

Improving Diabetes in Practice: Findings from the TRANSLATE Trial

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Objective: Determine whether implementation of a multi-component organizational intervention can produce significant change in diabetes care and outcomes in community primary care practices.

Research Design and Methods: Group-randomized controlled clinical trial evaluating the practical effectiveness of a multi-component intervention (TRANSLATE) in 24 practices. The intervention implemented an electronic diabetes registry, visit reminders, and patient-specific physician alerts. A site coordinator facilitated pre-visit planning and a monthly review of performance with a local physician champion. The principle outcomes were the percent of patients achieving target values for the composite of systolic blood pressure (SBP)<130mmHg, 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 control practices giving net increases: foot exams 35.0%(p<.0001); annual eye exams 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=.05) and LDL testing 8.6% (p< 0.001). Mean A1c adjusted for age, gender, and comorbidity decreased significantly in intervention practices (p<.02). At 12 months, intervention practices had significantly greater improvement achieving recommended clinical values for SBP, A1c, and LDL than control clinics (p= 0.002).

Conclusions: Introduction of a multi-component organizational intervention in primary care significantly increases the percentage of type 2 diabetes patients achieving recommended clinical outcomes.

Trial Registration: [Clinicaltrials.gov](https://clinicaltrials.gov). Identifier: [NCT00108927](https://clinicaltrials.gov/ct2/show/study/NCT00108927).

Although the achievement of evidence-based clinical goals significantly reduces the risk of morbidity and mortality in type 2 diabetes mellitus, 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 United States is well-documented; few clinical interventions have been shown to effectively improve patient outcomes in diverse primary care settings.(5) Since more than 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 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, while other systems lack 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 controls, 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 SBP has been more challenging.(15-18) The paucity of effective interventions to improve diabetes in primary care 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

Design—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 (MAFPRN), a primary care practice-based research network, and mail solicitation using addresses from the state medical society. Practices were eligible if they met the following criteria: 1) single-specialty community primary care (Family Medicine, General Internal Medicine) to reduce variation in clinic population, 2) availability of 24 months of billing data, 3) 3 to 22 FTE 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) located within 200 miles to limit travel costs. Practices that targeted racial or ethnic minorities were preferred to increase diversity in the cohort. Practices were excluded for: 1) existing electronic medical records, 2) existing electronic diabetes registry, or 3) participation in a diabetes specific quality improvement program within the past two years.

Approximately 104 primary care clinics were contacted from which 36 volunteered. Following a telephone screen 30 practices met 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 mellitus (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 diabetes patients age 18-89 years on the clinic start date were included in the study cohort. Patients were excluded if they were a) documented as not receiving diabetes care at the practice (referred care), b) deceased, c) no longer in the practice (documented transfer or no contact for ≥ 24 months), or d) permanently resident in a long term care facility. Individuals receiving some diabetes care at the practice (co-managed) 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.

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 re-abstracted. Differences were reviewed to ensure uniform interpretation of the record and corrected. Abstraction averaged 3 weeks per clinic, but varied due to 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 impacted 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 at the patient, the physician, and the clinic staff.⁽⁹⁾

In intervention practices, senior administration identified a site coordinator (SC) 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 SC trained in its use. Although laboratory values were initially updated manually, electronic interfaces were rapidly introduced. The SC facilitated pre-visit planning and printed patient-specific physician reminders before every visit by a diabetes patient. Reminders for unscheduled appointments were printed by rooming staff. Reminders graphed A1c, SBP, and LDL values versus time and indicated if the patient had achieved targets. An “alert” identified all incomplete or overdue tests. Foot exams, blood pressure, and eye exams were recorded on the reminder by clinic staff, collected after the patient visit, and entered manually. The SC notified patients of scheduled visits and contacted high risk patients with elevated A1c or SBP. The SC used the registry to provide a monthly summary describing operational activity and tracking clinical measures. Reports were reviewed monthly at a one-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 percent 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 prior to 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 NGSP standardized labs. Microalbumin measures included timed microalbumin, microalbumin-creatinine ratio, or dipstick microalbumin. Foot exams and eye exams were recorded as present only if both examination and finding were documented. LDL measures were done 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 replicated within patients over time using SASTM System statistical software (SAS Institute Inc. Version 9.1 Cary, North Carolina, 2006). (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 as well as the normal distribution.

Initial unadjusted GLMMs were used for the quality of care measures and the secondary outcomes with binomial link function employed. All remaining models were adjusted for patient variation including age, gender, 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 = .05 and Type II error = .80) using the general rule $\Delta/SE(\Delta) \geq t_{df,1-\alpha/2} + t_{df,power}$. With $df=22$, $t_{df,1-\alpha/2} = 2.07$ and $t_{df,power} = 0.86$, and using $SE(\Delta) = 0.030$ then $\Delta = 0.030 \times 2.93 = 0.088$ The standard deviation of the composite measure in the population using baseline data was used to interpret 0.088 of the detectable difference with an estimated ICC of about 0.3. The study therefore had 80% power of detecting a net difference of 0.088 in the composite score.

Human Subjects Protection—The East Metro Diabetes Initiative (EMDI), 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

Disposition of Study Patients—From 13,531 patients identified as having type 2 diabetes mellitus from billing codes, 343 were adjudicated not to have type 2 diabetes. An additional 4,783 did not meet 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; 618 intervention). The eligible cohort therefore included 7,101 patients (3131 control; 3970 intervention).

During the 12 month intervention, 214 cohort patients made no visit to their practice. (average 2.9% per clinic, range 0% to 7%). Following the intervention period, all practices were asked to determine the status of these patients and have them return for an A1c. From this group 151 (71%) returned for evaluation (101 control, 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 co-managing an average of 62 type 2 patients per full time equivalent (FTE) provider (NB. excludes referred patients). On average, each practice actively managed 296 (range 113 – 595) type 2 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 controls.

Both intervention and control practices showed statistically significant declines in mean SBP for the total diabetes population adjusted for age, gender, and CCI, dropping -1.50 ± 0.368 mmHg ($p < .002$) in controls and -1.26 ± 0.321 mmHg ($p < .002$) in intervention practices. Intervention practices significantly lowered the proportion of patients with SBP ≥ 140 mmHg (-4.3 ± 1.2 %, $p < .002$), although controls did not (-1.2 ± 1.3 %, $p = \text{NS}$). Intervention practices achieved recommended SBP values significantly more often than controls, attaining target SBP in an average of 45.0% of patients compared to 40.6% for controls ($p < 0.001$).

Intervention practices demonstrated significant declines in mean A1c for the cohort adjusted for age, gender, and CCI to 7.26% ($p < .02$). Controls had no significant change in mean A1c (7.37%, $p = \text{NS}$). Intervention practices achieved recommended A1c values significantly more often than controls, attaining target A1c in an average of

49.0% of patients compared to 43.8% in controls ($p < 0.001$).

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

Evaluation of all six process measures demonstrates that intervention practices recorded significantly more recommended exams than control practices (Table 4).

Evaluation of the composite for clinical targets demonstrates that at 12 months intervention practices had achieved significantly more recommended targets in patients than controls. (Table 4). Intervention practices significantly increased simultaneous achievement of A1c, SBP, and LDL to 12.6% of patients compared to 8.5% in control practices ($p < 0.001$).

DISCUSSION

The TRANSLATE trial demonstrates that 12 months after the introduction of a multi-component organizational intervention primary care practices improve significantly more than controls in their ability to help patients achieve recommended clinical targets. This change is associated with substantial increases in NCQA 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 more targets achieved for every 100 individuals after 12 months. The scale of change was large, involving 232 providers and 7101 patients. Previous work has demonstrated that patients who achieve these targets simultaneously can reduce their risk of cardiovascular events by up to 53%. (39)

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 hour per provider FTE per month, and LPCs were reimbursed for one hour per month. Two-thirds of practices had software added to existing computers, while 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. Additionally, 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.

CONCLUSIONS

The introduction of a multi-component organizational intervention in community primary care practices significantly improves the percent of type 2 diabetes patients achieving recommended values for a composite of SBP, LDL, and A1c. Additional studies are needed to examine sustainability, and it is unknown whether this methodology will similarly benefit other chronic disease care. This combination of components provides a proven strategy for initiating improvement in clinical diabetes care for many primary care practices.

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Table 1. Essential components of the intervention.

Intervention Component	Description
T arget High Risk	Identify and begin with patients at highest risk.
R egistry	Create a registry for data collection, reporting, and support.
A dministration	Administration oversees changes in roles and responsibilities. Enhances continuity during staff turnover.
N otify and Remind	Notify patients of targets and appointments. Remind providers at time of visit with patient-specific alerts.
S ite coordinator	Identify a site coordinator to facilitate the clinic operations.
L ocal physician champion	Identify a lead provider to work with the site coordinator and facilitate the intervention with colleagues.
A udit and Feedback	Audit and review monthly. Provide feedback to improve progress.
T rack	Track process measures, outcomes, and operational activity.
E ducation	Educate and update all staff in diabetes management techniques.

Table 2. Baseline characteristics of type 2 diabetes patients.

	Control Clinics (n =3131)	Intervention Clinics (n =3970)	p value
Age (years) [†]	63.2 ± 0.92	62.4 ± 0.91	0.540
Female	50.5 %	49.0 %	0.531
Number of Physician Visits [†]	4.85 ± 0.28	4.41 ± 0.28	0.285
Number 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	133.2 mmHg	132.3 mmHg	0.448
Average LDL	103.6 mg/dl	104.1 mg/dl	0.709
Hypertension (SBP>130)	68.6 %	70.4 %	0.526
Hyperlipidemia (LDL>100)	60.4 %	61.9 %	0.758
Charlson Comorbidity Index	1.70 ± 0.05	1.77 ± 0.04	0.283

[†]Value is mean ± standard error of the mean.

* p < .05

Table 3. Percentage of patients meeting diabetes mellitus performance measures at baseline and following 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 %	p = 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 %	p < 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 %	p < 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 %	p < 0.001
Control Clinics	39.1 ± 4.2 %	33.5 ± 3.9 %	-5.6 ± 5.4 %		
Hemoglobin A1c Testing					
IMPACT Clinics	88.2 ± 1.5 %	90.1 ± 1.1 %	2.8 ± 0.9 %	8.1 ± 1.5 %	p < 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 %	p < 0.001
Control Clinics	64.3 ± 3.2 %	64.6 ± 3.2 %	0.3 ± 1.6 %		

* P value based on DF = 22.

† Value is mean ± standard error of the mean.

Table 4. Age, gender, and Charlson Comorbidity Index adjusted process of care index (Poisson Mean) and composite outcome measure (Poisson Mean) at baseline and following 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					
(Number of Criteria Measured) †					
IMPACT Clinics	3.29 ± 0.114	4.58 ± 0.110	1.29 ± 0.042	1.07 ± 0.044	p < 0.001
Control Clinics	3.48 ± 0.114	3.70 ± 0.113	0.22 ± 0.038		
Composite Outcome					
(Number of Criteria Met)					
IMPACT Clinics	1.22 ± 0.054	1.39 ± 0.061	0.17 ± 0.030	0.15 ± 0.030	p = 0.002
Control Clinics	1.16 ± 0.052	1.18 ± 0.053	0.02 ± 0.029		

* P value based on DF = 22.

† Process of Care Index includes annual blood pressure monitoring, renal testing, eye examination, foot examination, A1C testing, and LDL cholesterol testing.