Randomized Trial of Quality Improvement Intervention to Improve Diabetes Care in Primary Care Settings

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OBJECTIVE — To assess the impact of a quality improvement (QI) intervention on the quality of diabetes care at primary care clinics.

RESEARCH DESIGN AND METHODS — Twelve primary care medical practices were matched by size and location and randomized to intervention or control conditions. Intervention clinic staff were trained in a seven-step QI change process to improve diabetes care. Surveys and medical record reviews of 754 patients, surveys of 329 clinic staff, interviews with clinic leaders, and analysis of training session videotapes evaluated compliance with and impact of the intervention. Mixed-model nested analyses compared differences in the quality of diabetes care before and after intervention.

RESULTS — All intervention clinics completed at least six steps of the seven-step QI change process in an 18-month period and, compared with control clinics, had broader staff participation in QI activities ($P = 0.04$), used patient registries more often ($P = 0.03$), and had better test rates for HbA_{1c} (A1C), LDL, and blood pressure ($P = 0.02$). Other processes of diabetes care were unchanged. The intervention did not improve A1C ($P = 0.54$), LDL ($P = 0.46$), or blood pressure ($P = 0.69$) levels or a composite of these outcomes ($P = 0.35$).

CONCLUSIONS — This QI change process was successfully implemented but failed to improve A1C, LDL, or blood pressure levels. Data suggest that to be successful, such a QI change process should direct more attention to specific clinical actions, such as drug intensification and patient activation.

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The gap between recommended diabetes care and care actually received by patients is substantial (1,2). In a recent survey, even large medical groups often lacked practical resources, such as external incentives and information systems, to start or sustain quality improvement (QI) strategies (3). Evidence suggests that multicomponent QI interventions that tailor quality improvement solutions to particular clinics are more effective than "one-size-fits-all" approaches (4,5). A QI change process that is customized to clinics, implemented by clinic leaders, and involves a broad cross-section of clinic staff seems promising, especially in small independent practices (6).

QI has been widely applied in other industries to improve operational processes in a tailored way and is often applied as a strategy to implement needed changes in health care, including diabetes care. However, there have been no randomized trials of QI interventions in other industries and only a few in the health care field. Published studies (7,8) show mixed results, but enthusiasm for the application of QI in health care continues, as methods are revised and case reports of improvement continue. Clearly, more studies of this approach are needed.

For >15 years, the diabetes program at the Minnesota Department of Health has collaborated with clinics and health plans to develop and pilot test practical QI approaches to improve diabetes care (9). In this study, the Minnesota Department of Health collaborated with a large health plan (HealthPartners) to train primary care clinic personnel in a seven-step QI method to improve adult diabetes care processes (10). Before this randomized trial began, these partners conducted a survey of ~1,600 adults with diabetes to assess the quality of diabetes care and opportunities for improvement. Survey results showed substantial deficits in *1*) frequency of testing for HbA_{1c} (A1C), LDL, and eye, foot, and kidney complications and *2*) control of A1C, LDL, and blood pressure levels (11).

RESEARCH DESIGN AND METHODS

Hypothesis and study design

The main hypothesis tested was that the QI intervention would lead to improved quality of diabetes care at intervention

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Abbreviations: IDEAL, Improving Care for Diabetes Through Empowerment, Active Collaboration, and Leadership; QI, quality improvement.

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

clinics compared with control clinics (i.e., a time-by-condition interaction). Participating clinics selected a 10% decrease in A1C concentrations as a common principal goal.

Clinic recruitment and patient selection

We discussed the study with leaders of medical groups that had ~100 primary care clinics, but we were able to recruit only 12 primary care clinics to the study. Eligibility criteria for clinics included *1*) medical group participation in HealthPartners insurance products, *2*) lack of current commitment to other organized efforts to improve diabetes care, *3*) commitment of clinic leaders to participate fully in the intervention, and *4*) clinic agreement to cooperate with data collection by the research team to assess the impact of the intervention.

In each clinic, patients aged ≥19 years who had two or more ICD-9 diagnostic codes for diabetes (ICD-9 codes 250.xx) in a defined 12-month period were classified as having diagnosed diabetes. This method of diabetes identification has been validated and has an estimated sensitivity of 0.91, a specificity of 0.99, and a positive predictive value of 0.94 (12).

QI intervention

A detailed description of the IDEAL (Improving Care for Diabetes Through Empowerment, Active Collaboration, and Leadership) model and the seven-step QI process used in this study has been published (10). Preceding the launch of the clinic training, study investigators held a meeting with the clinic medical directors and clinic managers of the six intervention clinics to describe the study design, methods, and goals and to encourage interest in diabetes care improvement.

Each intervention clinic then sent a team to eight 3-h training sessions scheduled over an 18-month period. The clinic teams typically included a physician, a nurse, and another clinic staff person interested in diabetes care improvement at that clinic. At the first training session, the six teams agreed on the common project goal of decreasing A1C values by 10% from baseline values. Subsequently, each training session focused on one step of the seven-step QI process. At each meeting, teams shared data, ideas, and problems and obtained guidance from project staff. Between training sessions, QI training team members (L.I.S., T.P., L.M.C., and L.R.) used telephone contact and site visits to provide additional consultation and monitor clinic progress.

The project had three sequential phases over a 42-month period of time. In phase 1, 12 months of preintervention data were collected. In phase 2, the intended 12-month training and implementation period was extended to 18 months to give sufficient time for completion of each step in the QI process. In phase 3, 12 months of postintervention data were collected.

QI model

During the 18-month training and intervention period, the IDEAL QI training team, the six intervention clinic QI change teams, and diabetic patients each had specific responsibilities.

IDEAL QI training team

Stage 1. Recruit clinics and enlist support for change agenda through personal contacts with leaders of the medical groups and clinics involved in the study. This approach combines the Hakansson industrial theory of an interaction model of customer-supplier relationships with personal networking theories (13).

Stage 2. Training and consultation provided by the IDEAL QI training team based on a formalized seven-step model encouraging creation of a new care process rather than the sequential "tests-of-change" approach (8,10,14,15). Objectives of the training were to establish both *1*) a QI change process and *2*) a set of changes in each clinic's care process aimed at improving diabetes care.

Clinic QI change team

Stage 3. Implementation of the seven-step QI change process at each clinic by a clinic QI change team led by clinic attendees trained in stage 2. The seven QI steps taught were *1*) identify opportunities for improvement, *2*) collect data, *3*) analyze data, *4*) choose an approach, *5*) develop concepts and processes, *6*) implement processes, and *7*) evaluate and improve processes (10).

Stage 4. Development of changes in care processes by encouraging each intervention clinic to *1*) adopt a diabetes care guideline, *2*) collect internal data to assess gaps and appropriate targets for intervention, and *3*) formally map current clinic processes of care to inform the design of better systems. The choice of specific changes in clinic systems and processes was left to each clinic. Most clinics chose to focus on selection of a guideline; redesign of delivery systems for services, including use of flowsheets and chart labeling; support for patient self-management; information system changes, including establishment of a clinic diabetes registry; and expanded roles for nursing staff in patient education and support (10,16,17).

Stage 5. Implementation of changes in the care processes in the clinic required resources, leadership, and skills in change management by the internal clinic team. Clinics measured the impact of each change between training meetings and shared these data at training sessions. Clinic self-measurement was a key step in the improvement process that allowed team members to monitor their progress. Implementation of each step of the seven-step QI change process at each of the intervention clinics was supported by phone contacts and on-site visits by QI training team members.

Patients

Stage 6. Cooperation. Over time, diabetic patients visited the clinic seeking care or were contacted through outreach. Outcomes depended on the extent to which patients with diabetes cooperated with clinic recommendations to obtain tests, return for visits, etc.

Stage 7. Behavior changes. Finally, patients might cooperate with care process recommendations, but they also needed to make personal behavior changes to improve outcomes.

Study design and analysis

The 12 participating clinics were matched in pairs by number of physicians, urban or rural location, and medical group affiliation and were then randomized within those pairs. A priori matching is recommended for any study with <20 groups per condition (18). Clinics agreed in advance of randomization that those in the control group would abstain from competing improvement initiatives but be offered the study intervention if desired after evaluation of the intervention was completed.

On the basis of a priori power analysis, we drew a random sample of up to 150 potential study subjects from all adults identified with diabetes at each

study clinic, with a goal of having complete data on 100 patients per clinic for analysis. At a power of 0.80, this approach allowed detection of a difference of 13.7% between the intervention and control groups in variables for the process of care (e.g., diabetic eye examinations), with a two-tailed $\alpha = 0.05$.

The unit of randomization and the unit of analysis was the primary care clinic. Mixed-model regression techniques accounted for nesting in this group-randomized trial, according to procedures outlined by Murray (18). SAS PROC MIXED (Gaussian) and the GLIMMIX macro (binary) using REML estimation were used. The analytic model used to test the primary hypotheses was an intent-to-treat, time-by-condition analysis, with values adjusted for patient age, sex, education level, and duration of diabetes for a nested, pretest-posttest, control group design. Due to a change in ownership, one intervention clinic dropped out of the study, but follow-up data were still collected for analysis.

Data collection

Research data were obtained from baseline and follow-up surveys of adult diabetic patients and clinic staff and from review of patient medical records for defined 12-month periods before and after the intervention.

The 20-min patient survey included the Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance System diabetes module (19), demographics, confirmation of diabetes diagnosis, duration of diabetes, diabetes treatment, foot and eye exams, other preventive care, aspirin and tobacco use, diabetes education, self-monitoring of glucose, adherence, comorbidities, and complications. Surveys of clinic physicians and staff included assessment of clinic systems used to support diabetes care, attitudes toward diabetes, scope of QI activities, guideline use, patient registries, prioritization of patients, outreach to patients, and planning of clinic visits.

Medical records were reviewed for dates and values of A1C, LDL, and blood pressure measures and dates of eye and foot exams and nephropathy screening. Medical record reviews were done by trained research nurses who traveled to each clinic site and used structured chart abstraction forms. A random sample of charts was reaudited by a research team supervisor to detect any inaccuracies or missing data; there were few discrepancies.

When multiple measures of A1C or other dependent variables were available for a single patient, the most recent in each defined 12-month period was used in the analysis. Nephropathy screening was considered adequate for specified 12-month periods if *1*) a urine microalbuminuria test, an albumin-to-creatinine ratio test, or a 24-h urine test for protein, albumin, or microalbumin was performed or *2*) a standard urine dipstick test was positive for more than a trace of protein. Although there may be some variation across clinics in laboratory assay methods for A1C, analyses were based on change over time in each patient. During the study period, there were no major changes in techniques for measurement of A1C or LDL in the study clinics. No clinics used desktop analyzers for these tests.

Dependent variables

The analysis focused on two composite measures of care processes: the percentage of patients with annual tests for concentrations of A1C, LDL, and blood pressure and the percentage of patients with annual screening for foot, eye, or kidney complications. We also assessed a composite measure of outcomes of care: the percentage of patients who had A1C $<8\%$, LDL <130 mg/dl, and systolic blood pressure <135 mmHg. These clinical thresholds reflect recommended levels for clinical action at the time of the study (20,21). Data on changes in clinic systems used to support diabetes care were obtained from the staff and patient surveys.

Human subjects protection

The study was reviewed, approved, and monitored by the HealthPartners Institutional Review Board and the U.S. Department of Health and Human Services Office for Human Research Protection. Patients provided written informed consent.

RESULTS

Study clinics and study subjects

All 12 study clinics were primary clinics, with diabetes care provided by general internists or family physicians; none had endocrinologists or cardiologists at the clinic during the study, and no residents provided care at these clinics. Two clinics were owned by HealthPartners; these were paired and randomized as one to intervention and one to control group. All clinics were located in Minnesota; eight were in the Twin Cities metropolitan area and four were in rural areas within 100 miles of the Twin Cities.

The 754 adults with diabetes whose data were analyzed (Table 1) are those at the 12 study clinics who completed both pre- and postintervention surveys and consented to have a medical record review that covered both the pre- and postintervention period. Response rates to the survey were similar across study clinics, averaging 55–65%; missing data affected the number of patients available for some specific analyses. The number of subjects available for analysis varied across clinics in relation to the size of the clinics, but the pairing of clinics on size before randomization assured that similar numbers of patients were available for analysis within clinic pairs.

Table 1 shows that the clinics and patients in the intervention and control groups were similar in size and in patient mix, other than a greater proportion of patients who met listed criteria for possible type 1 diabetes and more being treated with insulin at baseline in the intervention group. Race and ethnicity were not significantly different in intervention versus control clinics; these factors were excluded from the analyses shown because of the low proportion of patients in minority groups. Subsequent analyses were adjusted for age, sex, duration of diabetes, and educational level because these may be related to both process and intermediate outcomes of care. We conducted additional analyses for A1C outcomes with adjustment for baseline use of insulin (data not shown) and the results were similar.

Implementation of intervention

Relative to staff at control clinics, staff at intervention clinics reported increased use of activities to improve the frequency of diabetes care procedures ($P = 0.04$), increased use of diabetic patient registries ($P = 0.03$), trends toward broader staff participation in diabetes QI teams ($P = 0.06$), and more use of data to assess diabetes care ($P = 0.07$). There were no differences in the use of diabetes guidelines ($P = 0.41$), use of active outreach to those

Table 1—*Characteristics of 428 patients at six intervention clinics and 326 patients at six control clinics in a randomized trial of quality improvement intervention for diabetes care*

	Intervention clinics	Control clinics	*P* value
Clinic characteristics			
Number of physician FTEs per clinic [median (range)]	12 (4–31)	10 (3–22)	—
Number of clinics with previous quality improvement experience	5	5	—
Number of patients evaluated	428	326	—
Patient characteristics (from patient survey data)			
Mean age (years)	57.6	58.0	0.70
Male (%)	53.7	54.9	0.75
High school education or more (%)	81.7	82.2	0.87
Non-Hispanic white (%)	96.2	97.2	0.46
Mean duration of diagnosed diabetes (years)	8.9	7.9	0.15
Diabetes patients using insulin (%)	43.7	31.1	0.0007
Mean BMI (kg/m^2)	30.0	30.5	0.36
Age at diagnosis <30 years and currently using insulin (%)	13.0	7.4	0.02
Current smokers (%)	11.9	15.6	0.16
Self-reported health status† (mean)	3.0	3.0	0.75
Self-reported health good or better (%)	71.8	71.3	0.88

†1 = excellent, 5 = poor. FTE, full-time equivalent position.

who need care ($P = 0.13$), use of data-driven plans to improve diabetic patient services ($P = 0.11$), or support for staff efforts to improve diabetes services ($P = 0.72$). Review of videotapes of all intervention sessions indicated that the five clinics that stayed in the intervention group completed at least step 6, and most reached the final step 7 of the QI process.

Changes in process and intermediate outcomes of diabetes care

Table 2 shows that processes of diabetes care improved significantly in the intervention clinics for the composite dependent variables of annual measurement of A1C, LDL, and systolic blood pressure ($P = 0.02$) but were not superior to changes in control clinics for other measures of processes of diabetes care. The same pattern of results was obtained in unadjusted analytic models (data not shown). Several diabetes care processes improved in all study clinics.

At both intervention and control clinics, LDL concentrations improved significantly over time across all clinics ($P < 0.0001$), but no clinically or statistically significant improvements in A1C concentrations or blood pressure levels over time were noted (Table 2). Intervention clinics set a goal of 10% improvement in A1C concentrations. Nevertheless, the QI intervention had no significant impact on the magnitude of change in concentrations of A1C ($P = 0.54$), LDL ($P = 0.46$), or blood pressure ($P = 0.69$) levels or in the composite measure of these three variables ($P = 0.35$).

CONCLUSIONS — The QI intervention significantly changed the approach these clinics took to diabetes care improvement and significantly improved one of two composite measures of the diabetes care process. However, the intervention did not improve other measures of process or intermediate outcomes of care. Although positive impact on quality of care was limited, these data are among the first from a randomized trial to demonstrate any clear benefit to diabetes care from using a QI intervention (22,23). The intervention was well received by clinic staff, and all participating clinics reached at least step 6 of the 7-step QI process. Staff surveys showed significant increase in use of patient registries ($P = 0.03$) and broader involvement of clinic staff at intervention clinics in diabetes care activities ($P = 0.04$).

Despite some encouraging findings, the bulk of the process measures and all the intermediate outcome measures indicate that this intervention did not achieve many desired improvements in diabetes care after 18 months of training and support from a skilled intervention team. We therefore conclude that this QI model, applied at the clinic level without financial incentives, may not be a sufficiently powerful intervention to achieve needed improvements in diabetes care.

The results of this trial provide a number of important insights that may improve the effectiveness of future QI interventions. Traditional QI is fundamentally a process-change model. However, there were no significant differences between intervention and control clinics in use of some key processes, including use of clinical guidelines, visit planning, clinical decision support, and patient-reported active outreach. Future interventions may need to be more proscriptive about implementation of improvement tools that have frequently been associated with improved care (24,30). For example, recent data suggest that clinical inertia, defined as failure to intensify therapy for A1C, blood pressure, or LDL when a patient is not at goal, occurs at well over 60% of office visits with diabetic patients. It is very difficult to improve levels of A1C, blood pressure, or LDL control without reducing physician clinical inertia, and the intervention clinics as a group did not emphasize this aspect of care (24–28). Furthermore, substantial data, including one meta-analysis, suggest that strong patient activation components increase the likelihood that QI interventions will lead to improved diabetes outcomes (25). A weakness of the intervention we deployed was that it focused more on clinic staff activation than on patient activation. Additonal emphasis on steps 6 and 7 may be needed.

The importance of external accountability, external incentives, and sophisticated information systems to sustain care improvement in medical groups has been recently emphasized (3,29). Our QI intervention strategy introduced substantial external accountability by providing active participation in periodic meetings with other clinics and by requiring preparation for clinic site visits from research team members. Although the intervention strategy we tested encouraged the use of patient registries and other care management systems, no monetary resources were provided to clinics to update or improve

Table 2—*Measures of change in processes and intermediate outcomes of diabetes care between baseline and follow-up in 428 patients at six intervention clinics and 326 patients at six control clinics*

	Baseline (%)	Follow-up (%)	ICC	Time × condition *P* value†	Change over time *P* value‡
Process measures					
Annual A1C test					
I	70	71	0.052	0.41	0.29
C	77	69			
Annual LDL measurement					
I	31	45	0.023	0.09	0.07
C	43	43			
Annual blood pressure measurement					
I	90	79	0.023	0.54	0.002
C	91	77			
Annual A1C, LDL, and blood pressure measurements					
I	26	43	0.003	0.02	0.002
C	38	41			
Annual kidney function test					
I	22	40	0.019	0.23	0.005
C	16	22			
Annual dilated eye examination					
I	35	33	0.088	0.44	0.47
C	39	32			
Annual foot examination					
I	57	57	0.013	0.51	0.57
C	58	54			
Annual kidney function, dilated eye, and foot examinations					
I	9	16	0.023	0.11	0.37
C	10	10			
Annual flu shot					
I	33	33	0.046	0.98	0.084
C	28	28			
Aspirin use ≥3 times/week					
I	24	30	0.000	0.55	0.002
C	21	28			
Weekly self-check of feet					
I	67	71	0.000	0.75	0.04
C	60	65			
Self-monitoring of blood glucose 2–3 times/week					
I	64	68	0.005	0.20	0.01
C	56	66			
Diabetes education from an allied professional					
I	17	26	0.051	0.10	0.42
C	18	14			
Diabetes education from a physician					
I	73	64	0.002	0.75	0.002
C	76	65			
Intermediate outcome measures					
Mean A1C value (%)					
I	8.1	8.0	0.027	0.54	0.21
C	8.0	7.8			

Continued on following page

information systems, and financial incentives were not part of the intervention.

Other areas to explore are the degree and type of staff training, technical assistance, and support needed for clinic teams to implement and sustain changes in office systems that support diabetes care within existing primary care systems. The configuration of infrastructure and

Table 2—Continued

	Baseline (%)	Follow-up (%)	ICC	Time × condition *P* value†	Change over time *P* value‡
Mean LDL cholesterol value (mg/dl)					
I	133	117	0.000	0.46	0.0001
C	130	109			
Mean systolic blood pressure (mmHg)					
I	136	135	0.009	0.69	0.21
C	137	136			
Proportion of diabetic patients who simultaneously have A1C <8%, LDL <130 mg/dl, and systolic blood pressure <135 mmHg (%)					
I	36	43	0.016	0.35	0.008
C	32	46			

*Analysis is a hierarchical mixed-model analysis for a nested cohort design. Patients nested in clinics are nested within condition. Values are adjusted for age, sex, and education. Other analyses (data not shown) also controlled for baseline insulin use, with similar results. †Change over time; ‡differences between groups. C, control; I, intervention; ICC, intraclass correlation coefficient.

incentives that need to be in place to start and sustain system changes in such settings remains uncertain. This intervention focused on clinic leaders as the principal vector for change, but some reports suggest that change strategies driven by medical group leaders may be more effective than those driven by clinic leaders (6,28,29).

Some may argue that insufficient time elapsed between the completion of training and the measure of A1C concentrations. However, it is unlikely that insufficient follow-up time could account for lack of response in process measures or in blood pressure or lipid concentrations, which respond more rapidly to medication changes (27).

As this trial was being conducted, QI strategies were evolving to a model with less planning time, extensive use of multiple small tests of change, and implementation of changes in steps rather than change only after an entire new approach is developed (8,30). This newer strategy has been used extensively in the breakthrough series of collaborative improvement efforts led by the Institute for Healthcare Improvement but has not yet been fully assessed (8,15,31).

The potential population impact of the QI intervention model we evaluated can be assessed using the RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) framework articulated by Glasgow (31). Reach of the intervention was low, with only 12 of ~100 eligible clinics agreeing to participate in the project. Although some selection bias was undoubtedly operating, clinics that were recruited seemed relatively typical of the overall sampling frame of primary care clinics in east central Minnesota, as the data in Table 1 suggests. Efficacy of the intervention was limited to selected process of care measures. Adoption of specific strategies for improved care (QI steps 1–5) was generally a strong point of the intervention, but implementation of specific strategies to reduce clinical inertia and increase patient activation received limited sustained attention across intervention clinics, in part because so much energy was devoted to other diabetes-related improvement activities, such as previsit chart preparation or manually updating diabetes registries. Maintenance of changes in processes of care that were adopted persisted for up to 18 months in some intervention clinics but was problematic in several intervention clinics due to turnover of key clinic staff or by competing clinical demands.

We sought to enroll "average" primary care clinics but were able to recruit <15% of primary care clinics within our sampling frame. The QI intervention required three key staff members from each clinic to participate in eight 3-h off-site meetings, each followed by a local clinic meeting and other improvement efforts. Many nonparticipating clinics reported that they were too busy with other quality initiatives or too overwhelmed by the daily clinical and economic realities of practice to participate. Even in participating clinics, time and resource sometimes slowed adoption, implementation, and maintenance. For example, one clinic implemented the intervention in only one department and not clinic wide. Intervention strategies that place less training and implementation burden on clinics may improve the reach of such intervention strategies in the primary care community.

A positive aspect of this study was the successful collaboration between a private health plan and a state department of health, which provides a model for other geographic areas and other clinical domains. Health plans, driven by public accountability and desire to control costs, are increasingly interested in improvement of health in the general population and in specific high-risk subgroups of members, such as those with diabetes. Health plans bring a defined population and coordinated delivery system to the table, and public health experts bring experience in population health appraisal and improvement (32). Although the direct impact of our intervention was modest, other dimensions of this collaboration between a health plan and a state health department appear to have contributed to clinically and statistically significant improvements in diabetes care in many regional medical groups, using a wide range of improvement strategies (32–34).

Despite its mixed results, this study is the first rigorously designed randomized trial to provide evidence that a QI-based intervention delivered to primary care clinics may improve the process of diabe-

tes care. Overall results suggest that this intervention was powerful enough to achieve significant changes in some important processes of diabetes care but that these process changes did not translate to population-wide improvements in diabetes care outcomes within the time frame of our evaluation. Our findings suggest that use of a more directive QI approach that emphasizes adoption, systematic implementation, and sustained use of well-defined and proven strategies to improve office systems; that activates patients directly; and that addresses necessary changes in physician behavior may yield more positive results.

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