Improving Diabetes Care in Practice

Findings from the TRANSLATE trial

KEVIN A. PETERSON, MD, MPH[1]
DAVID M. RADOSEVICH, PHD[1]
PATRICK J. O'CONNOR, MD, MPH[2]
JOHN A. NYMAN, PHD[1]
RONALD J. PRINEAS, MD, PHD[3]
STEVEN A. SMITH, MD[4]
THOMAS J. ARNESON, MD, MPH[5]
VICTOR A. CORBETT, MD[6]
JOYCE C. WEINHANDL, RD, CDE[1]
CAROL J. LANGE, RD, MPH[7]
PETER J. HANNAN, MSTAT[1]

OBJECTIVE — The purpose of this study was to determine whether implementation of a multicomponent organizational intervention can produce significant change in diabetes care and outcomes in community primary care practices.

RESEARCH DESIGN AND METHODS — This was a group-randomized, controlled clinical trial evaluating the practical effectiveness of a multicomponent intervention (TRANSLATE) in 24 practices. The intervention included implementation of an electronic diabetes registry, visit reminders, and patient-specific physician alerts. A site coordinator facilitated previsit planning and a monthly review of performance with a local physician champion. The principle outcomes were the percentage of patients achieving target values for the composite of systolic blood pressure (SBP) <130 mmHg, LDL cholesterol <100 mg/dl, and A1C <7.0% at baseline and 12 months. Six process measures were also followed.

RESULTS — Over 24 months, 69,965 visits from 8,405 adult patients with type 2 diabetes were recorded from 238 health care providers in 24 practices from 17 health systems. Diabetes process measures increased significantly more in intervention than in control practices, giving net increases as follows: foot examinations 35.0% ($P < 0.0.001$); annual eye examinations 25.9% ($P < 0.001$); renal testing 28.5% ($P < 0.001$); A1C testing 8.1%($P < 0.001$); blood pressure monitoring 3.5% ($P = 0.05$); and LDL testing 8.6% ($P < 0.001$). Mean A1C adjusted for age, sex, and comorbidity decreased significantly in intervention practices ($P < 0.02$). At 12 months, intervention practices had significantly greater improvement in achieving recommended clinical values for SBP, A1C, and LDL than control clinics ($P = 0.002$).

CONCLUSIONS — Introduction of a multicomponent organizational intervention in the primary care setting significantly increases the percentage of type 2 diabetic patients achieving recommended clinical outcomes.

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Although the achievement of evidence-based clinical goals significantly reduces the risk of morbidity and mortality in type 2 diabetes, the delivery of care in community practices and referral centers often falls short of these goals (1–4). Although the need to improve diabetes services in the U.S. is well documented, few clinical interventions have been shown to effectively improve patient outcomes in diverse primary care settings (5). Because >80% of adults with diabetes receive their care from primary care physicians, the community primary care practice is a logical focal point for implementing strategies that improve care delivery. Practical intervention strategies are needed to ensure that the latest and most effective scientific recommendations for diabetes care are rapidly translated to the community (6,7).

Problems with the organization and delivery of health care services contribute to the nation's inability to reach current evidence-based goals for optimal chronic disease control (8,9). Among large medical groups, fewer than half have implemented improvement tools such as diabetes registries, tracking systems, case managers, feedback to physicians, or clinical guidelines with reminders, whereas other systems lack the technology necessary to sustain quality improvement efforts (5,10–12). Many diabetes intervention studies are limited by inadequate sample size, nonrandomized patients and clinics, lack of control subjects, or limited scope of implementation within a single medical group or health system (11,13,14). Although some trials of quality improvement strategies have demonstrated small improvements in the process of care delivery, demonstrating improvement in control of A1C, LDL, and systolic blood pressure (SBP) has been more challenging (15–18). The paucity of effective interventions improving diabetes care in primary care settings led us to design a "practical clinical trial" to test whether implementation of an organizational intervention could improve both diabetes care processes and clinical outcomes in primary care (19).

RESEARCH DESIGN AND METHODS

— TRANSLATE was a group-randomized, controlled clinical trial conducted in 24 community primary care practices. The practice was the unit of assignment, and each was randomly allocated to either intervention or control (20,21). The intervention was designed as a practical tool from the perspective of the health care system and was implemented at the organizational level of the practice.

Practice selection and setting

Practices were recruited through the Minnesota Academy of Family Physicians Research Network, a primary care practice–based research network, and mail solicitation using addresses from the state medical society. Practices were eligible if

From the [1]University of Minnesota, Minneapolis, Minnesota; the [2]HealthPartners Research Foundation, Minneapolis, Minnesota; [3]Wake Forest University, Winston-Salem, North Carolina; the [4]Mayo Clinic, Rochester, Minnesota; [5]Stratis Health, Bloomington, Minnesota; [6]Allina Medical Systems, St. Paul, Minnesota; and the [7]East Metro Disease Initiative, St. Paul, Minnesota.
Corresponding author: Kevin A. Peterson, peter223@umn.edu.
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they met the following criteria: *1*) single-specialty community primary care (family medicine or general internal medicine) to reduce variation in the clinic population, *2*) availability of 24 months of billing data, *3*) 3–22 full-time equivalent providers, *4*) access to a computer with Internet capability to facilitate the electronic registry, *5*) willingness to join a regional quality improvement organization to provide data abstraction support, and *6*) location within 200 miles to limit travel costs. Practices that targeted racial or ethnic minorities were preferred because they increased diversity in the cohort. Practices were excluded for the following: *1*) existing electronic medical records, *2*) an existing electronic diabetes registry, or *3*) participation in a diabetes-specific quality improvement program within the past 2 years.

Approximately 104 primary care clinics were contacted, of which 36 volunteered. After a telephone screen, 30 practices met the eligibility criteria. The 24 practices with the greatest racial and ethnic diversity and staff interest in the study were selected.

Population

Each practice submitted billing records for all patients seen in the previous 24 months with one or more ICD-9-CM codes for diabetes (250.xx, 357.2, 362.0x, 366.41, or 648.0). All patients with type 1 or indeterminate classifications were adjudicated by an endocrinologist blinded to practice identification to reduce classification error. All type 2 diabetic patients aged 18–89 years on the clinic start date were included in the study cohort. Patients were excluded if they were *1*) documented as not receiving diabetes care at the practice (referred care), *2*) deceased, *3*) no longer in the practice (documented transfer or no contact for ≥24 months), or 4) permanently residing in a long-term care facility. Individuals receiving some diabetes care at the practice (comanaged) were included.

Randomization

Practices were randomized in blocks of four using six sets of opaque envelopes to ensure that equal numbers of control and intervention clinics were abstracted simultaneously. Envelopes were prepared by the statistician, assigned in order of postmark, and opened under observation.

Table 1—*Essential components of the intervention*

Intervention component	Description
Target high risk	Identify and begin with patients at highest risk.
Registry	Create a registry for data collection, reporting, and support.
Administration	Set up administration to oversees changes in roles and responsibilities and enhance continuity during staff turnover.
Notify and remind	Notify patients of targets and appointments. Remind providers at time of visit with patient-specific alerts.
Site coordinator	Identify a site coordinator to facilitate the clinic operations.
Local physician champion	Identify a lead provider to work with the site coordinator and facilitate the intervention with colleagues.
Audit and feedback	Audit and review monthly. Provide feedback to improve progress.
Track	Track process measures, outcomes, and operational activity.
Education	Educate and update all staff in diabetes management techniques.

Data collection

Medical records from all eligible patients were abstracted by trained reviewers concurrently in control and intervention practices from June 2003 to June 2004. Ten percent of records were randomly selected and reabstracted. Differences were reviewed to ensure uniform interpretation of the record and corrected. Abstraction averaged 3 weeks per clinic but varied because of chart organization, legibility, and medical records staffing. Study measures were abstracted in an identical fashion from all clinics exactly 12 months later.

Intervention

The intervention affected several domains in the Chronic Care Model (22). Specifically, practice redesign was supported by a clinical information system providing patient-specific clinical decision support and promoting proactive engagement of patients. Specific components were directed to the patient, the physician, and the clinic staff (9).

In intervention practices, senior administration personnel identified a site coordinator and local physician champion (LPC). A small sticker was affixed to medical records of patients with diabetes to assist identification. An electronic diabetes registry was placed on a new or existing computer, and the site coordinator was trained in its use. Although laboratory values were initially updated manually, electronic interfaces were rapidly introduced. The site coordinator facilitated previsit planning and printed patient-specific physician reminders before every visit by a diabetes patient. Reminders for unscheduled appointments were printed by the medical assistant when the patient was roomed. Reminders graphed A1C, SBP, and LDL values versus time and indicated whether the patient had achieved targets. An "alert" identified all incomplete or overdue tests. Foot examinations, blood pressure, and eye examinations were recorded on the reminder by clinic staff, collected after the patient visit, and entered manually. The site coordinator notified patients of scheduled visits and contacted high-risk patients with elevated A1C or SBP. The site coordinator used the registry to provide a monthly summary describing operational activity and tracking clinical measures. Reports were reviewed monthly at a 1-hour staff meeting chaired by the LPC. The LPC also coordinated two diabetes educational updates for staff. Essential elements of the intervention are summarized in Table 1.

Control practices were provided with a report of their process and outcome measures at baseline and were encouraged to continue usual quality improvement. All practices were instructed to target the same values.

Principal outcomes

The study evaluated the percentage of eligible patients achieving recommended values for SBP, A1C, and LDL. For targets to be achieved, the last recorded value had to be current and controlled on the designated abstraction date with SBP <130 mmHg, A1C <7.0%, and LDL cholesterol <100 mg/dl. Six diabetes-specific processes were measured for the 12-month period before the start date (baseline) and again 12 months later for the intervention period using National Committee on Quality Assurance criteria (23).

Staffs at all practices were instructed in American Heart Association blood

pressure measurement techniques to reduce granularity of SBP. All A1C measures were determined by National Glycohemoglobulin Standardization Program standardized laboratories. Microalbumin measures included timed microalbumin, the microalbumin-to-creatinine ratio, or dipstick microalbumin. Foot examinations and eye examinations were recorded as present only if both examination and finding were documented. LDL was measured using the calculations of Freidewald on fasting blood samples with triglycerides <400 mg/dl.

Analysis

Mixed models were used to account for clustering of patients nested within providers and within practices, and correlation of outcomes was replicated within patients over time using SAS statistical software (version 9.1; SAS Institute, Cary, NC) (24). For continuous outcomes we used the general linear mixed model procedure (proc MIXED). For categorical and count outcomes we used the generalized linear mixed model (GLMM) as implemented in the recently released GLIMMIX procedure (25). This SAS procedure accommodates correlated outcomes distributed as a member of the natural exponential family, which includes the binomial and Poisson distributions as well as the normal distribution.

Initial unadjusted GLMMs were used for the quality of care measures and the secondary outcomes with use of the binomial link function. All remaining models were adjusted for patient variation, including age, sex, and the Charlson Comorbidity Index (CCI). The CCI was used to measure coexistent diseases and reflect the severity of diabetes seen in the clinic (26,27). For the composite outcomes count measure we used GLMM with the Poisson distribution.

Making allowances for missing data, patient attrition, patient mortality, and clinic withdrawal from the study, we determined that 24 clinics with 250 patients each would provide a detectable difference in the composite measure (type I error = 0.05 and type II error = 0.80) using the general rule $\Delta/\mathrm{SEM}(\Delta) \geq t_{\mathrm{df},\,1-\alpha/2} + t_{\mathrm{df,\,power}}$. With d.f. = 22, $t_{\mathrm{d.f.},\,1-\alpha/2} = 2.07$, and $t_{\mathrm{d.f.,\,power}} = 0.86$ and using $\mathrm{SEM}(\Delta) = 0.030$, then $\Delta = 0.030 \times 2.93 = 0.088$. The SDs of the composite measure in the population calculated with baseline data were used to interpret 0.088 of the detectable difference with an estimated intraclass correlation of about 0.3. The study, therefore, had 80% power to detect a net difference of 0.088 in the composite score.

Table 2—*Baseline characteristics of type 2 diabetic patients*

	Control clinics	Intervention clinics	*P* value
n	3,131	3,970	
Age (years)	63.2 ± 0.92	62.4 ± 0.91	0.540
Female sex (%)	50.5	49.0	0.531
No. of physician visits	4.85 ± 0.28	4.41 ± 0.28	0.285
No. of diabetes complications	0.23 ± 0.03	0.26 ± 0.02	0.463
Nephropathy (%)	6.1	5.4	0.665
Neuropathy (%)	11.4	11.9	0.765
Retinopathy (%)	5.8	8.9	0.020*
Myocardial infarction (%)	16.1	18.9	0.189
Congestive heart failure (%)	4.2	3.4	0.352
Peripheral vascular disease (%)	4.3	4.3	0.986
Cerebrovascular disease (%)	5.3	6.5	0.106
Average A1C (%)	7.33	7.25	0.411
Average SBP (mmHg)	133.2	132.3	0.448
Average LDL (mg/dl)	103.6	104.1	0.709
Hypertension (SBP > 130 mmHg) (%)	68.6	70.4	0.526
Hyperlipidemia (LDL > 100 mg/dl) (%)	60.4	61.9	0.758
Charlson Comorbidity Index	1.70 ± 0.05	1.77 ± 0.04	0.283

Data are means ± SEM unless indicated otherwise. *$P < 0.05$.

Human subject protection

The East Metro Diabetes Initiative, a regional quality-improvement organization, installed registry software at all clinics, assisted with data abstraction, and de-identified all data released to researchers. The study protocol was reviewed, approved in advance, and monitored by the University of Minnesota Institutional Review Board.

RESULTS — Of 13,531 patients identified as having type 2 diabetes from billing codes, 343 were adjudicated not to have type 2 diabetes. An additional 4,783 did not meet the eligibility criteria. From 8,405 eligible patients, 1,304 died, transferred care to another practice, or were admitted permanently to a long-term care facility during the study period and were excluded from analysis (688 control and 618 intervention). The eligible cohort therefore included 7,101 patients (3,131 control and 3,970 intervention).

During the 12-month intervention, 214 cohort patients made no visit to their practice (average 2.9% per clinic, range 0–7%). After the intervention period, all practices were asked to determine the status of these patients and have them return for an A1C evaluation. From this group, 151 (71%) returned for evaluation (101 control and 50 intervention). Their average A1C values were not significantly different: 7.16% and 7.63% for control and intervention practices, respectively.

Eligible patients made 69,965 provider visits over 24 months. The 24 enrolled clinics included 238 providers actively managing or comanaging an average of 62 type 2 patients per full-time equivalent (FTE) provider (note that this number excludes referred patients). On average, each practice actively managed 296 (range 113–595) type 2 diabetic patients. The median size of the practices was 5.9 (range 2–14) FTE providers.

Table 2 summarizes baseline characteristics. No statistically significant differences existed between intervention and control practices in patient demographics, total number of diabetes complications, or relevant clinical measures.

Table 3 summarizes process measures from baseline and intervention periods, the change, and the net difference between groups. At 12 months, intervention practices had made significantly greater net improvement in all process measures than control practices.

Both intervention and control practices showed statistically significant declines in mean SBP for the total diabetes population adjusted for age, sex, and CCI, dropping −1.50 ± 0.368 mmHg ($P < 0.002$) in control practices and −1.26 ± 0.321 mmHg ($P < 0.002$) in intervention

Table 3—*Percentage of patients meeting diabetes performance measures at baseline and after intervention, with change, net difference, and statistical significance of the net difference in performance between control and IMPACT clinics*

	Baseline	Intervention period	Change	Net difference (I2 − I1) − (C2 − C1)	*P* value*
Blood pressure monitoring					
IMPACT clinics	95.1 ± 0.8	96.4 ± 0.6	1.3 ± 0.9	3.5 ± 1.7	0.050
Control clinics	94.3 ± 1.1	92.2 ± 1.2	−2.1 ± 1.4		
Renal testing					
IMPACT clinics	40.9 ± 4.4	64.1 ± 4.2	23.2 ± 5.0	28.5 ± 7.0	<0.001
Control clinics	37.1 ± 4.3	31.8 ± 4.0	−5.3 ± 4.6		
Annual eye examination					
IMPACT clinics	35.5 ± 3.0	62.5 ± 3.1	27.0 ± 2.9	25.9 ± 4.2	<0.001
Control clinics	24.8 ± 2.5	26.0 ± 2.6	1.2 ± 2.3		
Foot examination					
IMPACT clinics	39.4 ± 4.2	68.8 ± 3.8	29.4 ± 5.6	35.0 ± 5.6	<0.001
Control clinics	39.1 ± 4.2	33.5 ± 3.9	−5.6 ± 5.4		
A1C testing					
IMPACT clinics	88.2 ± 1.5	90.1 ± 1.1	2.8 ± 0.9	8.1 ± 1.5	<0.001
Control clinics	87.5 ± 1.5	82.3 ± 1.9	−5.3 ± 1.2		
LDL cholesterol testing					
IMPACT clinics	69.6 ± 3.0	78.0 ± 2.4	8.9 ± 1.3	8.6 ± 1.9	<0.001
Control clinics	64.3 ± 3.2	64.6 ± 3.2	0.3 ± 1.6		

Data are means ± SEM. *P value based on d.f. = 22. C1, control practices at baseline; C2, control practices at 12 months; I1, intervention practices at baseline; I2, intervention practices at 12 months.

practices. Intervention practices significantly lowered the proportion of patients with SBP ≥140 mmHg (−4.3 ± 1.2%, $P < 0.002$), although control practices did not (−1.2 ± 1.3%, NS). Intervention practices achieved recommended SBP values significantly more often than control practices, attaining target SBP in an average of 45.0% of patients compared with 40.6% for control practices ($P < 0.001$).

Intervention practices demonstrated significant declines in mean A1C for the cohort adjusted for age, sex, and CCI to 7.26% ($P < 0.02$). Control practices had no significant change in mean A1C (7.37%, NS). Intervention practices achieved recommended A1C values significantly more often than control practices, attaining target A1C in an average of 49.0% of patients compared with 43.8% in control practices ($P < 0.001$).

Intervention and control practices demonstrated significant decreases in mean LDL to 99.8 and 99.5 mg/dl, respectively. Intervention practices achieved recommended LDL values significantly more often than control practices, attaining target LDL in 43.0% of patients compared with 35.5% in control practices ($P < 0.001$).

Table 4 compares the overall improvement between control practices and intervention practices. Although both groups demonstrated improvement, intervention practices improved their index of performance measures significantly more than control pracatices ($P < 0.001$). More importantly, evaluation of the composite outcome demonstrated that the net improvement in the average number of recommended clinical targets (A1C, SBP, and LDL) achieved across their entire patient population by intervention practices from baseline to 12 months was significantly greater than that achieved by control practices from baseline to 12 months ($P = 0.002$). Intervention practices significantly increased simultaneous achievement of A1C, SBP, and LDL in 12.6% of patients compared with 8.5% in control practices ($P < 0.001$).

CONCLUSIONS — The TRANSLATE trial demonstrates that 12 months after the introduction of a multicomponent organizational intervention, primary care practices improve significantly more than control practices in their ability to help diabetic patients achieve recommended clinical targets. This change is associated with substantial increases in National Committee on Quality Assurance measures. The intervention provided an electronic diabetes registry that supported visit reminders, patient-specific physician alerts, proactive support of patients at risk, and a monthly progress review. This strategy was broadly effective across primary care practices from 17 different health care systems and resulted in 15

Table 4—*Age-, sex-, and Charlson Comorbidity Index-adjusted process of care index (Poisson mean) and composite outcome measure (Poisson mean) at baseline and after intervention with change, net difference, and statistical significance of the net difference in measures between intervention and control clinics*

	Baseline	Intervention period	Change	Net difference (I2 − I1) − (C2 − C1)	*P* value*
Process of Care Index†					
IMPACT clinics	3.29 ± 0.114	4.58 ± 0.110	1.29 ± 0.042	1.07 ± 0.044	<0.001
Control clinics	3.48 ± 0.114	3.70 ± 0.113	0.22 ± 0.038		
Composite outcome					
IMPACT clinics	1.22 ± 0.054	1.39 ± 0.061	0.17 ± 0.030	0.15 ± 0.030	0.002
Control clinics	1.16 ± 0.052	1.18 ± 0.053	0.02 ± 0.029		

Data are mean ± SEM number of criteria measured. *P value based on d.f. = 22. †Process of Care Index includes annual blood pressure monitoring, renal testing, eye examination, foot examination, A1C testing, and LDL cholesterol testing. C1, control practices at baseline; C2, control practices at 12 months; I1, intervention practices at baseline; I2, intervention practices at 12 months.

more targets achieved for every 100 individuals after 12 months. The scale of change was large, involving 232 providers and 7,101 patients. Previous work has demonstrated that patients who achieve these targets simultaneously can reduce their risk of cardiovascular events by up to 53% (28).

Important work flow changes in practices included *1*) identification and case management of patients not achieving goals, *2*) provider alerts with integrated decision support during visits, and *3*) monthly review by the LPC with feedback to individual providers. The establishment of an electronic registry was integral to supporting these efforts.

Although all practices significantly improved process measures, only intervention clinics significantly improved clinical outcomes. The weak association between process and outcome measures has implications for the selection of quality measures for diabetes care and confirms that process measures are more quickly and easily improved than clinical outcomes.

A detailed economic analysis is underway; however, the total cost of the intervention was small from the perspective of the health care system. Site coordinators contributed 1 h per provider FTE per month, and LPCs were reimbursed for 1 h per month. Two-thirds of practices had software added to existing computers, whereas the remaining third required one computer and a printer for implementation.

Although a significant difference in clinical outcomes was seen at 12 months, the study does not suggest how long improvement would continue or the maximal improvement expected. The study was not powered to evaluate the success of introducing individual intervention components. At the completion of the 12-month intervention period, all control clinics chose to implement the TRANSLATE intervention. To date, all 24 clinics continue to use the diabetes registry or have converted to an electronic health record with similar functionality.

Despite the use of a randomized controlled design with rigorous attention to implementation details, a number of factors limit interpretation. Practices were in a single geographic region and volunteered for the study. Effects may be different in other regions with different organizational systems or in practices unwilling or unable to change. In addition, average A1C among practices was very good at baseline (7.3%) and may have limited overall improvement. Intervention practices with the highest baseline A1Cs experienced the largest decrease.

In summary, the introduction of a multicomponent organizational intervention in community primary care practices significantly improves the percentage of type 2 diabetic patients achieving recommended values for a composite of SBP, LDL, and A1C. Additional studies are needed to examine sustainability, and it is not known whether this methodology will have similar benefits in care of other chronic diseases. This combination of components provides a proven strategy for initiating improvement in clinical diabetes care for many primary care practices.

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