referred the patient for psychosocial services (e.g., adjacent mental health clinic for depression) as needed and with notification to the primary care provider. Interventionists recorded clinical notes for each visit by free text using a “whiteboard” panel on the dashboard to facilitate internal team communication and patient handoff between sessions.

The diabetes nurse and diabetes dietitian interventionists created clinical care recommendations for providers on pharmacological management of abnormal blood glucose, blood pressure (BP), and lipid levels (e.g., Supplementary Fig. 2) after several initial diabetes education evaluation and education sessions to develop rapport, assess current medication adherence, and provide individualized diabetes education and support. A patient safety and triage plan refined by the primary care providers was used for patients who presented at intervention visits as symptomatic for shortness of breath, chest pain, headache, BP >180 mmHg, or BG >350 mg/dL with presence of ketones. Presence of these symptoms triggered a notification to the provider, covering physician, or clinical nurse for action. To address the cultural needs of the Latino patients that were the focus of this study, the intervention included the following: 1) delivery of the intervention and diabetes education materials in the patient’s preferred language (Spanish or English), 2) literacy and numeracy screening using a brief, practical assessment tool we had used in prior research (22), 3) encouragement of attendance by family members in intervention sessions, 4) inclusion of ethnic foods and modified ethnic recipes in the provision of medical nutrition therapy, and 5) assessment of alternative healers and home remedies by patients and encouragement of patients to discuss these alternative practices for their safety and risk with their primary care provider.

Training for the diabetes interventionist team included training in the use of the dashboard as well as a diabetes medication treatment protocol provided for the management of blood glucose, BP, and lipid medications in T2D based on national guidelines (19). Three hours of training were provided to the diabetes team as one in-person session and two conference calls by study interventionists created clinical sessions and patient handoff between sessions.

**UDC**

The UDC condition was delivered by four additional bicultural, bilingual diabetes nurses and diabetes dietitians who comprised the clinical site’s long-standing, in-house diabetes program. This program was designed as part of the Robert Wood Johnson Foundation Diabetes Initiative to advance the delivery of culturally sensitive care for patients with T2D in primary care (23,24). The UDC condition involved a series of individual patient visits with education content. Visit frequency was based on individual patient needs as determined by program clinicians. Patients also had access to lifestyle and diabetes self-management support groups run at the clinics by peer volunteers and clinical staff. Patients in the UDC condition completed the same assessment battery (i.e., Diabetes Self-Care Profile [18]) as that completed by patients in the IC. However, data from this assessment was used only for research purposes and was not used to guide clinical care delivered within the UDC condition. Both IC and UDC patients received routine medical care from their healthcare providers for any acute and emergent problems based on established clinic standards and procedures.

**Measurements**

**Clinical Measures**

Patients attended a 1-hour baseline research assessment and a 30-min follow-up assessment at 6 months. The primary study outcome was defined as the percentage of patients achieving good blood glucose control (i.e., HbA1c <7% [53 mmol/mol]). HbA1c was obtained using a validated finger stick blood test kit (Apprrove Home HbA1c Kit; Heritage Laboratories International LLC). Heritage Laboratories is certified by the National Glycohemoglobin Standardization Program. The Apprrove Home HbA1c Kit produces accurate and reliable test results equivalent to whole blood tests collected in physicians’ offices. Other clinical variables assessed the percentage of patients at target BP (<130/80 mmHg) and BMI. Systolic and diastolic BP measurements were obtained by research staff during baseline and follow-up research visits based on a single seated assessment using an automatic digital BP monitor (Omron model HEM-705CP). BMI was calculated as weight in kilograms divided by the square of height in meters. Hypoglycemia was defined in the Diabetes Self-Care Profile as any “low blood sugars or sweating, nausea, heart pounding, trembling, cold and clammy skin, difficulty concentrating, and irritability” over the past month.

**Psychosocial Measures**

We used the Diabetes Self-Care Profile survey (18) to assess diabetes distress, social distress, and depression (secondary study outcomes). Assessment of diabetes distress involved the short (five-item) version of the Problem Areas In Diabetes (PAID) questionnaire that assesses the emotional burden of diabetes and its treatment. PAID is a valid and widely used measure that uses a 0–100 scale, with higher scores denoting greater distress (25,26). We measured social distress on a 0–100 scale using the 20-item Tool for Assessing Patients’ Stress (TAPS) questionnaire, a measure with evidence of internal reliability and construct validity and found acceptable to urban poor T2D patients (6,16,27). TAPS assesses recent distress related to taking care of family needs and problems, lack of money for basic living needs or having
family conflicts, legal problems, overcrowding, living in an unsafe neighborhood, physical or mental abuse, discrimination, and job loss or underemployment, among other significant social and family issues targeted. We measured depression using the Patient Health Questionnaire, a validated, widely used nine-item self-report measure of depression (28). Other patient data collected at baseline included age, sex, race, ethnicity, and duration of diabetes in years.

Data Analyses
We described characteristics of the study population using means and SDs for continuous covariates and Student t test to assess whether differences in means between the two treatment conditions were statistically significant. For categorical covariates, we reported the number and percentage of patients within each category and examined differences between treatment groups using Fisher exact test, which is more conservative than the χ² and is appropriate for both large and small cell frequencies.

We conducted outcome analyses as intention to treat, such that we analyzed patients with the group they were randomized to regardless of how many intervention visits they completed. We conducted an efficacy subset analysis approach to address missing research data, as loss to follow-up was small, with <10% of patients having missing research data at follow-up. For comparisons of outcomes by treatment status, we conducted a sensitivity analysis in which we used multiple imputation methods to address missing data.

We evaluated associations between treatment group and the dichotomous HbA₁c control status variables using unadjusted and multiple logistic regression, with HbA₁c control status as the dependent variable. We evaluated associations between treatment group and the continuous outcome variables using unadjusted and multiple linear regression. We adjusted models for baseline values and considered covariates that were associated with treatment status or HbA₁c at P < 0.20 on univariable analysis for inclusion in our final multiple regression models. We included covariates in the final multiple regression models if their addition resulted in at least a 10% change in the β coefficient for the treatment status variable.

We performed analyses using SAS software version 9.3 (SAS Institute, Cary, NC) and Stata (version 12.0; StataCorp, College Station, TX) (29). The SAS commands we used included proc freq for categorical comparisons and proc GLM for modeling continuous variables. To examine the influence of missing data, we used multiple imputation to replace missing values (i.e., Stata’s “mi impute mvn” command). Assuming an underlying multivariate normal distribution, the command imputes missing values through an iterative MCMC approach. We created 20 imputed datasets to reduce sampling variability from the imputation process.

RESULTS
Screening, Recruitment, and Retention
Figure 1 shows the recruitment and retention of patients into this clinical trial. In brief, 75.4% of eligible patients invited to participate in the study were subsequently enrolled and randomized to either the intervention (n = 199) or control (n = 200) study conditions. IC patients completed an average of 3.8 ± 1.5 visits with the study interventionists. Although data were not collected on the number of clinic visits for individual UDC patients, patients receiving UDC at our clinical site attended an average of 5.2 visits with clinic providers during a 5–6-month time frame based on an unpublished internal clinic report and from interviews of diabetes staff members following the intervention phase. Follow-up research visits were completed by 86.4% of IC patients and 90.5% of UDC patients.

Sample Characteristics
Participant baseline characteristics are shown in Table 1. There were no significant differences between the study conditions in terms of demographic (sex, age, and race), clinical (HbA₁c, BP, and BMI), and most psychosocial (depression status, social distress, and perceived social support) variables. However, a significant baseline difference between the groups was observed in diabetes distress (62.9% for IC vs. 50.5% for UDC, P < 0.03), although both groups were at clinically high levels.

Clinical Outcomes
Rates of HbA₁c control were higher among IC patients at follow-up, such that 15.8% of IC patients were at the treatment goal of HbA₁c <7% (53 mmol/mol), as compared with 7.0% of UDC patients (P < 0.01). In an analysis of patients with an HbA₁c >8.0% (64 mmol/mol) at baseline, 45.2% of IC patients vs. 25.3% of UDC patients met the goal of HbA₁c <8.0% at follow-up (P < 0.001). In multiple linear regression adjusting for baseline HbA₁c, adjusted mean ± SE HbA₁c at follow-up was significantly lower by 0.81 ± 0.15% units in the IC group as compared with the UDC group (P < 0.001; IC 8.4 ± 0.10%; UDC 9.2 ± 0.10%) (Table 2). Results for mean HbA₁c at follow-up were similar in our sensitivity analysis based on imputed data, such that HbA₁c at follow-up was 0.82 ± 0.15% units lower in IC versus UDC participants (P < 0.001).

We also examined descriptive clinical data on BP and BMI at follow-up using multiple linear regression adjusted for baseline values and found no significant difference between the groups in terms of these variables (Table 2). Results were similar when multiple imputation methods were used to fill in missing data (data not shown).

Self-reported hypoglycemia symptoms improved in both groups. In the IC group, 34.7% of patients reported having hypoglycemia symptoms in the prior month to baseline. Of those patients, only 49.3% reported hypoglycemia symptoms at follow-up. In the UDC group, 38% of patients reported
hypoglycemia symptoms at baseline, and only 44.7% of those patients reported symptoms at follow-up. There were no statistical differences between the IC and UDC conditions. There were also no differences between the two conditions in new reports of hypoglycemia at follow-up (22 vs. 20.6%, no significance).

Psychosocial Outcomes
The results showed lower diabetes distress at follow-up for IC patients (40.4 ± 2.1) as compared with UDC patients (48.3 ± 2.0) (P < 0.01) and also lower social distress (32.2 ± 1.3 vs. 27.2 ± 1.4, P < 0.01) (Table 2). There was a similar, statistically significant (P < 0.01) improvement for both groups in the proportion of patients moving from depressed status at baseline to nondepressed at follow-up (i.e., 41.8 vs. 40%), with no significant difference between groups in terms of change in depression status.

CONCLUSIONS
This clinical trial conducted at two affiliated urban safety net clinics focused on Latino T2D patients in poor glycemic control and demonstrated the clinical effectiveness of a diabetes care program enriched by use of a diabetes dashboard application to support team care. The dashboard provided the diabetes team with timely clinical alerts and reminders of diabetes-specific medical and psychosocial issues, encounter and treatment plan templates, and diabetes education resources and generated summary reports of intervention sessions to share with providers. Despite the artificiality inherent in delivering a time-limited (6-month) clinical research intervention within a busy primary care setting, the diabetes dashboard helped organize the work of the diabetes educator team (i.e., diabetes nurses and diabetes dietitians) and supported the provision of patient-centered and evidence-based diabetes care. The diabetes dashboard also created a bridge to the clinic providers via the individual session summary reports and medication change recommendations sent to the providers following intervention sessions. The UDC control condition consisted of a long-standing comprehensive diabetes care program designed as part of a Robert Wood Johnson Foundation Diabetes Initiative to advance the delivery of culturally sensitive care for patients with T2D (23,24).

The study findings showed that twice as many IC patients achieved a goal of HbA1c <7% (53 mmol/mol) compared with the UDC condition (i.e., 15.8 vs. 7.0%, respectively). For an HbA1c cutoff of <8% (64 mmol/mol), the results were 45.2 vs. 25.3%, respectively. The intervention provided a statistically and clinically significant mean HbA1c improvement (reduction) of −0.6% (−6.6 mmol/mol) compared with a worsening for the UDC condition of +0.2% (±2.2 mmol/mol). As a benchmark to interpret this difference in intermediate diabetes outcomes, landmark national studies have shown that for every 1% (10.9 mmol/mol) reduction in HbA1c, the risk of developing eye, kidney, and nerve disease is reduced by 40% while the risk of heart attack is reduced by 14% (30).

Analysis of our secondary psychosocial outcomes showed a significant reduction in both diabetes distress and social distress for the IC compared with the UDC condition. Both conditions showed high baseline levels of distress, consistent with findings from prior studies of urban poor T2D populations.

Table 1—Comparison of intervention groups at baseline

| Continuous variables | Usual diabetes care, n = 200 | Intervention condition, n = 199 | P value
|----------------------|-------------------------------|--------------------------------|--------|
| Age (years)          | Mean ± SD                     | Mean ± SD                      | 0.72   |
| BMI (kg/m²)          | 55.2 ± 11.9                   | 54.8 ± 10.3                    | 0.6     |
| HbA1c (% units)      | 33.9 ± 7.5                    | 35.4 ± 7.7                     | 0.06   |
| HbA1c (mmol/mol)     | 9.0 ± 1.5                     | 8.9 ± 1.4                      | 0.74   |
| Systolic BP (mmHg)   | 75.0 ± 16.4                   | 74.0 ± 5.3                     | 0.74   |
| Diastolic BP (mmHg)  | 136.2 ± 19.4                  | 135.3 ± 21.3                   | 0.68   |
| BMI (kg/m²)          | 77.0 ± 10.4                   | 78.3 ± 11.3                    | 0.22   |
| Diabetes distress    | 51.9 ± 32.3                   | 59.0 ± 30.5                    | 0.03   |
| Social distress      | 34.5 ± 1.6                    | 35.8 ± 1.6                     | 0.55   |
| Categorical variables (%) | % | % | 0.09 |
| Female               | 59.0                           | 60.8                           | 0.71   |
| White race           | 98.5                           | 98.0                           | 0.69   |
| Hispanic ethnicity   | 100.0                          | 100.0                          | 0.01   |
| High diabetes distress | 50.5   | 62.9                           | 0.01   |
| Major depression     | 41.2                           | 32.7                           | 0.09   |

1Based on Student t test for continuous variables and Fisher exact test for categorical variables.
2Measured using the PAID questionnaire, scored from 0 to 100, with higher scores indicative of greater diabetes distress; a score of >50 is indicative of high diabetes distress.
3Measured using TAPS, scored from 0 to 100, with higher scores indicative of greater social distress.
4Remaining patients self-identified as black/African American.
5Measured using the Patient Health Questionnaire nine-item depression measure; patients endorsing five or more items are categorized as having major depression.

Table 2—Clinical and psychosocial outcomes by IC

| Clinical outcomes | Usual diabetes care, n = 200 Mean ± SE | Intervention condition, n = 199 Mean ± SE | P value
|-------------------|---------------------------------------|------------------------------------------|--------|
| BMI (kg/m²)       | 35.0 ± 0.1                            | 34.9 ± 0.1                               | 0.50   |
| HbA1c (% units)   | 9.2 ± 0.1                             | 8.4 ± 0.1                                | <0.001 |
| HbA1c (mmol/mol)  | 77.0 ± 1.1                            | 68.0 ± 1.1                               | <0.001 |
| Systolic BP (mmHg)| 137.0 ± 1.3                           | 137.2 ± 1.3                              | 0.93   |
| Diastolic BP (mmHg)| 76.9 ± 0.7                             | 77.5 ± 0.7                               | 0.54   |
| Psychosocial outcomes |                                       |                                          |        |
| Diabetes distress | 48.3 ± 2.0                             | 40.4 ± 2.1                               | <0.01  |
| Social distress   | 32.2 ± 1.3                             | 27.2 ± 1.4                               | <0.01  |

1Adjusted P values based on linear regression; models are adjusted for baseline values, with no additional variables retained in these final models. 2Measured using the PAID questionnaire, scored from 0 to 100, with higher scores indicative of greater diabetes distress; a score of >50 is indicative of high diabetes distress. 3Measured using TAPS, scored from 0 to 100, with higher scores indicative of greater social distress.
Improvement in depression status was seen among patients in both study conditions (~40% of those screening positive for major depression at baseline were subsequently in remission at follow-up) but with no statistically significant difference found between the conditions at follow-up.

These results for psychosocial outcomes provide empirical support for the value of systematically assessing and actively managing T2D patients who report diabetes-related psychosocial challenges, as has been recommended in prior reviews (7,33). It is notable that the Institute of Medicine has recently recommended that patient-reported assessments capturing a patient’s experience of illness should be routinely incorporated into the EMRs, including emotional distress and depression (34). The diabetes dashboard thus provides a strategy for primary care clinics to meet these new recommendations, with modifications and updates over time, as appropriate.

We explored the effect of intervention treatment dose on outcomes in poststudy sensitivity analyses and found that greater exposure produced greater poststudy sensitivity analyses and found that the Institute of Medicine has recently recommended that patient-reported assessments capturing a patient’s experience of illness should be routinely incorporated into the EMRs, including emotional distress and depression (34). The diabetes dashboard thus provides a strategy for primary care clinics to meet these new recommendations, with modifications and updates over time, as appropriate.

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