Translating the Chronic Care Model Into the Community

Results from a randomized controlled trial of a multifaceted diabetes care intervention

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OBJECTIVE — To determine whether using the chronic care model (CCM) in an underserved community leads to improved clinical and behavioral outcomes for people with diabetes.

RESEARCH DESIGN AND METHODS — This multilevel, cluster-design, randomized controlled trial examined the effectiveness of a CCM-based intervention in an underserved urban community. Eleven primary care practices, along with their patients, were randomized to three groups: CCM intervention (n = 30 patients), provider education only (PROV group) (n = 38), and usual care (UC group) (n = 51).

RESULTS — A marked decline in HbA1c was observed in the CCM group (−0.6%, P = 0.008) but not in the other groups. The magnitude of the association remained strong after adjustment for clustering (P = 0.01). The same pattern was observed for a decline in non-HDL cholesterol and for the proportion of participants who self-monitor blood glucose in the CCM group (non-HDL cholesterol: −10.4 mg/dl, P = 0.24; self-monitor blood glucose: +2.22%, P < 0.0001), with statistically significant between-group differences in improvement (non-HDL cholesterol: P = 0.05; self-monitor blood glucose: P = 0.03) after adjustment. The CCM group also showed improvement in HDL cholesterol (+5.5 mg/dl, P = 0.0043), diabetes knowledge test scores (+6.7%, P = 0.07), and empowerment scores (+2, P = 0.02).

CONCLUSIONS — These results suggest that implementing the CCM in the community is effective in improving clinical and behavioral outcomes in patients with diabetes.

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Diabetes affects ~7% of the U.S. population and has reached epidemic proportions (1). Diabetes represents a significant public health burden worldwide by decreasing quality of life and causing death and disability at great economic cost (2). Though quality diabetes care is essential to prevent long-term complications, care often falls below recommended standards regardless of health care setting or patient population, emphasizing the necessity for system change (3–6).

The chronic care model (CCM) (3,4,7,8) is a multifaceted framework for enhancing health care delivery. The model is based on a paradigm shift from the current model of dealing with acute care issues to a system that is prevention based (3,5,7–9). The premise of the model is that quality diabetes care is not delivered in isolation and can be enhanced by community resources, self-management support, delivery system redesign, decision support, clinical information systems, and organizational support working in tandem to enhance patient-provider interactions (3,4,7–13).

The objective of the current study was to determine the effectiveness of an intervention based on the CCM in primary care settings. We hypothesized that patient clinical (glycemic, blood pressure, and lipid control), behavioral (self-monitoring of blood glucose), psychological/psychosocial (quality of well-being and empowerment scores), and diabetes knowledge outcomes would improve in patients who received the CCM intervention compared with those who did not.

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Abbreviations: ADA, American Diabetes Association; CCM, chronic care model; CDE, certified diabetes educator; DSMT, diabetes self-management training; WHO-QWB10, World Health Organization (Ten) Quality of Well-Being; RCT, randomized controlled trial.

A table elsewhere in this issue shows conventional and Systeme International (SI) units and conversion factors for many substances.

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The study design is outlined in Fig. 1. Details of implementation of the CCM are outlined in Table 1.

**Phase 1: cross-sectional chart review**
A chart audit was conducted to establish benchmarks for adherence to the American Diabetes Association (ADA) standards of care (16) and to determine the generalizability of the population randomized in the RCT. Twenty-four general, family, and internal medicine practices, encompassing 42 providers with admitting privileges to the local community hospital, were eligible for the study. These practices were free-standing practices in the community whose patients were insured by a variety of carriers. Letters were sent to all providers in these practices inviting them to participate. Eleven practices, representing 24 providers (21 physicians, 2 nurse practitioners/physician assistants, and 1 behaviorist) participated in the baseline chart audit (phase I). One hundred percent of providers within each of the practices participated. Participating providers were slightly younger and had significantly less time practicing in comparison to the providers who chose not to participate (46 vs. 51 years of age, \(P = 0.08\) and 17.1 vs. 27.3 years of age, \(P < 0.0001\), respectively). Additionally, of the providers who chose to participate, 82.6% were from a group practice in comparison to those who did not participate, in which 42.1% were from a group practice. There were no differences by board certification (participating providers versus nonparticipating providers: internal medicine: 60.9 vs. 47.4%; family practice: 30.4 vs. 42.1%, \(P = 0.85\)). One of the participating providers was an endocrinologist but also served as a primary care provider. All participating providers gave informed consent.

Medical charts that included a confirmed diagnosis of diabetes by ICD-9 codes (250.xx), problem lists (type of diabetes), and lab results (two or more fasting glucose readings >126 mg/dl or two random glucose readings >200 mg/dl or HbA1c [A1C] >7% or use of diabetes medication) during or before calendar year 1999 were audited by a trained chart reviewer. Charts for 762 patients met the diagnosis criteria and were audited.

**Phase II: interventions**
Upon completion of the chart audit, practices were randomized into one of three study groups (Fig. 1). An initial block randomization procedure was undertaken, with practice size (determined by the number of people with diabetes in each practice) as the blocking factor. The randomization resulted in three practices receiving the CCM intervention, three practices receiving only provider education (PROV group), and five practices receiving usual care (UC group).

The CCM intervention involved patient and provider education, as well as the provision of other CCM elements in the community (Table 1). Provider-based diabetes education was offered to all providers via attendance at one problem-based learning session (Table 1). Additionally, providers randomized to the CCM intervention were encouraged to redesign the process in which they saw patients with diabetes for routine visits (Table 1). A certified diabetes educator (CDE) was placed in the practices on provider-specified “diabetes days” and was available to all patients with diabetes and to the providers for consultation. The CDE remained in the practices for 6 months.

Patients receiving care from providers randomized to the CCM intervention were invited to participate in six diabetes self-management training (DSMT) sessions, which were facilitated by a CDE and held weekly, followed by monthly support groups held until the time of their 1-year follow-up visit. The curriculum for the sessions was based on the University of Michigan DSMT curriculum (17). This included the required diabetes education content areas set forth in the ADA stan-

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**Figure 1—Study design. Group practices (more than one physician): n = 7. Internal medicine practices: \(n = 4\). General medical practices: \(n = 3\). Three solo practitioners were internists; one was a general practitioner.**
At the first session, subjects received their clinical data results along with information about self-care behaviors that could be taken to influence their results. All of the subsequent DSMT sessions were structured in a similar manner and were based on the empowerment approach to diabetes education (19). Classes started with an open-ended question and discussion. DSMT content areas were discussed, examples were provided, and questions were answered throughout the session. Topics were often rediscussed as participants gathered more information and considered it during the week. Greater than 75% of the participants attended at least three-fourths of the six classes. Monthly support groups were formed when the participants completed the classes. Support group topics included foot care, a cooking class focused on healthy eating and recipe modification, alternative treatments, and problem solving skills. Over half of the participants attended at least two-thirds of the available support groups.

Provider education–only group (PROV group). This intervention consisted of the providers attending one problem-based learning session (Table 1). All providers in the CCM and PROV groups received their chart audit results. The reports were reviewed by the CDE using academic detailing (20). In contrast to those providers in the CCM intervention group, the CDE was not placed in these

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PBL, problem-based learning.
practices but was made available to these providers for consultation during a 6-month period of the study.

**Usual care (UC group).** Providers in the UC group were mailed their practice’s chart audit report and decision support items. Recruitment of participants began in September 2001 when the consented providers mailed letters, written for them by study investigators, to their patients with diabetes, inviting them to participate in the study. Patients were instructed to contact study staff for appointment scheduling and to answer any questions they may have had. The 762 patients identified from the chart audit, made up the pool of eligible subjects. One hundred and nineteen subjects, 30 from the CCM group, 38 from the PROV group, and 51 from the UC group, chose to participate. Recruitment ended in June 2002. To determine whether the RCT population was a representative sample of the chart audit population, RCT participants were compared with chart audit subjects. No significant differences were observed in any demographic characteristics (age: RCT: 67.6 years [95% CI 65.6–69.6] vs. chart audit: 65 years [63.9–66.1]; diabetes duration: RCT: 11.9 years [9.9–13.9] vs. chart audit: 9.3 years [8.6–10]; percent male: RCT: 50.4 [40.8–58.4] vs. chart audit: 46.9 [35.7–58.1]; and percent nonwhite: RCT: 8.4 [3.4–13.3] vs. chart audit: 8.2 [7.2–9.2]).

**Measures**
After providing informed consent at baseline, all participants had height, weight, and blood pressure measured according to standard protocol. Subjects also had a nonfasting blood draw for lipids and A1C and provided a urine sample to test for microalbuminuria. Following testing, all subjects participated in a 1-h question-and-answer session with a CDE, at which time they completed a series of questionnaires (outlined below), which have all been validated and tested in adult populations with type 2 diabetes. These measures were also collected at 12-month follow-up. One hundred and seven participants had follow-up data. Two provided no clinical data. The final follow-up response rate was 90%.

**Survey instruments**

**Modified Diabetes Care Profile.** The Modified Diabetes Care Profile is a self-administered questionnaire that contains scales that assess patients’ diabetes health care utilization, diabetes self-care, medication use, and comorbidities (21). Sections of the original diabetes care profile (21) that did not directly relate to our study objectives were removed (i.e., social and personal factors, attitudes toward diabetes, diet adherence, monitoring barriers and understanding management practice, exercise barriers, and long-term care benefits).

**Diabetes Empowerment Scale.** The Diabetes Empowerment Scale, a 30-item psychosocial self-efficacy scale developed specifically for empowerment-based DSMT, contains three subscales addressing patients’ management of the psychosocial aspects of diabetes care, dissatisfaction and readiness to change, and readiness to set and achieve diabetes-related goals (22).

**Diabetes Knowledge Test.** The 23-item Diabetes Knowledge Test represents a test of general diabetes knowledge. Questions address understanding of medication effects, self-monitoring of blood glucose, and nutrition (23).

**World Health Organization (Ten) Quality of Well-Being Index (WHO-QWB10).** The WHO-QWB10 includes negative and positive aspects of well-being in a single uni-dimensional scale (24).

**Laboratory methods**
A1C was determined with the DCA 2000 analyzer (Bayer HealthCare, Elkhart, IN). The Cholestech LDX system (Cholestech, Hayward, CA) was used to measure total and HDL cholesterol and triglycerides. Non-HDL cholesterol was calculated (total cholesterol – HDL cholesterol). Microalbuminuria was measured using Chemstrip Micral test strips.

**Study outcomes**
The primary outcomes of the RCT included reduction in A1C, non-HDL cholesterol, and blood pressure levels. Secondary outcomes for the study were improvements in quality of well-being, diabetes knowledge, empowerment, and the frequency of self-monitoring of blood glucose. The University of Pittsburgh Institutional Review Board approved the study protocols, and all patients gave informed consent.

**Analyses**
Analyses and results presented in this report will focus on the RCT. Changes in provider practice patterns will be examined in a forthcoming report. In univariate analyses, paired t tests for continuous data and McNemar’s test for categorical data were used to determine within-group differences between baseline and 12-month follow-up. To examine differences between the three study groups, a combined between- and within-group ANOVA was performed for each outcome of interest. Stepwise linear or logistic regression was then used as a screening mechanism to identify whether differences existed between the outcome and process/demographic characteristics, before the incorporation of multilevel modeling. Mixed modeling (25) was used to analyze the change in outcome values from baseline to 12-month follow-up between study groups. The effect of study group was adjusted for the clustering of patients within provider practices, age, and insulin use in all models. Baseline values of the dependent variable were adjusted for if significant differences occurred between baseline and follow-up.
RESULTS — Demographic characteristics of the 119 subjects participating in the RCT are shown in Table 2 by study group. Demographic characteristics were similar across groups, with the exception of age, where subjects were older in the CCM group (CCM intervention: aged 69.7 years, PROV group: aged 64.4 years, and UC group: aged 68.6 years, *P* = 0.04).

Analysis of the change in clinical outcomes among subjects from baseline to follow-up was conducted on the 105 subjects who had complete laboratory data at both time points (Table 3). A1C values declined significantly in the CCM group, with no change in the other groups (CCM intervention: 7.6% to 7.0%, *P* = 0.008; PROV group: 7.3% to 7.3%, *P* = 0.92; and UC group: 6.9% to 6.8%, *P* = 0.15). When the effect of group was adjusted for the clustering of patients within practices, age, insulin use, and baseline A1C value, the magnitude of the association remained strong (*P* = 0.01). The same pattern of results was observed for non-HDL cholesterol (CCM intervention: 153.7 to 143.3 mg/dl, *P* = 0.24; PROV group: 147.9 to 168.8 mg/dl, *P* = 0.79; and UC group: 147.3 to 148.7 mg/dl, *P* = 0.78), with a statistically significant between-group difference in improvement (*P* = 0.05) after adjustment in the multivariate models (Table 3). There was no intervention effect on blood pressure levels. We further adjusted for treatment intensification (medication dosage increase and/or medication class change) with no change in interpretation.

The change in psychological/psychosocial and behavioral outcomes among subjects was also examined. Results are detailed in Table 3. After adjustment for the clustering of patients within practices, age, insulin use, and baseline values, there were no statistically significant between-group intervention effects on the Diabetes Knowledge Test, WHO-QWB10, and Diabetes Empowerment Scale scores. Within-group differences in the aforementioned outcomes, though, were observed. Subjects in the CCM group demonstrated improvement in Diabetes Knowledge Test scores (55.2%–61.9%, *P* = 0.07) and mean total Diabetes Empowerment Scale scores (3.8–4.0, *P* = 0.02). WHO-QWB10 scores decreased significantly in the PROV group (19 vs. 17.2, *P* = 0.02). Lastly, there were statistically significant within- and between-group differences in the frequency of self-monitoring of blood glucose. Frequency of self-monitoring of blood glucose increased significantly in the CCM group, with no change in the other groups (CCM group: 77.8–100%, *P* < 0.0001; PROV group: 84.4–90.6%, *P* = 0.16; and UC group: 81.3–81.3%, *P* = 1.000). When the effect of group was adjusted for the clustering of patients within practices, age, insulin use, and baseline self-monitoring of blood glucose, the magnitude of the association remained strong (*P* = 0.03).

CONCLUSIONS — This pilot study found that a CCM-based intervention was effective in improving clinical, behavioral, psychological/psychosocial, and diabetes knowledge outcomes in patients with diabetes. The CCM group, which received both patient and provider education, demonstrated significantly improved A1C levels, non-HDL cholesterol levels, and rates of self-monitoring of blood glucose compared with the other study groups. Moreover, clinical outcomes improved even after adjusting for treatment intensification. In addition, within the CCM group, improvements in non-HDL cholesterol levels, diabetes knowledge, and empowerment scores were observed. These results are important, as they demonstrate that a multifaceted intervention can improve diabetes outcomes in an underserved urban community.

These data confirm the majority of findings of others, which noted improvements in process and outcome measures related to DSMT interventions. In a systematic review on the effectiveness of DSMT in type 2 diabetes, studies that used a collaborative approach, as we did, demonstrated positive effects on glycemic control in the short term (26). While the positive synergistic effect of combining patient education with various provider interventions has previously been shown in a range of settings and among those with type 1 and type 2 diabetes (23), there have also been negative studies of patient-centered interventions and quality improvement projects. Just recently, O’Connor et al. (27) and Gerber et al. (28) conducted well-designed interventions, but produced null results in both clinical and behavioral outcomes.

Had we not block randomized our practices and adjusted for the clustering of patients within practices, our data would have been at risk for contamination or over estimation of the effect size. Indeed, most multifaceted studies to date...
group started the study with lower mean A1C levels than the CCM group. This was taken into consideration when we adjusted for the differences in baseline values in the multivariate models. Additionally, our RCT was underpowered to detect significant differences in the primary and secondary outcomes due to our small sample size, which was largely due to regulatory constraints. The university institutional review board did not permit us to contact patients directly. Therefore, it was the responsibility of the provider practices to recruit patients into the trial using predetermined recruitment methods developed by the study investigators. In initial sample size calculations, we estimated that 70 people in each of the three study groups would provide sufficient power to determine whether differences truly existed between the intervention group and usual care. It is possible that type II error may have affected the results observed. Thus, if there were improvements in other outcomes, we may have been unable to detect them.

We have demonstrated in this pilot study that outcomes for people with diabetes in an underserved urban community can be improved by implementing the CCM (3,4,7,8). As a result of this study, the University of Pittsburgh Medical Center health system has redesigned the way in which diabetes care is delivered (31). CDEs now use the empowerment approach (22) to deliver DSMT at point of service in several primary care practices throughout western Pennsylvania (31). Additionally, recent efforts have been aimed at acquiring reimbursement for CDEs. As of November 2005, CDEs who deliver DSMT at point of service can now bill for their services in the University of Pittsburgh Medical Center health system. Our community partnerships, population-based sample of participants, flexible patient-centered approach to DSMT, and primary care practice redesign suggest that this model for improving diabetes care in the community is feasible and effective and could be applied to other chronic illnesses. Future large-scale research studies are needed to demonstrate the effectiveness of this approach.

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