Improving and Sustaining Diabetes Care in Community Health Centers With the Health Disparities Collaboratives

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Background: In 1998, the Health Resources and Services Administration's Bureau of Primary Health Care began the Health Disparities Collaboratives (HDC) to improve chronic disease management in community health centers (HCs) nationwide. The HDC incorporates rapid quality improvement, a chronic care model, and best practice learning sessions.

Objectives: To determine whether the HDC improves diabetes care in HCs over 4 years and whether more intensive interventions enhance care further.

Subjects: Chart review of 2364, 2417, and 2212 randomly selected patients with diabetes from 34 HCs in 17 states in 1998, 2000, and 2002, respectively.

Measures: American Diabetes Association standards.

Research Design: We performed a randomized controlled trial with an embedded prospective longitudinal study. We randomized 34 HCs that had undergone 1–2 years of the HDC. The standard-intensity arm continued the baseline HDC intervention. High-intensity arm centers received 4 additional learning sessions, provider training in behavioral change, and patient empowerment materials. To assess the impact of the HDC, we analyzed changes in clinical processes and outcomes in the standard-intensity centers. To determine the effect of more intensive interventions, we compared the standard- and high-intensity centers.

Results: Between 1998 and 2002, HCs undertaking the standard HDC improved 11 diabetes processes and lowered hemoglobin A1c [−0.45%; 95% confidence interval (CI), −0.72 to −0.17] and low-density lipoprotein cholesterol (−19.7 mg/dL; 95% CI, −25.8 to −13.6). High-intensity intervention centers had greater use of angiotensin converting enzyme inhibitors [adjusted odds ratio (OR), 1.47; 95% CI, 1.07–2.01] and aspirin (OR, 2.20; 95% CI, 1.28–3.76), but lower use of dietary (OR, 0.24; 95% CI, 0.08–0.68) and exercise counseling (OR, 0.34; 95% CI, 0.15–0.75).

Conclusions: Diabetes care and outcomes improved in HCs during the first 4 years of the HDC quality improvement collaborative. More intensive interventions helped marginally.

Key Words: quality improvement, community health center, diabetes, health disparities

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In 1998, the Health Resources and Services Administration's Bureau of Primary Health Care (BPHC), the branch of the federal government that oversees the 5000 community health center (HC) sites that care for the medically underserved,[1] began the Health Disparities Collaboratives (HDC) to improve the management of chronic diseases nationwide. This ambitious initiative, an example of a quality improvement (QI) collaborative,[2] brings HCs together in learning sessions. HCs learn rapid-cycle QI techniques using the Plan-Do-Study-Act paradigm and a chronic care model, and they share best practices. The BPHC also supplied central supporting infrastructure such as regional coordinators and information technology support beyond the typical QI collaborative. This multiyear initiative by the BPHC is the largest, longest, and most substantial national commitment to the QI collaborative model.

HCs have most frequently chosen diabetes as their target disease for implementing the HDC, with 683 (68%) of 1009 participating HCs choosing diabetes (Charles Daly, Health Resources and Services Administration, April 19, 2007, personal communication). Diabetes is prevalent and costly, and causes much morbidity. Currently, there are more than 13 million Americans diagnosed with diabetes, producing over $100 billion in direct and indirect costs each year.[3] Nationally, African

Americans and patients of lower socioeconomic status suffer disproportionately high morbidity from diabetes,[4] and racial disparities in the quality of diabetes care are prevalent.[5] Diabetes is a paradigmatic disease for chronic care management.

Because community HCs are vanguard providers to over 16 million indigent patients per year,[1] the HDC are particularly important to clinicians, administrators, and policymakers seeking to improve the care of the most vulnerable patients with diabetes and other chronic diseases.[6–8] The HDC also have general interest because successful interventions in this challenging setting may hold promise for other health care sites. The HDC are an especially rich model for understanding the strengths and limitations of the QI collaborative approach. QI collaboratives, such as the Institute for Healthcare Improvement's Breakthrough Series, have become increasingly popular in recent years across many public and private health care settings.[9] Still, evaluation has been limited and thus spread of the method may have outpaced the existing evidence.[2] Most prior published studies of QI collaboratives have shown improvements in the quality of care over short time periods, most commonly with 1 year pre-post analyses.[9–15] However, a controlled trial of a human immunodeficiency virus QI collaborative in Ryan White clinics did not show an effect in improving quality of care over a 1-year period.[16] In addition, a recent controlled trial of asthma, cardiovascular, and diabetes care in the HDC found improvements in processes of care but not outcomes comparing data 1 year precollaborative to 1 year postcollaborative.[17] These contradictory findings raise uncertainty about the short-term effects of the QI collaboratives. Moreover, the key question is what happens over longer time periods—whether improvements in care can be sustained and if certain outcome goals may take more time to attain. For example, it is easier to improve the process of care of hemoglobin A1c measurement in patients with diabetes compared with improving the intermediary outcome of the actual hemoglobin A1c value. Short-term studies are more likely to capture improvements in processes of care but may not capture eventual effects on outcomes.

Therefore, we aimed to answer 2 major questions about the HDC. First, what impact do the HDC have on care and outcomes related to diabetes over a sustained period? Second, what is the effect of varying the intensity of the intervention? Specifically, in addition to the standard HDC, do more intensive QI efforts that incorporate organizational change, provider behavioral change, and patient empowerment improve care further?

METHODS

We analyzed changes in the quality of care in the standard HDC over 4 years in a prospective longitudinal study. We also performed a randomized controlled trial to compare the standard HDC to the HDC plus a more intensive intervention.

Participants

We invited all 99 HCs from the Midwest and West Central clusters that had participated in either the first (October 1998–1999) or second (1999–2000) Diabetes Collaborative initiative of the BPHC into the Improving Diabetes Care Collaboratively in the Community project. Thirty-four HCs from 17 states enrolled. Over the 4-year period of the study, 6 HCs dropped out because of time constraints (1 from each intervention group before data collection began, and 1 high-intensity and 3 standard-intensity sites before the final year of data collection). Dropout did not differ significantly by intervention group ($P = 0.66$, Fisher exact test), although power to detect a difference is low. Data are included until the time of dropout.

The Standard HDC

We have previously described the HDC.[10] In brief, each participating HC formed a HDC team that met regularly with the support of senior administrative leadership. Each center also created a registry of patients with diabetes to help track clinical care. A Model for Improvement developed by Associates in Learning called the Plan-Do-Study-Act cycle was introduced into each HC.[18] This model adapts elements of continuous quality improvement into a process designed to improve the quality of care at an accelerated pace.

The program is grounded in the MacColl Chronic Care Model, which aims to create practical, supportive interactions between an informed, activated patient and a proactive, prepared clinical team.[19] Specific targets for QI are patient self-management, delivery system redesign, decision support, clinical information systems, leadership and health system organization, and community outreach.

The Institute for Healthcare Improvement provided the centers initial instruction at a national learning session, and then regional cluster coordinators and Institute staff assisted through telephone conference calls, a computer listserv, feedback on required monthly progress reports, patient registry and information systems support, and 3 regional meetings. At the regional and national learning sessions, team members and administrators from HCs met to learn QI techniques and share lessons among themselves.

Improving Diabetes Care Collaboratively in the Community Project

The 34 centers were then randomized into a standard-intensity arm and a high-intensity arm, stratifying by region and whether the HC had participated in the first or second Diabetes Collaborative.

Standard-Intensity Arm

The centers in the standard-intensity arm received continued interaction and support from the BPHC. This consisted of quarterly progress reports from the QI teams and senior leadership, conference calls with other centers and cluster coordinators, and a yearly in-person meeting with the other HCs.

High-Intensity Arm

The high-intensity arm included additional support in organizational change techniques and chronic care management, as well as interventions designed to facilitate behavioral change in patients to get them more actively involved in their care. Specifically, the high-intensity intervention consisted of the standard-intensity activities plus:

1. Four biannual 1.5-day learning sessions. The learning sessions covered QI topics, clinical subjects, and planning

time for the center teams. The core elements were HC-led workshops in which HCs shared model programs, interventions, and lessons learned.

2. Training in patient-provider communication and behavioral change techniques. One diabetes QI team member from each HC attended a week-long train-the-trainer course, "Clinician-Patient Communication to Enhance Health Outcomes for Patients with Diabetes" at the Bayer Institute for Health Care Communication (now known as the Institute for Healthcare Communication), and then returned to his or her home HC to train its providers in a sequence of 4 two-hour or 8 one-hour learning sessions to be conducted over 4 months. These learning sessions were adapted from 2 standard Bayer Institute workshops, "Clinician Patient Communication"[20] and "Choices and Changes"[21] with emphasis on educating and facilitating behavior change in patients with diabetes using a Stages of Change model[22] and principles of motivational interviewing.[23]
3. Patient empowerment video, brochure, and processes of care card. We created English and Spanish versions of a 14-minute video designed to empower patients to play a more active role in their care and ask for 6 key processes of diabetes care (hemoglobin A1c test, cholesterol test, blood pressure measurement, dilated eye examination, foot examination, urine microalbumin test).[24–27] The written materials and video were distributed to the centers to give and show to their patients.
4. Monthly conference calls. We held 16 one-hour conference calls with HC representatives to discuss issues important to the HCs, receive input and feedback for the different components of the intervention, and update the HCs on the project.

Data

Retrospective Chart Review for American Diabetes Association Standards

The chart review instrument collected information for calendar years 1998, 2000, and 2002 on patient demographics, process of care measures, and laboratory values to assess adherence to clinical recommendations of the American Diabetes Association.[28] We collected 2000 data for several reasons. First, for the assessment of the standard HDC, the 1998–2000 analysis is comparable to the most common short-term evaluation period of other studies in the literature. Results from the short-term analysis could then be compared with the 1998–2002 long-term analysis to help determine if certain improvements from the QI collaborative appear after a more prolonged period of QI activities or if improvements decline over time. Second, for the comparison of the standard and high-intensity interventions in the randomized controlled trial, year 2000 data serve as the baseline because that is the year randomization occurred. The chart review instrument was accompanied by a codebook, and each center was instructed in the chart abstraction process. For each year, each center was asked to identify patients with diabetes through administrative records and *International Classification of Diseases—Clinical Modification*, 9th edition diagnostic code 250.x or else patient registries,[29] and then perform chart review on 80 diabetic patients (confirmed by chart review) aged 18–75 years chosen by random number generator, or else all diabetic patients aged 18–75 years if their center had fewer than 80. Pregnant women were excluded. We did not follow the same patients longitudinally because institutional review board confidentiality requirements made this approach unfeasible.

Organizational Survey

We distributed an organizational survey in 2003 to 31 remaining HDC team leaders to gain information about the general characteristics of the HC and to administer the Assessment of Chronic Illness Care (ACIC) survey.[30] The ACIC survey identifies areas for improvement in chronic illness care and evaluates improvements made as a result of QI interventions. We received 29 (93.5%) completed surveys.

Data Analysis

Standard HDC Intervention

We first estimated means and proportions of chart audit processes of care and clinical outcome measures for each chart audit year, using mixed linear and logistic regression of patient level outcomes on intercept, with HC as a random effect, to obtain confidence bounds that incorporated correlation due to nesting of patients within HCs. Calculation of proportions from logistic regression coefficients included the rescaling factor $15\pi/16\sqrt{3}$ to correct for attenuation.[31] Models were fit using the xtreg and xtlogit procedures in STATA/SE 9.1 (StataCorp LP, College Station, TX). We then conducted longitudinal analysis of change over time using hierarchical linear or logistic regression of patient level outcome on year, with HC and the year by HC interaction as random effects.[32,33] This model structure reflects the cross-sectional sampling of patients within HCs over time. Models controlled for region (Midwest, West Central), Diabetes Collaborative (I, II), urban versus rural location, and patient characteristics (age, sex, race, insulin treatment, comorbidities, and complications of diabetes). Models were fit using the 3-level logistic model in HLM 5 (Hierarchical Linear and Nonlinear Modeling, SSI Scientific Software International, Lincolnwood, IL) for proportions and the mixed procedure in SAS Version 8 (SAS Institute Inc., Cary, NC) for continuous outcomes. We carried out model selection using backward elimination, retaining covariates if statistically significant at $P \leq 0.10$ or if they modified the time effect. Region and Diabetes Collaborative were included in all models, regardless of significance.

Standard HDC Versus High-Intensity Intervention

We evaluated the effect of the high-intensity intervention using mixed linear and logistic regression models, with HC as a random effect and stratification factors (region, collaborative) as fixed effects, to incorporate sources of variation arising from the stratified cluster randomized design of the study. Dependent variables were 2002 chart audit processes of care and clinical outcomes, and the patient was the unit of analysis. Models included adjustment for urban versus rural location, baseline (2000) values of the dependent variable, and baseline demographic and clinical characteris-

TABLE 1. Health Center and Patient Characteristics at Baseline* (1998) and at Randomization (2000)

	1998†		2000†	
	Standard‡ (n = 16)	High‡ (n = 15)	Standard‡ (n = 16)	High‡ (n = 16)
Health center characteristics				
Clinic sites per health center, mean§	3.7	3.4	3.7	3.4
Nonprofit, %§	100	93	100	93
Rural, %¶	44	60	44	63
Urban	56	40	56	38
Patient characteristics				
No. patients	1190	1174	1168	1249
Age (yr), mean (SD)	54.5 (13.6)	56.9 (14.7)	55.8 (14.2)	56.6 (14.9)
Female, %	67	64	65	62
Race/ethnicity, %¶				
American Indian/Alaska native	1	2	1	1
Asian/Pacific Islander	1	1	2	1
Black (non-Hispanic)	29	20	26	24
Hispanic/Latino (all races)	32	28	34	29
White (non-Hispanic)	37	49	37	45
Other	2	1	2	1
Insurance, %¶‖				
Medicare-Medicaid dual eligible	8	7	7	8
Medicare	20	27	23	25
Medicaid	18	15	14	17
Private	13	10	16	9
Other	9	10	8	7
No insurance	32	32	32	33
Comorbidities/complications, %				
Hypertension	59	57	63	60
Myocardial infarction	4	5	4	3
Retinopathy	7	4	8	6
Neuropathy	11	8	13	10
Peripheral vascular disease	5	6	6	6
Renal failure	2	6	3	5
Proteinuria	7	8	9	7

*Before Diabetes Collaborative participation: 1998.
†Chart audit year.
‡Intervention group.
§Based on 2003 Organizational Survey.
¶Numbers may not add up to 100% because of rounding to nearest whole number.
‖Insurance categories are mutually exclusive. Each category includes patients with the given type of insurance, possibly supplemented by private or other types of insurance.

tics of the HCs' patient populations. Specifically, because individual patients were not followed over time, baseline covariates consisted of HC level means and percentages and included mean age, % female, % African American, % Hispanic, % on insulin, % with selected comorbidities (hypertension, myocardial infarction), and complications of diabetes (neuropathy, peripheral vascular disease, renal failure). We excluded additional covariates, such as retinopathy, due to collinearities with the remaining covariates. We carried out model selection in the logistic models using backward elimination, retaining covariates if statistically significant at $P \leq 0.10$ or if they modified the intervention effect. We retained the baseline summary measure of the dependent variable in all models. In the linear mixed models for continuous outcomes, we retained all covariates, with results nearly indistinguishable from parsimonious models. Because one site failed to collect baseline data on insurance, reported models do not include this covariate. Sensitivity analyses indicated that insurance type did not affect the magnitude or significance of the intervention effect, except where noted in the results. Models were fit using the xtreg and xtlogit procedures in STATA/SE 9.1.

Dropouts

Sites that dropped out before the 2002 chart audit were compared with those that completed the study, for 1998 and 2000, using mixed linear and logistic models with patient level outcomes as the dependent variable, dropout status as the independent variable, and site as a random effect. Finally, the mixed linear and logistic models used to evaluate the time trend and the intervention effect were refit with 2000 values for dropout sites carried forward to 2002.

RESULTS

HC and Baseline Patient Characteristics

Almost all centers were nonprofit and about half were rural (Table 1). At baseline in 1998, the mean age of patients was 56 years. About half the patients were African American or Hispanic/Latino, and about two-thirds were women.

Implementation of the HDC

Implementation of the Chronic Care Model was reasonably good as indicated by ACIC scores ranging from 6.7 to 8.1 for each domain of the Chronic Care Model, where 0 is worst and 11 is best.

Quality of Care for Centers Undergoing the Standard HDC

Table 2 presents the percentage of patients meeting diabetes care standards across study years. Significant improvements over time were found between 1998 and 2002 for 11 processes of diabetes care, and hemoglobin A1c [−0.45%, 95% confidence interval (CI) −0.72 to −0.17] and low-density lipoprotein (LDL) cholesterol (−19.7 mg/dL; 95% CI, −25.8 to −13.6) were lowered as measured through chart review (Table 3).

Standard HDC Versus High-Intensity Intervention

At baseline in 2000, despite randomization, standard-intensity HDC centers were more likely to be urban than the high-intensity centers (Table 1) and had higher rates of diabetes education [odds ratio (OR) (95% CI) = 2.90 (1.08–7.78)] and dietary [2.53 (1.06–6.03)] and exercise [4.69 (1.88–11.71)] counseling. After adjustment for baseline rates and baseline demographic and clinical characteristics of the HCs' patient populations, HCs in the high-intensity intervention arm compared with the standard-intensity HDC centers showed higher odds of angiotensin converting enzyme inhibitor use (OR, 1.47; 95% CI, 1.07–2.01), aspirin use (OR, 2.20; 95% CI, 1.28–3.76), and measurement of urine microalbumin (OR, 2.03; 95% CI, 1.01–4.05) (Table 4). However, rates of other process of care and outcome measures

TABLE 2. Chart Audit Process of Care and Outcome Measures by Year in Health Centers in Standard Health Disparities Collaboratives Group

	*Percent of Patients (95% CI), N		
	1998	2000	2002
Processes of care			
At least 1 HbA1c	71 (64–78), 1076	88 (83–92), 1136	92 (90–94), 1044
Two or more HbA1c 3 mo apart	24 (16–34), 1185	49 (42–56), 1163	55 (48–62), 1050
Lipid assessment	52 (44–60), 1190	65 (57–72), 1168	70 (63–75), 1050
Microalbumin assessment	15 (9–25), 1190	35 (23–48), 1168	35 (23–50), 1050
Angiotensin converting enzyme inhibitor	33 (22–45), 1190	42 (33–53), 1168	50 (41–59), 1050
Aspirin	22 (16–30), 1190	37 (27–47), 1168	41 (29–54), 1050
Dental referral	3 (2–5), 1190	13 (8–21), 1168	19 (12–30), 1050
Eye examination or referral	25 (18–34), 1190	33 (24–43), 1168	40 (28–54), 1050
Foot examination or referral	31 (21–44), 1190	55 (45–64), 1168	56 (46–66), 1050
Influenza vaccination	28 (22–35), 1190	35 (27–44), 1168	38 (30–47), 1050
Home glucose monitoring prescribed	44 (32–56), 1190	58 (46–69), 1168	55 (41–68), 1050
Dietary counseling or referral	42 (29–57), 1190	56 (41–70), 1168	51 (36–66), 1050
Exercise counseling	31 (19–45), 1190	49 (36–63), 1168	52 (38–65), 1050
Diabetes education	49 (37–62), 1190	65 (52–76), 1168	53 (38–68), 1050
Clinical outcomes: thresholds			
LDL cholesterol <100 mg/dL	28 (23–34), 380	34 (30–39), 641	44 (39–49), 639
LDL cholesterol <130 mg/dL	59 (52–65), 380	67 (63–71), 641	74 (70–78), 639
Blood pressure <130/80 mm Hg	26 (24–29), 1170	24 (20–29), 1147	27 (24–31), 1035
HbA1c <9.5%	71 (63–77), 744	71 (66–76), 986	79 (76–82), 963
	†Mean Value (95% CI), N		
Clinical outcomes: measures			
HbA1c (%)	8.6 (8.2–9.0), 744	8.5 (8.2–8.8), 986	7.9 (7.7–8.2), 963
LDL cholesterol (mg/dL)	127 (122–132), 380	116 (112–119), 641	108 (104–112), 639
Systolic blood pressure (mm Hg)	133 (132–134), 1171	135 (133–137), 1148	133 (131–134), 1035
Diastolic blood pressure (mm Hg)	79 (78–80), 1170	80 (78–81), 1147	78 (77–79), 1035

*Estimates from mixed logistic regression, within each year, with health center as random effect.
†Estimates from mixed linear regression, within each year, with health center as random effect.

TABLE 3. Change Over Time in Chart Audit Process of Care and Outcome Measures Among Health Centers in Standard Health Disparities Collaboratives Group*

Dependent Variable	N	Odds Ratio (95% CI)† 2000 vs. 1998	2002 vs. 1998	2002 vs. 2000
Processes of care				
At least 1 HbA1c	3151	3.14 (1.92 to 5.13)‡	4.78 (2.81 to 8.14)‡	1.52 (0.88 to 2.64)
Two or more HbA1c 3 mo apart	3337	3.33 (1.91 to 5.82)‡	4.45 (2.47 to 8.00)‡	1.34 (0.75 to 2.39)
Lipid assessment	3391	1.75 (1.21 to 2.53)§	2.13 (1.45 to 3.15)‡	1.22 (0.82 to 1.80)
Microalbumin assessment	3285	4.02 (1.76 to 9.18)§	4.42 (1.83 to 10.7)§	1.10 (0.46 to 2.61)
Angiotensin converting enzyme inhibitor	3285	1.56 (0.96 to 2.53)¶	2.53 (1.52 to 4.23)§	1.62 (0.97 to 2.70)¶
Aspirin	3391	2.29 (1.63 to 3.22)‡	2.94 (2.05 to 4.21)‡	1.28 (0.90 to 1.83)
Dental referral	3297	4.36 (2.33 to 8.18)‡	6.46 (3.43 to 12.2)‡	1.48 (0.85 to 2.59)
Eye examination or referral	3285	1.48 (0.88 to 2.49)	2.37 (1.37 to 4.11)§	1.60 (0.93 to 2.76)¶
Foot examination or referral	3297	3.25 (1.97 to 5.36)‡	3.71 (2.18 to 6.32)‡	1.14 (0.67 to 1.94)
Influenza vaccination	3179	1.36 (0.80 to 2.29)	1.50 (0.86 to 2.59)	1.10 (0.64 to 1.91)
Home glucose monitoring prescribed	3179	2.19 (1.21 to 3.95)‖	2.06 (1.10 to 3.87)‖	0.94 (0.50 to 1.77)
Dietary counseling or referral	3285	2.21 (1.07 to 4.55)‖	1.85 (0.86 to 4.01)	0.84 (0.39 to 1.82)
Exercise counseling	3244	3.07 (1.54 to 6.12)§	3.68 (1.76 to 7.68)§	1.20 (0.58 to 2.47)
Diabetes education	3285	2.33 (1.31 to 4.14)§	1.52 (0.83 to 2.79)	0.65 (0.35 to 1.20)
Clinical outcomes: thresholds				
LDL cholesterol <100 mg/dL	1640	1.37 (1.02 to 1.84)‖	2.02 (1.51 to 2.71)‡	1.48 (1.16 to 1.88)§
LDL cholesterol <130 mg/dL	1660	1.43 (1.07 to 1.91)‖	2.00 (1.49 to 2.69)‡	1.40 (1.07 to 1.83)‖
Blood pressure <130/80 mm Hg	3257	0.90 (0.71 to 1.15)	1.11 (0.87 to 1.42)	1.23 (0.96 to 1.58)¶
HbA1c <9.5%	2540	1.01 (0.80 to 1.29)	1.46 (1.13 to 1.88)§	1.44 (1.14 to 1.83)§
		Mean Difference (95% CI)		
Clinical outcomes: measures				
LDL cholesterol (mg/dL)	1559	−11.8 (−17.9 to −5.73)‡	−19.7 (−25.8 to −13.6)‡	−7.88 (−13.3 to −2.43)§
Systolic blood pressure (mm Hg)	3132	1.15 (−0.98 to 3.28)	−1.81 (−4.03 to 0.40)	−2.96 (−5.19 to −0.73)‖
Diastolic blood pressure (mm Hg)	3130	0.48 (−0.66 to 1.62)	−0.79 (−1.98 to 0.40)	−1.27 (−2.46 to −0.08)‖
HbA1c (%)	2540	−0.03 (−0.30 to 0.24)	−0.45 (−0.72 to −0.17)§	−0.41 (−0.68 to −0.15)§

*Three-level hierarchical regression of patient level outcomes on year, with health center and year within health center as random effects, controlling for region (Midwest, West Central) and Diabetes Collaborative (I, II). Candidate covariates: urban versus rural location, age, sex, race, insulin treatment, comorbidities (hypertension, myocardial infarction), and complications of diabetes (retinopathy, neuropathy, peripheral vascular disease, renal failure).

†Significance levels at or below 0.001, 0.01, 0.10, 0.05 are denoted by ‡, §, ¶, and ‖, respectively.

were similar, and the high-intensity HDC centers had lower documentation of diabetes education (OR, 0.16; 95% CI, 0.06–0.44) and dietary (OR, 0.24; 95% CI, 0.08–0.68) and exercise counseling (OR, 0.34; 95% CI, 0.15–0.75).

Dropouts

Differences between sites that dropped out before the 2002 chart audit and those that completed the study were few in number relative to the 14 processes of care, 4 clinical outcome thresholds, and 4 clinical outcome measures that were assessed (not shown). Moreover, they were inconsistent in direction and the variables that differed varied from 1998 to 2000. Specifically, in 1998, dropout sites had lower rates of HbA1c testing, higher rates of prescribing angiotensin converting enzyme inhibitors, and higher rates of diabetes education. None of these differences persisted to 2000; rather, at that time, dropout sites had lower rates of influenza vaccination, lower rates of LDL below 100 mg/dL, higher mean LDL, and higher diastolic blood pressure. On the other hand, dropout sites showed greater improvement in performance of eye examinations from 1998 to 2000.

Time trend effects in the carry-forward analysis were qualitatively the same as in the main analysis with 2 minor exceptions involving only marginally significant effects. In carry-forward analysis of the intervention effect, most results were qualitatively the same as when dropouts were excluded, with the following important exceptions. With values for dropout sites carried forward, the effect of the high-intensity intervention on microalbumin assessment was attenuated and no longer statistically significant; similarly, the marginally significant effect of the intervention on foot examinations and referrals became nonsignificant. On the other hand, rates of dietary counseling or referral, diabetes education, and LDL cholesterol <100 mg/dL, which were lower under the high-intensity intervention, did not differ significantly between groups in the carry-forward analysis.

CONCLUSIONS

Diabetes care and outcomes in HCs improved between 1998 and 2002 during the first 4 years of the HDC. The prior literature on QI interventions in HCs is limited, and generally

TABLE 4. Effect of High-Intensity Intervention on Year 2002 Chart Audit Process of Care and Outcome Measures, Adjusted for Baseline* (2000) Covariates

Dependent Variable	N	Intervention Effect†‡§ Odds Ratio¶	95% CI
Processes of care			
At least 1 HbA1c	2190	1.14	0.71 to 1.85
Two HbA1c 3 mo apart	2205	1.01	0.69 to 1.46
Lipid assessment	2212	1.08	0.81 to 1.46
Microalbumin assessment	2212	2.03‖	1.01 to 4.05
Angiotensin converting enzyme inhibitor	2212	1.47‖	1.07 to 2.01
Aspirin	2212	2.20**	1.28 to 3.76
Dental referral	2212	1.01	0.45 to 2.27
Eye examination or referral	2212	1.37	0.81 to 2.30
Foot examination or referral	2212	2.01††	0.996 to 4.07
Influenza vaccination	2212	1.05	0.65 to 1.68
Home glucose monitoring	2212	1.53	0.83 to 2.83
Dietary counseling or referral	2212	0.24**	0.08 to 0.68
Exercise counseling	2212	0.34**	0.15 to 0.75
Diabetes education	2212	0.16‡‡	0.06 to 0.44
Clinical outcomes: thresholds			
LDL cholesterol <130 mg/dL	1376	0.96	(0.75 to 1.24)
LDL cholesterol <100 mg/dL	1376	0.79††	(0.63 to 1.002)
Blood pressure <130/80 mm Hg	2179	1.12§§	(0.90 to 1.39)
HbA1c <9.5%	2015	1.14	(0.90 to 1.44)
		Coefficient¶¶	**95% CI**
Clinical outcomes: measures			
HbA1c (%)	2015	0.01	(−0.34 to 0.36)
LDL cholesterol (mg/dL)	1376	3.40	(−3.90 to 10.7)
Systolic blood pressure (mm Hg)	2179	0.37	(−2.34 to 3.07)
Diastolic blood pressure (mm Hg)	2179	−0.30	(−1.82 to 1.22)

*Baseline for evaluation of the intervention effect is 2000, when randomization occurred.
†Mixed linear or logistic regression with health center as random effect.
‡Covariates included in all models: (i) stratification factors: Region (Midwest, West Central), Diabetes Collaborative (I, II); (ii) baseline site-level summary of dependent variable.
§Potential covariates: urban location, baseline site-level summaries of patient age (mean), sex (% female), race (% African American, % Hispanic), diabetes type (% type 1), diabetes treatment (% on insulin), comorbidities (% hypertension, % myocardial infarction), and complications of diabetes (% retinopathy, % neuropathy, % peripheral vascular disease, % renal failure).
¶Significance levels at or below 0.05, 0.01, 0.10, 0.001 are denoted by ‖, **, ††, and ‡‡, respectively.
§§Intervention effect significant ($P < 0.05$) or marginally significant ($P < 0.10$) when adjusted for 2000 site-level insurance (% Medicare, % Medicaid, and/or % No Insurance), with magnitude and significance of effect sensitive to values imputed for the site that did not report insurance in 2000.
¶¶Fully adjusted model.

reports successful interventions conducted within a few sites.[34] The HDC are the most extensive, comprehensive, and generalizable national QI effort in community HCs to ever be undertaken.

The observed improvements from the standard HDC may be partially attributable to secular trends. Determining secular trends for HCs is challenging because no natural control group exists. For example, HC patients are poorer and more vulnerable than managed care patients in the Health Plan Employer Data and Information Set,[35] and within the HC community, HCs opting to participate in the HDC may be more motivated and organized than nonparticipating HCs. Nonetheless, a recent nationally representative study of changes in diabetes processes of care and outcomes during our project period using the National Health and Nutrition Examination Survey and Behavioral Risk Factor Surveillance System found no changes in mean hemoglobin A1c percentage and a modest increase in use of aspirin.[36] In contrast, we found a statistically and clinically significant reduction in hemoglobin A1c in our study and a larger increase in the use of aspirin, suggesting that the standard HDC truly did have a beneficial effect on the quality of diabetes care.

Our short-term results analyzing changes between 1998 and 2000 are consistent with the findings from the Landon et al controlled study[17] comparing data from 1 year precollaborative to 1 year postcollaborative. Both studies found improvements in processes of care but not actual hemoglobin A1c value. Contrary to the Landon et al study, we did find an improvement in LDL cholesterol level in the short-term. However, comparing 1998 to 2002 data in long-term follow-up, we found improvements in processes of care and improvements in both hemoglobin A1c and LDL cholesterol levels. Glycemic control is a complicated task involving patient self-management, diet, exercise, and medications. Improving complex patient outcomes, such as glucose control, may require prolonged commitment to a QI approach, and thus, positive effects might not be captured in short-term studies.

The addition of a more intensive intervention on top of the baseline HDC showed mixed results, with some improvements and decrements in diabetes care. The high-intensity intervention increases use of angiotensin converting enzyme inhibitors and aspirin, 2 particularly important processes for reducing morbidity in clinical trials and making diabetes management programs societally cost-effective.[37–40] Somewhat paradoxically given its components in communication and behavioral change, the high-intensity intervention was associated with less documentation of diabetes education and dietary and exercise counseling. These findings suggest tradeoffs between intensifying medication use and participating in diabetes education and dietary/exercise counseling. However, lifestyle counseling is probably more prone to documentation variation across HCs compared with laboratory outcomes such as hemoglobin A1c value or use of medications such as angiotensin converting enzyme inhibitors. Thus, the negative correlation of the high-intensity centers with the counseling processes must be viewed with caution.

Our study has important implications for HCs and other health care organizations. Specific to HCs, it demonstrates that a powerful governmental organization, the Health Resources and Services Administration's BPHC, which controls a significant portion of each HC's financial stream, can facilitate sustained QI in a national network of generally highly motivated, idealistic HCs by training, lending assistance, and conveying that the QI collaborative approach should be done. More generally, motivated hard-working health care staff can improve care and diabetes outcomes when given autonomy and support to create change. The rapid QI approach and Chronic Care Model are paradigms that allow flexibility. HC staff are used to working creatively in resource-constrained environments.

In addition, the marginal effect of the high-intensity intervention suggests that either the standard HDC QI collaborative model is sufficiently powerful or empowering, or that additional interventions will need to be stronger than our high-intensity intervention to lead to marked improvement. Of note, the standard HDC intervention evolved to a progressively more intensive effort during the course of the study, as the amount and frequency of support from the cluster coordinators and BPHC increased, thus lessening the difference between the high- and standard-intensity arms. Finally, although improvements in processes of care occurred rapidly, it took 4 years before hemoglobin A1c values decreased, suggesting the importance of enduring commitments to the QI intervention and long-term outcome studies.

Limitations of our study include the previously described difficulty determining the role of secular trends. In addition, the HCs in our study are a subset of all HCs that participated in the HDC; these centers might be more motivated and organized than the typical HC. A few HCs dropped out of the study, although dropout was reasonably well balanced between high- and standard-intensity arms. Also, implementation of the high-intensity intervention probably varied across diverse HCs. Although 34 HCs is a large sample for this type of study, power is still limited. Still, our evaluation adds important information to the QI field because it has the longest follow-up period of a QI collaborative evaluation, tests the incremental effect of additional support in organizational change and patient self-management, and also studies socioeconomically disadvantaged patients at particularly high risk for poor outcomes.

In summary, a sustained QI collaborative seems to have improved care and outcomes in HCs that care for underserved populations who are at risk for health disparities.[41] Reducing health disparities can be done, but this will require incentives, resources,[40,42] leadership, and commitment over time.

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