

Quality Care Improvement Program in a Community-Based Participatory Research Project: Example of Project DIRECT

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A continuous quality care improvement program (CQIP) was built into Project DIRECT (Diabetes Interventions Reaching and Educating Communities Together) to improve providers' patterns of diabetes care and patients' glycemic control. Project DIRECT consisted of a comprehensive program aimed at reducing the burden of diabetes in the vulnerable high-risk African-American population of southeast Raleigh, NC. Forty-seven providers caring for this target population of adult diabetes patients were included in this quasi-experimental study. At the initial session, providers learned about the CQIP components, completed a planning worksheet, and chose a CQIP coordinator. Educational events included continuing education in practices and through conferences by experts, and guideline distribution. Follow-up was accomplished through phone calls and visits. Effectiveness was measured by a change in prevalence of selected patterns of care abstracted from 1,006 medical charts. Appropriate statistical methods were used to account for the cluster design and repeated measures. At the fourth follow-up year, approximately 40% of providers still participated in the program. Among the providers who stayed in the program for the whole study period, most selected quality care patterns showed significant upward trends. Glycemic control indicators did not change, however, despite an increased number of hemoglobin A1c tests per year. A diabetes CQI program can be effectively implemented in a community setting. Improved performance measures were not associated with improved outcomes. These results suggest that a patient-centered component should reinforce the provider-centered component.

Key words: diabetes ■ continuous quality improvement program ■ community-based participatory research ■ African Americans

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INTRODUCTION

The complex set of health status determinants, the disproportionate disease burden experienced in marginalized communities, and the limited effectiveness of traditional prevention research, particularly in minority communities, have increased the demand for more comprehensive and participatory approaches to public health research and practice.¹ In 1985, the Secretary of Health and Human Services Task Force on Black and Minority Health identified diabetes as a major contributor to mortality among minorities in the United States.² To respond to the excessive, unnecessary burden of diabetes among African Americans, the Centers for Disease Control and Prevention (CDC) led the development, implementation, and evaluation of Project DIRECT (Diabetes Interventions Reaching and Educating Communities Together) in southeast Raleigh, NC.²

Diabetes is a major burden for individuals and society in North Carolina,³ especially Wake County.⁴ In 1993, at the inception of Project DIRECT and during the preintervention phase, Research Triangle Institute conducted a pilot survey in Wake County among 1,474 civilian, noninstitutionalized and nonpregnant persons aged 20-74 recruited through a stratified, multistage area probability sampling of 3,000 households.⁴ Among the 902 participants who underwent a complete survey and examination, the overall prevalence (SE) of total diabetes (diagnosed and undiagnosed) in Wake County was 4.6% (0.7%). The prevalence (\pm SE) for African Americans was three times that of whites ($10.3\% \pm 3.0\%$ vs. $3.1\% \pm 0.7\%$, $p < 0.05$), and that of impaired glucose tolerance twice as high, though not significantly ($11.4\% \pm 7.5\%$ vs. $6.3\% \pm 3.5\%$, $p = \text{NS}$).

In the mid-90s, the modest results reported by the three largest U.S. community interventions designed to test the feasibility and sustainability of cardiovascular disease programs led the scientific community to rethink the concept of community intervention by giving more importance to the understanding of commu-

nity dynamics that influence changes and targeting high-risk communities.⁵ Many community-based studies targeting adult diabetes have adopted such a participatory design, i.e., they have involved community stakeholders to variable extents in the research process and used culturally relevant intervention contents.⁶⁻¹³ All studies but two carried out in Native Hawaiians⁹ and Pima Indians¹⁰ have been conducted out of the United States in high-risk populations. One study used a randomized design,¹⁰ and the others a quasi-experimental design without or with control communities. These studies focused on lifestyle interventions; two actively involved community practitioners as community agents but not through a CQIP.^{8,14} The need to improve the quality of healthcare practices is well documented. For example, Chin et al. identified a gap between usual care and optimal diabetes care as recommended by the American Diabetes Association, especially in safety-net healthcare settings, which they relate to diabetic patients' behavior enhancement, affordability, accessibility, and efficiency.¹⁵

CDC implemented Project DIRECT as a demonstration project to assess the viability of using community participatory strategies to improve a community's diabetes-related outcomes in the target population of African Americans residing in southeast Raleigh.² It was the largest and most comprehensive U.S. community demonstration project and was implemented through a partnership that includes the CDC, North Carolina State Department of Health and Human Services, Wake County Human Services, and southeast Raleigh community. North Carolina State and Central Universities, the University of NC at Chapel Hill, and Wake Forest University School of Medicine provided expertise as consultants from the project's inception.

Project DIRECT had three arms: a) diabetes care (DC) with two components, the first aimed at improving DC practice in a sample of providers (as described in this report) and the second at improving the self-management skills in a community-based sample of patients; b) nutrition and physical activity education of diabetes patients; and c) outreach to churches and the general population, through which a population-based diabetes screening was conducted (see Figure 1 for details). Patients for the patient-based programs were self- or physician-referred. Details of the design are published elsewhere.² Evidence suggests that a multifaceted intervention strategy is more effective in yielding positive outcomes than is a single intervention strategy.¹⁶ The southeast Raleigh community participated as one of four equal partners, including the Wake County Human Services, the State Department of Health, and the CDC. Community volunteers played different roles depending on whether they were members of the large community coalition and/or of the intervention-

domain-restricted workgroups (Figure 2). Those in the former were very involved in raising Project DIRECT awareness, visibility, and support in the community. In fact, the DIRECT office was located in the community. Those in the workgroups were very active in defining/refining the intervention content, suggesting the most appropriate recruitment and retention strategies, and were actors for implementing some interventions (e.g., lay exercise leader and church-based nutrition education). The positions of chair and vice-chair on the executive committee (EC) were reserved to the community volunteers elected by members of the coalition. The EC community representatives later became advocates for diabetes policy making at the level of the Black Caucus of the NC General Assembly.

This report focuses on the continuous quality improvement program (CQIP) of the DC component from its inception in August 1996 to June 2000. This evaluation asks whether a targeted provider recruitment and retention plan facilitates CQIP participation by primary care providers and can produce a 70% provider retention; whether a multifaceted diabetes intervention program, which includes education, resources distribution, and consultation, improves DC patterns (i.e., an annual 10% increase in the percentage of diabetes patients with measures of care documented in their charts); and whether glycemic control for the diabetes patient population concomitantly improves.

METHODS

The CQIP used a one-group pre- and post-test design. The target population included African-American residents of southeast Raleigh, the historical center of Raleigh's African-American community. The DC component was initiated in August 1996; the ongoing intervention is at its institutionalization phase. The North Carolina State University, Wake Forest University, and CDC Institutional Review Boards approved Project DIRECT protocols during the study.

Study Population

By November 1995, the DC Workgroup (DCW), composed of DIRECT staff, community volunteers, physicians, and other healthcare providers, obtained and reviewed a list of providers in Wake County, from the three local hospital systems and compiled a list of healthcare providers in the county who were likely to serve patients with diabetes in the target area. The physician census in Wake County was 390 primary care physicians (93 family physicians, 15 general practitioners, 127 general internists, 65 obstetrician/gynecologists and 90 pediatricians) who are in active practice. Also, mid-level providers (i.e., 46 nurse practitioners and 55 physician assistants) practicing in Wake County were also eligible.

This is the population of providers from which a

convenience sample of 30 providers was targeted for participation. The sampling was relaxed from random process to opportunity sampling. Because physicians know one another and have contact through various hospitals and other affiliations, they have first-hand knowledge about providers in the southeast Raleigh area serving African Americans. Recruitment of providers and practices commenced with the DCW physicians personally contacting providers and practices on the list with whom they are familiar. The contacts occurred through phone calls, office visits, and/or more informally via meetings or grand rounds. The goal of each encounter was to include discussion about the goals and objectives of Project DIRECT, the medical record review process, and the time commitment involved in participation. If the practices were interested, the recruiter assessed eligibility based on the following criteria.

The inclusion criteria were a Wake County practice location; ≥10% of clients who were African Americans and southeast Raleigh residents; and a healthcare provider who practiced general, family, or internal medicine, or obstetrics and gynecology. Providers signed a consent form stating their willingness to participate in the CQIP and chart review.

Forty-seven providers, accounting for approximately 12% of primary care providers in Wake County at the project's inception, agreed to participate and were included in the study at baseline.

The Intervention: Continuous Quality Improvement Plan

Once providers were recruited, they completed the baseline survey instrument about provider and patient

population demographics and current diabetes management. The DIRECT staff also conducted a baseline chart review. These initial data were analyzed by the North Carolina Center for Urban Affairs and Community Services and compiled as provider's performance profiles (snapshots) that were later returned so providers could set new performance goals during the October 1996 orientation session.

The DIRECT staff conducted orientation sessions so each practice could establish a CQIP plan, adapted with permission from the Minnesota Diabetes Control Program.¹⁷ During the orientation session, participants completed a "planning worksheet" that included selection of a DIRECT office coordinator who was committed to the diabetes program; assessment of how to incorporate DIRECT office resources into their practices; identification of a patient education system either on-site (provide patient education and distribute, display, reorder, and stock materials), or by referral (initiate, track, and document the referral and to whom and how often); and determination of ways to implement the CQIP in their practices. They were then given a practice resource and provider quality improvement manuals and told about the Record Review Abstraction Form. They also received several diabetes reminder systems to select or adapt. By December 1996, all practices had chosen CQI coordinators and completed planning worksheets and summaries.

The Retention Plan

The retention plan included two major components: an education component with interactive feedback during regular and periodic follow-up visits, and

Figure 1. Overview of

Three Main

Primary Prevention of Diabetes

I M P A C T	HEALTH PROMOTION Risk Factors Prevention		
	Increase physical activity	Decrease dietary fat consumption	Health needs assessment
P R O C E S S	"Ready, Set, Walk" and "Lay Exercise Leader" Programs	Diabetes Population: Church nutrition training General Population: nutrition education classes & food demonstration	Church health assessment tool/ Church health action plan
	MEDIA COVERAGE		and

diabetes-pertinent material distribution. Education programs included in-service training in the practices, grand-round sessions, and education programs with Continuing Medical Education credits organized in collaboration with diabetes experts from the University of North Carolina and Duke University, and a quarterly newsletter. Education sessions were first conducted collectively (conferences and grand rounds) and based on general diabetes topics; later, providers asked that sessions be held onsite and tailored to practice needs and based on snapshot results. As a result, during the second year, programs on nephropathy testing and foot exam and a traveling nursing education program accredited by Wake Area Health Education Center were developed. The former consisted of in-service programs, including providers' training in foot care and microalbuminuria testing and distribution of kits and tools, teaching tools, patients' education and providers' education materials; seven practices made time for this learning session. The latter was based on the one-hour program, "Survival skills for the nurse providing diabetes education in the primary care setting" and was run in six practices. A county-specific resource directory was developed, updated annually, and freely distributed to participating providers. Contacts were established through monthly phone calls and periodic visits.

OUTCOMES DEFINITION AND MEASUREMENT

Process Outcome

Retention plan. The plan was evaluated by the annual number of contacts with primary care

providers recorded on DC practice records. These contacts were defined as a continuous variable and used to assess the objective's implementation by the DIRECT staff. Overall attendance at education events was monitored, but attendance of specific CQIP providers was not transcribed.

Objective Outcome

Providers' retention. Practice and provider characteristics reported by providers on the baseline survey instrument were used to describe the study population. The quantitative objective was to retain 70% of the providers yearly; the choice of this cutpoint was based on the investigators' previous experience in practice-based research. Outcomes were defined as year-to-year and overall retention. Year-to-year retention was measured as the proportion of providers still actively participating in the program at the end of each fiscal year over the number of providers present at the beginning of the year. Overall retention was measured as the proportion of providers present at the end of each fiscal year over the original number of providers.

Patterns of care. This outcome was the main measure of effectiveness of the intervention and was assessed by medical chart data abstraction during four audit sessions.

Chart reviews were conducted by trained chart reviewers. The criteria for selecting records for review were patient age between 18 and 75, diagnosed diabetes, African-American ethnicity, at least one visit within the last year, at least 50% of visits over the past two years with the named provider, and absence of terminal disease. The initial plan was for

Project DIRECT Intervention					
Components					
Diabetes Early Detection			Diabetes Control/Secondary Prevention of Complications		
OUTREACH			DIABETES CARE		
Diabetes Awareness	Undiagnosed diabetes screening	Increase referral process	Increase self-management	Improve quality of diabetes care	
Media and community-based organization	Community-based diabetes screening	Partnership with federally-funded health centers	Diabetes self-management workshops	Quality improvement initiative for providers	
COMMUNITY PARTICIPATION					

the practice managers each to pull 20 records meeting the above criteria, for each provider, and from which the reviewers would randomly select 10 records per provider for review. If the practice staff was unable to find enough charts that met study requirements, they pulled all available charts. In three instances in 1996–1997 and 1999–2000, the reviewers pulled <10 charts/provider. In the second case, it was because the providers had just joined the practice and did not have enough charts. In 1997–1998, when it appeared that it was difficult to relate charts to providers because the providers’ turnover in this teaching hospital was very rapid, the DIRECT investigators decided to abstract data from a fixed number of 50 charts per year for the whole institution for the remaining study period.

The Project DIRECT Record Review Abstraction Form encompassed nine sections: demographics, smoking status, vitals (weight, blood pressure), glucose control (medications, self-management, hypoglycemia assessment, home glucose monitoring), dietary assessment or counseling, physical activity assessment, depression screen, physical exam (vascular, peripheral nerve, foot, ophthalmologic referral), and lab testing (HbA1c and its most recent value, proteinuria, microalbuminuria, blood urea nitrogen and creatinine, sodium and potassium, high-density- and low-density-lipoprotein, sickle cell disease, keto-acidosis), and the number of times these tests were performed during the current and previous years. Documentation of selected care was defined as “whether there was documented evidence that the specific exam/procedure had been *ordered, discussed, recommended, or performed within* the last two years.” Regarding the ethnicity criterion, instructions were given to practices to pull charts of African Americans, and patients were assumed to be African Americans. Midway through the project it was noted by the reviewers that occasionally a non-African-American chart was provided. In such cases, the reviewers then handwrote in the race on the abstraction form. Because

of the inconsistent abstraction of this variable, it was not coded, and we do not have information on patient race. It is believed, however, the proportion of non-African-American residents included in the sample size is low.

The CQIP effectiveness was defined as a 10% incremental annual change in the prevalence of selected DC measures. Although the project started prior to Diabetes Quality Improvement Program (DQIP), for the sake of comparison, we organized these into measures of accountability and of quality improvement as defined by the DQIP.¹⁸ Accountability measures included the percentage of the population with at least one HbA1c performed in the year, poor HbA1c control (HbA1c >9.5%), documented annual dilated eye exam, lipid profile (HDL and LDL cholesterol) performed in the year, monitoring for nephropathy (proteinuria, microalbuminuria), and controlled blood pressure (BP <140/90 mmHg). The percentage of persons with controlled lipid level was not available in DIRECT CQIP dataset because HDL/LDL cholesterol values were not abstracted. However, monitoring of lipid profile values began in July 2000.

The quality improvement measures included the percentage of patients with well-documented foot exams and distribution of HbA1c and BP. We included other measures suggested in the latest version of DQIP, although they were measured via chart abstraction rather than by patient survey as recommended in the DQIP.¹⁸ These measures are smoking cessation counseling for the accountability set, and diabetes self-management, diet, and physical activity education for the quality improvement set. Accountability measures allow comparisons across healthcare settings; quality improvement measures allow internal QI monitoring.¹⁸

Glycemic control. The most recent HbA1c (%) values were recorded on the abstraction form. They were analyzed as a continuous variable and categorized according to DQIP criteria of <7, 7–7.9, 8–8.9, 9–9.9, and ≥10%.¹⁸

Table 1. Retention of Practices and Providers over Time. Project DIRECT, 1996–2000

	Baseline	Year 1	Year 2	Year 3	Year 4
Practices, n	15	12	10	10	6
Single practitioner	5	5	4	4	4
Multiple practitioner	10	7	7	6	2
Healthcare provider, n	47	30	25	22	18 [‡]
Y-to-Y retention,* %		64	83	88	82
Overall retention, † %		64	53	53	38

* Y-to-Y: year to year, measure of annual objective achievement; denominator = number of practitioners at the end of previous year; † Measure of intervention overall effectiveness: denominator = number of practitioners at start of intervention; ‡ Five newly recruited healthcare providers in a participating practice.

ANALYSES

Provider Retention

An analysis of retention was performed for a one-group pre- and post-test design with repeated measures over time on the same practices and providers. Baseline characteristics of providers who remained in the project were contrasted with those of providers who did not. Differences in the distribution were tested by Chi-squared statistics for categorical variables and by t-test for continuous variables. Unadjusted estimates of year-to-year prevalence and overall retention rate were derived from a repeated-measures regression model of retention status on year.

Patterns of Care and Glycemic Control

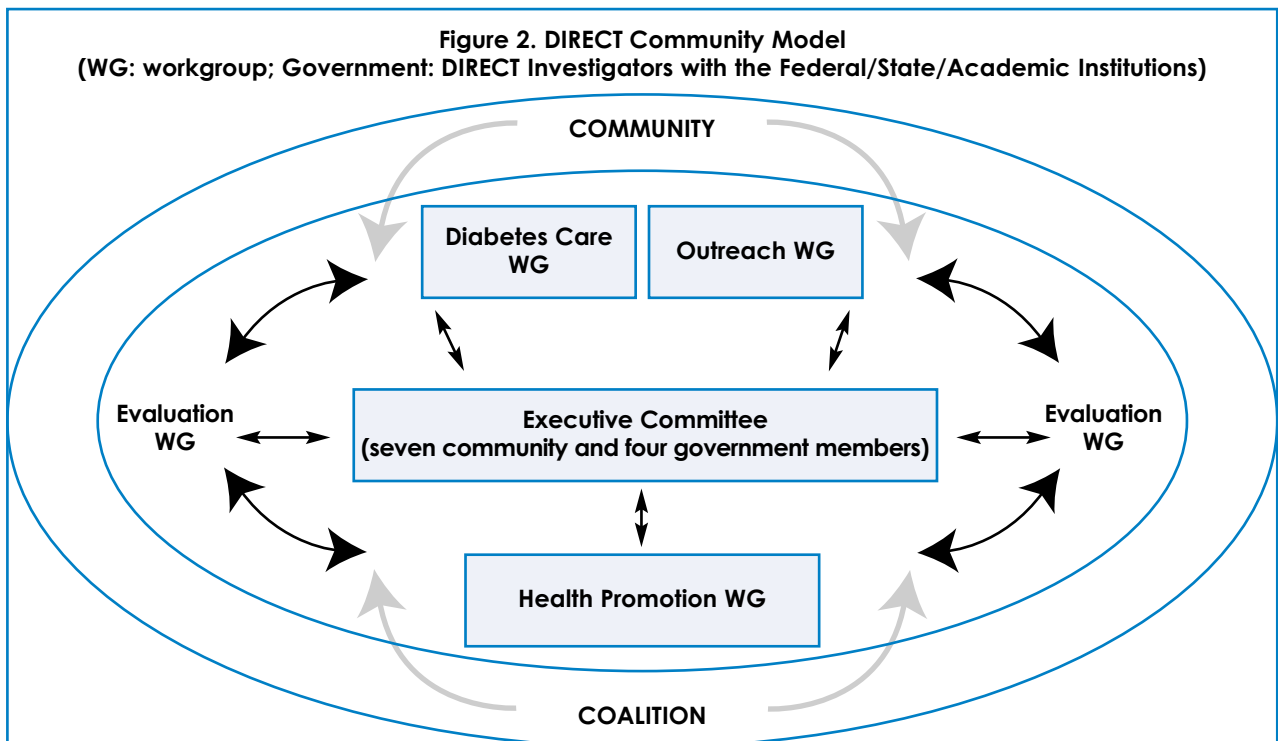
Practices were the first stage of a two-stage sampling and charts were the unit of observation. The types of correlation examined are within-practice/physician correlation for each year, and across time. The former were accounted for using generalized linear mixed models to model random effects for practitioners; the latter was treated as a fixed effect (GLIMMIX macro, SAS Inc., Cary, NC).¹⁹ Prevalence-of-care measures and mean HbA1c were computed for each year, and tests for linear trends of these values were obtained from these models. For technical and conceptual reasons, all analyses were carried out on providers who stayed in the program the entire study period. Analyses for the QI measures with more than two levels are not supported by

GLIMMIX and were analyzed by Chi-squared statistics for the association test and the Mantel-Haentzel test for the trend test. Conceptually, analyzing only those who stayed four years eliminates a bias introduced by the fact that practices that dropped out had lower HbA1cs at baseline than did those who stayed—a finding noted in our exploratory analyses. Analyses were performed with Statistical Analyses software, version 8 (SAS Inc., Cary, NC).²⁰ The nominal p-value for statistical significance was set to <0.05 for all analyses.

RESULTS

Provider Retention

Forty-seven healthcare providers practicing alone or in a group in 15 institutions were recruited to participate in the CQIP program (Table 1). All but two providers were physicians. These providers were a physician assistant affiliated with a practice that dropped out at the end of the first year and a nurse practitioner with a practice that stayed three years in the program. No new practice entered the project after it started. However, following expansion of one practice in 1999–2000, four new physicians were enrolled. The biggest drop-out occurred at the end of the first intervention year because of disbandment of three practices with 14 providers that were owned by the same group (the medical director for these practices left and the providers discontinued their participation) and withdrawal of one provider. Thereafter, the drop-out rate remained constant (12–14%), with



about 40% of providers still participating at the end of the fourth year. On a year-to-year basis, however, the project objective of retaining 70% of providers was met (83%, 88%, and 82% the last three study years, respectively). It is of interest to note that single practitioners were more likely to stay in the program. The reasons for withdrawing varied. Only one single-practitioner practice truly declined CQIP participation; others left for migration out of Raleigh (n=2 practices with six providers), retirement (two providers in a practice that remained in the program), and practice disbandment or reorganization (n=6 practices with 21 providers).

Practices that remained in the program were located mainly in the southeast Raleigh target area; those that dropped out were located outside the target area, though they saw patients who resided in southeast Raleigh (Table 2). Those who remained in the program also had a greater African-American (range: 44–90% vs. 8.5–50% patient, p<0.0003) and minori-

ty patient and provider mix and a greater relative diabetic population size than those who dropped out. The majority of institutions were community-based practices (only one out of the 15 practices was an academic institution). In addition, the mean HbA1c at baseline for patients in practices who participated in all four years was higher than for those in practices that dropped out in years two through four (9.9% ± 0.7% vs. 8.9% ± 0.4%, p<0.05). Providers who stayed in the program did not differ from those who left, except for the distribution of specialties (Table 2), and there was no significant difference in the total amount of yearly contacts. The mean number of contacts ± standard deviation increased from 3.1 ± 3.5 the first year to 6.7 ± 1.9 the fourth year, with a reduction in the third year to 2.3 ± 2.9.

Patterns of Care Over Time

Data for patterns of care were abstracted from 1,006 charts, of which 410 were collected in practices

Table 2. Baseline Characteristics of the Practice/Providers by Retention Status. Project DIRECT, 1996–2000

Characteristics	Retention Status in CQIP Intervention		P Value* mean _R = mean _D
	Yes	No	
N practices	6	9	
N providers	18	29	
<i>Practice-Related</i>			
Location: southeast Raleigh vs. not, %	85.7	0.0	
Size of the practice: mean number of HCPs	3.1	4.7	0.33
Percentage of providers surveyed	77.4	82.6	0.74
Patient population size and management			
Absolute number of diabetic patients/week/provider	36.5	15.7	0.05
Absolute total number of patients/week/provider	113.1	85.4	0.32
Relative diabetic population size/week/per provider†	0.3	0.2	0.05
Patients' ethnic mix:			
% African Americans	66.7	29.0	0.0003
% all minority populations	71.7	34.6	0.0001
Percentage of African-American providers			
Percentage of African-American providers	38.1	16.7	0.30
Percentage of minority providers	52.4	25.0	0.21
<i>Provider-Related</i>			
Age	45.3	40.0	0.17
Gender, % male	50.0	52.0	0.90
Years since degree, median (range)	11.5 (2-62)	10 (0-27)	0.52
Providers' specialty, %			
General medicine	14.3	20.0	0.002
Internal medicine	50.0	3.3	
Family medicine	35.7	70.0	
Psychiatry	0.0	6.7	
* Mean _R = mean among retained providers; Mean _D = mean among providers who dropped out; † Relative diabetic population size at baseline = (weekly # diabetic patients/weekly # all patients).			

that stayed in the program all four years. Characteristics of the population were assessed on the former, whereas prevalence of care was assessed on the latter.

Ages of the patient population ranged from 20 to 90 years, mean (SD) 55.3 ± 13.0 years and did not vary across time. Based on medical insurance, the population was underserved: 75% had public-type (Medicare/Medicaid), 15% no insurance, and only 3.1% had private insurance. Health insurance coverage and participant weight significantly changed over time. The percentage of patients whose insurance type was not documented—7.2%—increased over time, and the diabetes patient population’s mean weight increased by approximately 10 pounds in the four-year study period (data not shown).

At baseline, BP and weight measurement, HDL/LDL and glucose testing, and diet assessment were at the highest end of documented care (75–100%), whereas microalbuminuria was at the lowest (3.2%) (Tables 3–5). HbA1c analyses, foot skin integrity, and vascular examination were documented in 50–75% of charts, referral for dilated eye exam in about one-third of charts, and foot care counseling in about one-fifth.

The prevalence of most of the accountability patterns of care increased over time, well above the pro-

ject’s goal of a 10% yearly change, for most of them (Table 3). The increase was statistically significant, however, only for HbA1c, referral for eye exam, and microalbuminuria test. During the study period, providers tended to increase the periodicity of HbA1c testing to more than once a year. The prevalence of controlled diabetes decreased, and only part of the indicators of patient lifestyle and diabetes self-management behavior showed statistically significant increases (Table 4). Documentation of peripheral nerve exam decreased, but monofilament use for neurological examination increased from no use at baseline to 8% (p < 0.05) use four years later (Table 5).

The periodicity of HbA1c and blood glucose testing and vascular exam increased over time. The median number of times per year these assessments were performed increased from one to two for HbA1c (annual range, 0–6) and vascular exam (annual range, low 0–5 to high 0–14), and from three to four for blood glucose (annual range, low 0–12 to high 0–35). Referral of diabetes patients or persons at risk for diabetes to DIRECT risk-reduction programs was very poor (less than 5%) during the study period.

Glycemic Control over Time

Based on cross-sectional samples of patients in

Table 3. Prevalence of Accountability Patterns of Care Over Time. Project DIRECT, 1996–2000

	Year 1	Year 2	Year 3	Year 4	Year 1–Year 4 Relative Difference, † %	P Value	
						Association = 0	Linear Trend = 0
HbA1C tested	54.5	76.4	92.6	91.7	68	0.0001	0.0009
% with HbA1c >9.5%	55.2	27.8	57.3	33.5	-39	0.008	0.29
<i>HbA1c periodicity</i> ‡							
0/year§	6.9	6.5	6.2	7.0	1	0.002	0.006
1/year	45.5	40.4	29.3	28.7	-37		
>1/year	47.5	53.0	64.4	64.4	36		
Referral for eye exam	32.5	52.5	50.3	71.5	120	0.0001	0.0001
HDL/LDL cholesterol tested	85.7	74.7	79.3	69.8	-29	0.10	0.02
<i>Diabetic nephropathy</i>							
Microalbuminuria test	3.2	10.0	2.5	17.3	440	0.02	0.02
Proteinuria test	66.2	76.2	79.4	76.5	16	0.24	0.09
<i>Blood pressure control, %</i>							
Normal BP (<140/90 mm Hg)	49.1	67.3	53.3	46.1	-6	0.07	0.54
Foot skin integrity exam	66.8	87.1	78.8	84.0	26	0.05	0.04
Smoking cessation counseling	23.0	33.7	35.9	44.3	93	0.52	0.13

† Relative difference = [(value4-value1)/value1]; ‡ Not DQIP variable; § Periodicity of HbA1c not adjusted for intrapractice/physician correlation because of multilevel categories.

practices that stayed in the program for four years, mean HbA1c did not vary and remained at 9.9% ± 0.7%, 9.0% ± 0.7%, 10.2% ± 0.6%, and 9.2% ± 0.6% at years one through four (p=0.17).

Office System Change Variables

Use of reminder systems by providers or practices reflective of office system changes was low initially and increased over time. Sticker use increased from no use at baseline to about 35% in the second year and thereafter (p <0.05). Flow sheet use increased from 17.1% at baseline to 38.2% in the fourth year among the providers who stayed the four-year study period (p <0.05).

DISCUSSION

This evaluation of Project DIRECT showed that at the end of the four-year study period, 40% of enrolled providers still participated in the program.

Among these providers, major patterns of DC (e.g., HbA1c testing, dilated eye exam, foot care, and microalbuminuria) significantly improved, but indicators of glycemic control were unchanged. In addition, office system change as evaluated by use of reminder systems also improved. There are no comparison studies using community-based participatory CQIP in the current literature.

Several program implementation factors may explain some of the results. Turnover in practices and provider drop-out was notable. Turnover in Project DIRECT personnel also played a role. The months-long lack of an evaluator may explain the differential tracking of follow-up activities and variability in the periodicity of follow-up contacts with providers. Snapshots, which were greatly appreciated by the providers, were not provided after 1998 because of turnover in the DC co-PI, DC coordinator, and evaluator positions. Finally, in 1997, new

Table 4. Prevalence of Quality Improvement Patterns of Care over Time. Project DIRECT, 1996–2000

	Year 1	Year 2	Year 3	Year 4	Year 1–Year 4 Relative Difference, † %	P Value	
						Association = 0	Linear Trend = 0
<i>HbA1c categories, %‡</i>							
<7%	56.5	38.2	23.6	27.8	-51	0.0004	0.001
7–7.9%	4.7	11.2	10.9	15.9	238		
8–8.9%	9.4	16.9	17.3	12.7	35		
9–9.9%	1.2	7.9	10.9	11.1	93		
≥10%	28.2	25.8	37.3	32.5	15		
<i>Systolic blood pressure, mmHg, %‡</i>							
<140	49.4	36.0	50.9	50.8	3	0.60	0.31
140–159	30.6	44.9	34.6	33.3	1		
160–179	15.3	13.5	9.1	11.1	-37		
180–209	4.7	4.5	4.6	4.8	0		
≥210	0.0	1.1	0.9	0.0	0		
<i>Diastolic blood pressure, mmHg, %‡</i>							
<90	77.7	70.8	76.4	80.1	16	0.03	0.04
90–99	8.2	23.6	16.4	14.3	74		
100–109	7.1	5.6	5.5	3.2	-55		
110–119	4.7	0.0	1.8	1.6	-66		
≥120	2.4	0.0	0.0	0.0	0		
Diet assessment	77.1	87.6	76.3	72.9	-5	0.11	0.30
PA assessment	33.2	52.6	28.4	39.5	19	0.06	0.91
Diabetes education	49.0	91.7	87.6	92.0	88	0.001	0.0001
HbGM assessment	58.6	78.2	87.2	89.4	53	0.03	0.0001
Hypoglycemia assessment	43.3	35.4	32.5	38.1	-12	0.71	0.48
Foot care counseling	17.7	55.2	28.0	50.0	82	0.001	0.10

† Relative difference = [(value4-value1)/value1]; ‡ Not DQIP variable; § Periodicity of HbA1c not adjusted for intrapractice/physician correlation because of multilevel categories; PA: physical activity; HBGM: home blood glucose monitoring

requirements for IRB submission caused interruptions of project implementation. Characteristics of providers who dropped out may become part of the exclusion criteria for community-based projects, i.e., retirement (upper age limit), migration out of target area, and practice disbandment.

A few methodological limitations are related to provider recruitment and chart selection. A provider's location appears *a posteriori* to be strongly associated with drop out, as none of the providers who dropped out and about 86% of the providers who stayed in the program were from southeast Raleigh (Table 2). We note that the original inclusion criteria—location in southeast Raleigh—was modified to include providers practicing outside southeast Raleigh. This modification occurred because several practices and/or providers within targeted practices had migrated from the southeast Raleigh to other parts of Wake County over the past few years while still maintaining their stable client base from within the target region. In addition, other participating practices were affiliated with those located within the target area, and therefore, in order to recruit the southeast Raleigh sites, we needed to open participation to the other satellite sites as well.

Chart selection criteria were modified for one practice (a teaching hospital) because it was difficult to assign patients to a single provider, and random chart selection did not apply in all cases. In addition, it is difficult to know how representative of a provider's usual care practice are data derived from 10 charts.²¹ Mobility of providers, e.g., recruitment of new practitioners who did not participate in the intervention, may have diluted the effect of the intervention in later years. Providers' selection affects the generalizability of results, and the chart selection

process and providers' drop-out/drop-in limit internal validity of results. The latter may dilute the program effect through lack of program continuity or inclusion of other ethnic groups that typically receive better DC, e.g., whites.

Retention is an issue in community-based participatory studies;^{7,22} it varied between 70% and 30% in one diabetes intervention.⁷ The high attrition rate of providers/practices raises the sampling unit issue in community interventions: the practice (up-down hierarchy) or individual providers (down-up hierarchy). In the former, the practice management team adopts the intervention, particularly system-changing components, and then relays them to providers; the outcomes may be favorable if the adoption process is participatory.²³ In the latter, the responsibility for running the intervention lies with the providers. A similar issue involves single- vs. multi-practitioner institutions because drop-out of the latter has more consequences for sample size. These issues are important because high and differential attrition rates challenge the project's sustained implementation, and hence the validity of observed results. Despite the methodological threat, the characteristics of providers more likely to stay in the program can be used as inclusion criteria in community-based replication studies, i.e., single, community-based practitioners with high minority and diabetes patient populations and if multipractitioner institution, high minority practitioners.

Competing interventions were not documented; hence, their effect cannot be evaluated. We can nevertheless compare our results with those of similar community-based projects that used DQIP measures. Baseline levels of care in DIRECT were generally greater than those described in Project IDEAL

Table 5. Prevalence of Provider's Other Assessment Activities and Cares over Time. The Project DIRECT, 1996–2000

	Year 1	Year 2	Year 3	Year 4	Year 1–Year 4 Relative Difference, † %	P Value	
						Association = 0	Linear Trend = 0
<i>Medication Evaluation</i>							
ACE inhibitors	39.8	55.2	66.3	58.1	46	0.01	0.01
Insulin	52.4	54.6	59.4	55.9	7	0.86	0.54
Hypoglycemic oral agent	64.6	71.0	82.7	83.8	30	0.01	0.001
<i>Complications Monitoring</i>							
Peripheral nerve exam	32.5	67.3	44.9	27.2	-16	0.0001	0.28
Monofilament use ‡	0	5.0	0.9	8.0	8	0.03	0.06
Vascular exam	50.9	74.9	81.4	83.0	63	0.0001	0.0001
Depression assessment	13.5	19.6	7.1	13.2	-2	0.26	0.56

† Relative difference = [(value4-value1)/value1]; ‡ Not DQIP variable; § Periodicity of HbA1c not adjusted for intrapractice/physician correlation because of multilevel categories; ACE: Angiotensin Converting Enzyme

(Improving Diabetes Education, Access to Care, and Living), a statewide initiative to improve the quality of DC for underserved North Carolinians.²⁴

In DIRECT, we observed a positive change in providers' documented patterns of care but not in indicators of patient glycemic control over time. Renders et al. came to a similar conclusion in a nonrandomized trial that contrasted QIP with usual care.²⁵ The provision of DC improved by all indicators, but none of the indicators for patient outcomes (HbA1c, BP, lipid profile, and weight control) had significantly changed 42 months later.²⁵ Conversely, the Indian Health Services (IHS) adopted the DQIP measures to monitor their Diabetes Care and Outcomes Audit, and an upward, improving trend was observed for patient care and patient outcomes measures over time,²⁶ perhaps owing to the fact that the IHS is a more limited system of care with a long-standing diabetes surveillance system in a smaller community.

Paradoxically, we did not observe improvement in glycemic control, despite improved measures of care. Variability in lab testing may not account for this finding because the population and laboratories were geographically stable over time. Lack of power is not a reason, as the number of charts audited each year provided enough power to detect significant difference in HbA1c as low as $0.3\% \pm 0.7\%$. As an outcome measure, glycemic control is subject to many patient-related factors (e.g., patient knowledge and understanding of the disease and risk-factor reduction strategies and application)¹⁸ other than quality of care that we did not measure.

Another important reason may be the lack of a patient-centered intervention component because a recent review of DQIP interventions²⁷ indicated that multifaceted interventions that added patient education to professional (healthcare professionals education) and/or organizational (e.g., systems change and nurse role enhancement) appeared to improve both processes of care and patient outcomes. In addition to improving clinical care, DIRECT providers were encouraged to refer diabetes patients to other DIRECT preventive activities. Referral rates were poor all four years, perhaps because providers did not document this in the chart.

These observations call for the addition of a formal patient education component to the DIRECT CQIP, or any diabetes QIP, emphasizing not only diabetes education but prevention of cardiovascular complications. Supporting this suggestion are preliminary results from a small subset of participants in the DIRECT diabetes self-management workshops (n=41). Their pre- and postintervention data showed a downward, though not significant, trend of HbA1c values (8.7% [8.1, 9.4] to 8.2% [7.4, 9.1]; D. Porterfield, unpublished, poster presentation at the DIRECT

National Forum, Raleigh, NC, Mars 2002). Patient education is now understood to be so important that the DQIP second version included patient survey of self-management skills, interpersonal care from providers, and satisfaction with and access to care.¹⁸

CONCLUSIONS

In conclusion, this first multilevel community-based participatory project to reduce the burden of diabetes in African-American adults has demonstrated that a community CQI program, though challenging, is feasible. An effort to maintain or add providers is warranted for increased intervention effectiveness. Among providers who sustained the effort, short- and long-term improvements were observed in diabetes quality care but not in indicators of patient glycemic control. Lack of glycemic control is the pathophysiological basis for costly and disabling complications, thus, a patient-centered component, also strongly suggested by current research, may enhance a clinical QIP program.

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