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 HbA_{1c} 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: +22.2%, $P < 0.0001$), 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, $P = 0.0004$), 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). Currently, few efforts exist to implement multifaceted approaches to improve quality of care in diabetes despite studies that demonstrate their proven effectiveness (3,4,11,14,15).

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.

RESEARCH DESIGN AND METHODS

— This study was a multilevel, nonblinded, cluster-design, randomized controlled trial (RCT) that took place in an underserved urban suburb of Pittsburgh, Pennsylvania, between 1999 and 2003. The target community was a former home to the steel industry and a victim of industrial downsizing, with increased rates of unemployment and an out-migration of the young and more affluent. This resulted in an elderly community in a socioeconomically depressed area with a high prevalence of chronic diseases. The study was carried out in three phases: phase I, cross-sectional chart review to determine baseline patterns of care; phase II, randomization and provision of the intervention with 12-month follow-up including clinical assessment; and phase III, repeat chart review to catalog postintervention patterns of care.

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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 Système International (SI) units and conversion factors for many substances.

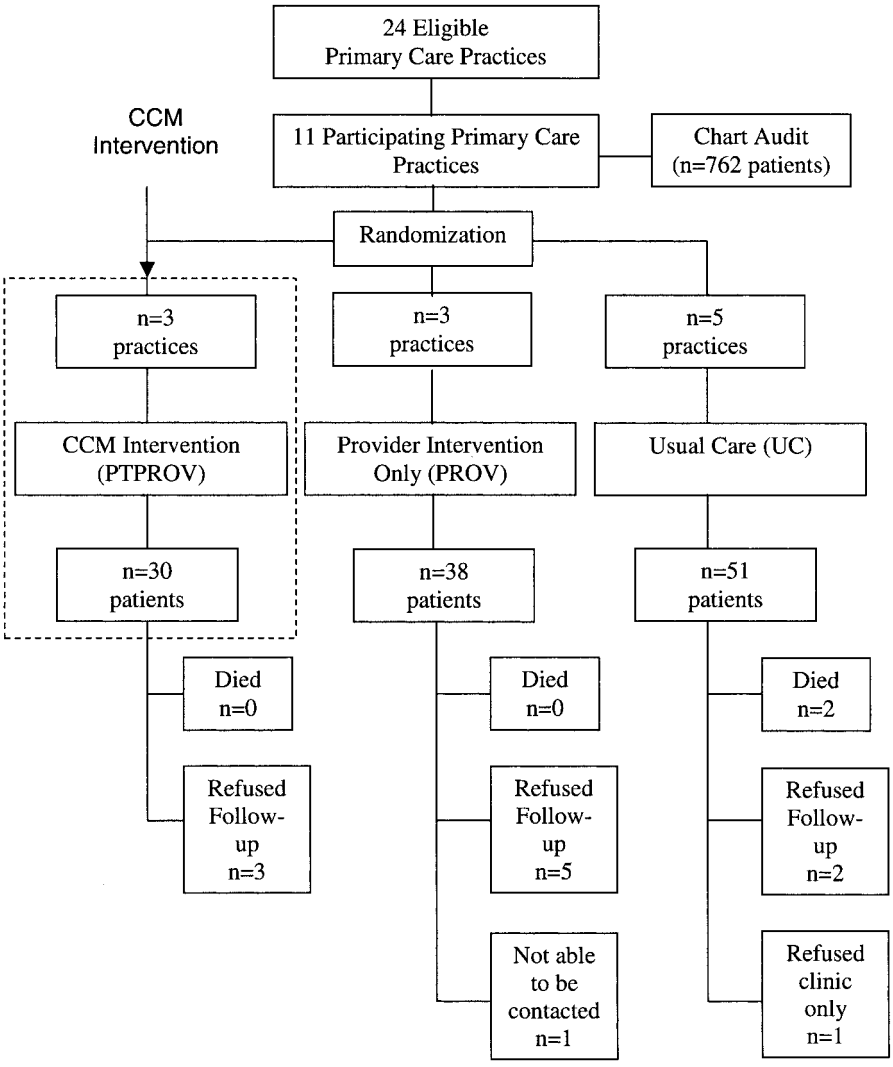

Figure 1—*Study design. Group practices (more than one physician):* n = *7. Internal medicine practices:* n = *4. General medical practices:* n = *3. Three solo practitioners were internists; one was a general practitioner.*

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 generalizabilty 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 glucoses >200 mg/dl or HbA_{1c} [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-

Table 1—*Implementation of the CCM*

Element	Study group	Phase	Activity
Community (resources and policies)	CCM, PROV, and UC	I–III	Community partnerships and collaborations were made between the University of Pittsburgh and leaders in the local community, including physicians, the community hospital foundation, and the Lion's Clubs.
Self-management support	CCM	Phase II	Patients receiving care from those providers randomized to CCM were invited to participate in six DSMT sessions that were facilitated by a certified diabetes educator (CDE) and held weekly, followed by monthly support groups. Curriculum included the required diabetes education content areas set forth by the ADA (15). The empowerment approach to diabetes education was used (22).
Delivery system design	CCM	Phase II	Providers randomized to CCM were encouraged to redesign the process in which they saw patients with diabetes for routine visits. A CDE was made available to them on a day of their choosing. Office staff were encouraged to schedule routine visits on these days. These "diabetes days" were designed with the idea that the provider would be more focused on diabetes for that particular day. Providers were encouraged to refer patients to the CDE for point of service education whenever possible.
Decision support	CCM and PROV	Phase II and III	One PBL session was held for providers. An endocrinologist presented cases and lead the providers through a series of diabetes management questions. A CDE demonstrated patient-focused problem solving and goal-setting strategies. All providers received a benchmarking report, comparing their adherence with recommended process and outcome variables from the chart audit with that among their peers in the community and to the ADA standards of care (15). This was subsequently explained using academic detailing (20). The following decision support items were given to all providers regardless of study group.
	UC		ADA standards of care for people with diabetes, flow sheets that incorporated ADA guidelines, a packet of posters and information from Pennsylvania KeyPRO and the Lower-Extremity Amputation Prevention Program to assist in complying with the ADA standards of care (15), and tracking of patient testing and results.
Clinical information systems	CCM, PROV, and UC	Phase I	The majority of provider offices did not have a computer, let alone an electronic medical record, and a baseline chart audit was conducted to establish benchmarks for adherence to the ADA standards of care (15) and to enhance provider feedback.
Organizational support	CCM, PROV, and UC	I–III	The principle investigator met with each of the providers who agreed to take part in the study to determine provider needs. This was done to enhance provider "buy in" and acknowledge chronic care as a priority. Additionally, funding was obtained from the local community hospital foundation and from the parent hospital system.

PBL, problem-based learning.

dards for DSMT (18). 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

Table 2—*Baseline demographic characteristics of the clinical trial population by study group*

	CCM group	PROV group	UC group	*P* value
n	30	38	51	
Age (years)	69.7 ± 10.7	64.4 ± 8.9	68.6 ± 8.6	0.04
Age at diagnosis (years)	60.0 ± 12.4	53.1 ± 12.4	55.8 ± 12.6	0.09
Duration (years)	10.3 ± 8.4	11.5 ± 9.0	13.1 ± 10.9	0.46
Sex (male)	50.0 (15)	39.5 (15)	58.8 (30)	0.2
Race (nonwhite)	13.3 (4)	2.6 (1)	9.8 (5)	0.26
Education (less than a high school education)	50.0 (15)	57.9 (22)	60.8 (31)	0.63
Income (<$20,000/year)	44.4 (12)	52.8 (19)	44.4 (20)	0.72
Insulin use	26.7 (8)	42.1 (16)	25.5 (13)	0.2
Microvascular complications	28.6 (26)	18.3 (13)	23.3 (17)	0.31
Macrovascular complications	20.6 (67)	18.0 (32)	19.6 (49)	0.79
Any complication	63.8 (88)	47.7 (42)	57 (61)	0.06

Results are % (*n*) or means ± SD.

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-monitoriing 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

Table 3—*Changes in clinical and behavioral outcomes across study groups following the CCM intervention*

	CCM group (n = 27)			PROV group (n = 32)			UC group (n = 46)			
	Baseline	Follow-up	P value†	Baseline	Follow-up	P value†	Baseline	Follow-up	P value†	Adjusted P value*
A1C (%)	7.6	7.0	0.008	7.3	7.3	0.92	6.9	6.8	0.15	0.01
Non-HDL cholesterol (mg/dl)	153.7	143.3	0.24	170.9	168.8	0.75	147.3	148.7	0.78	0.05
HDL cholesterol (mg/dl)	39	44.5	0.0004	48.4	49.7	0.23	43.8	47.4	0.02	0.52
Systolic blood pressure (mmHg)	142.5	141.8	0.84	142.2	140.5	0.62	146.7	143.3	0.3	0.43
Diastolic blood pressure (mmHg)	73.4	73.7	0.84	77.5	75.6	0.26	76.1	76	0.96	0.43
Diabetes Knowledge Test score (%)	55.2	61.9	0.07	68.8	67.3	0.35	69.2	70	0.48	0.88
WHO-QWB10 index total score (range 0–30)	21.3	20	0.33	19	17.2	0.02	20.3	19.8	0.37	0.17
Empowerment Scale score (range 1–5)	3.8	4.0	0.02	4.0	3.9	0.72	3.9	3.9	0.92	0.75
Self-monitoring of blood glucose (%)	77.8	100	<0.0001	84.4	90.6	0.16	81.3	81.3	1.000	0.03

*Effect of group is adjusted for the clustering of patients within practice, age, and insulin use. Baseline values were adjusted for if significant differences occurred between baseline and follow-up values. †P value for within-group differences.

values (SAS Version 8.2; SAS Institute, Cary, NC).

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%, 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: 170.9 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 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

(23) have included inadequate concealment allocation and randomization errors, thereby making them prone to contamination.

Our pilot intervention differs from previous efforts in that we implemented the entire CCM as a multifaceted intervention. There is a paucity of literature regarding implementation of the entire CCM in diabetes care. We have therefore not attempted to dissect out the efficacy of individual components of our intervention. Rather, we have implemented the entire CCM as our multifaceted intervention. With the exception of a Danish study (29), in which representative general practices significantly improved long-term control of diabetes through a variety of educational interventions, there have not been other published RCTs to our knowledge implementing a combination of interventions to improve quality of care for people with diabetes. In contrast to the Danish study (29) and our current study, most studies choose to implement one aspect of the CCM (13). Bodenheimer et al. (8) conducted a systematic review of studies of diabetes care programs featuring the four main elements of the CCM (self-management support, decision support, delivery system design, and clinical information systems). Each study was classified on the basis of whether it detected significant improvements in the processes of care, patient outcomes, or both, based on the number of elements that were implemented. Patient outcomes improved in the five studies that implemented the four main elements of the CCM; however, outcomes also improved in the majority of studies that did not implement all four elements. Although specific elements of the CCM cannot be teased out of the aforementioned studies or our study as essential to improvement, Bodenheimer et al. note that 19 of 20 interventions that included a self-management component improved a process or outcome of care (8).

In conducting translational research, circumstances and environments are not "controllable," like efficacy-based research (30); therefore, limitations exist. For example, the baseline A1C values were quite low for an underserved community. Thus, there was potential for a floor effect. One way to elucidate whether there was a floor effect is to follow the subjects longitudinally to observe if the improvements could be sustained. This issue will be presented in a forthcoming report. Along those same lines, the UC 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 sizes 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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