A Controlled Trial of Population Management

Diabetes Mellitus: Putting Evidence into Practice (DM-PEP)

Richard W. Grant, MD, MPH[1,2,3,4]
Enrico Cagliero, MD[4,5]
Christine M. Sullivan, RNC, FNP[3]
Anil K. Dubey, MD[4,6]
Greg A. Estey[6]
Eric M. Weil, MD[3,4]
Joseph Gesmundo, MD[3,4]
David M. Nathan, MD[4,5]
Daniel E. Singer, MD[1,2,4]
Henry C. Chueh, MD[4,6]
James B. Meigs, MD, MPH[1,2,4]

OBJECTIVE — Population-level strategies to organize and deliver care may improve diabetes management. We conducted a multiclinic controlled trial of population management in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — We created diabetic patient registries (n = 3,079) for four primary care clinics within a single academic health center. In the intervention clinic (n = 898), a nurse practitioner used novel clinical software (PopMan) to identify patients on a weekly basis with outlying values for visit and testing intervals and last measured levels of HbA_{1c}, LDL cholesterol, and blood pressure. For these patients, the nurse practitioner e-mailed a concise patient-specific summary of evidence-based management suggestions directly to primary care providers (PCPs). Population changes in risk factor testing, medication prescription, and risk factor levels from baseline (1 January 2000 to 31 August 2001) to follow-up (1 December 2001 to 31 July 2003) were compared with the three usual-care control clinics (n = 2,181).

RESULTS — Patients had a mean age of 65 years, were mostly white (81%), and the majority were insured by Medicare/Medicaid (62%). From baseline to follow-up, the increase in proportion of patients tested for HbA_{1c} ($P = 0.004$) and LDL cholesterol ($P < 0.001$) was greater in the intervention than control sites. Improvements in diabetes-related medication prescription and levels of HbA_{1c}, LDL cholesterol, and blood pressure in the intervention clinic were balanced by similar improvements in the control sites.

CONCLUSIONS — Population-level clinical registries combined with summarized recommendations to PCPs had a modest effect on management. The intervention was limited by good overall quality of care at baseline and temporal improvements in all control clinics. It is unknown whether this intervention would have had greater impact in clinical settings with lower overall quality. Further research into more effective methods of translating population registry information into action is required.

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From the [1]General Medicine Division, Massachusetts General Hospital, Boston, Massachusetts; the [2]Clinical Research Program, Massachusetts General Hospital, Boston, Massachusetts; the [3]Revere Health Care Center, Massachusetts General Hospital, Revere, Massachusetts; [4]Harvard Medical School, Boston, Massachusetts; the [5]Diabetes Unit, Massachusetts General Hospital, Boston, Massachusetts; and the [6]Laboratory of Computer Science, Massachusetts General Hospital, Boston, Massachusetts.

Address correspondence and reprint requests to Richard W. Grant, MD, MPH, 50-9 Staniford St., Boston, MA 02114. E-mail: rgrant@partners.org.

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Abbreviations: DM-PEP, Diabetes Mellitus: Putting Evidence into Practice; EMR, electronic medical record; PCP, primary care provider.

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

Many patients with diabetes are not optimally managed despite the availability and efficacy of interventions to control glycemia, blood pressure, and hyperlipidemia (1–8). This gap between optimal and actual care constitutes a wide "quality chasm" (9) and underscores the need for innovative approaches to change the current practice of diabetes care (10,11).

Barriers to effective care exist at the medical system, physician, and patient levels (12). All three elements of medical care, the medical system, the actions (or inactions) of physicians and other providers, and the behavior of patients (and their families and communities), play a critical role in the overall goal of achieving optimal diabetes control (13,14). It is not known which of these elements are most amenable to interventions and which interventions will have the greatest impact on clinical outcomes (15,16).

We conducted a controlled trial of population-based diabetes management entitled Diabetes Mellitus: Putting Evidence into Practice (DM-PEP). Population management represents an "overview" approach to diabetes care that uses patient registries to identify outliers within a defined population (17,18). Our intervention relied on an advanced clinical informatics platform, a clinical nurse practitioner, and weekly registry review independent of scheduled patient visits. We hypothesized that an iterative intervention by a "population manager," who would identify patients with missing or elevated results and then inform the primary care providers (PCPs) of these deficiencies, would result in significantly better overall diabetes management compared with a population of control patients receiving usual care.

We have previously reported an analysis of the first 150 patients reviewed by the population manager in DM-PEP, which demonstrated a small but statistically significant impact on physician practice (19). We report here the final clinical outcomes of the DM-PEP study

with regard to management of three diabetes-related risk factors (hyperglycemia, hyperlipidemia, and hypertension), urine microalbumin screening, and prescription of aspirin or ACE inhibitors.

RESEARCH DESIGN AND METHODS

— The populations in our study were defined as groups of patients with diagnosed diabetes who were cared for in one of four outpatient primary care medical clinics within our academic medical center. Patients and physicians at the intervention site received population management, while patients and physicians at three nearby control clinic sites affiliated with the same academic medical center continued with usual care. The intervention took place over a 20-month period (1 December 2001 to 31 July 2003) and was preceded by a baseline data collection period (1 January 2001 to 31 August 2001) and a 3-month "run-in" period during which we resolved technical problems with our registry software. For both the baseline and intervention periods, we calculated the proportion of patients in each clinic's diabetes registry with measurements for HbA_{1c}, LDL cholesterol, and blood pressure, last recorded values of each risk factor for each time period, and medication regimens at the end of each time period.

Data were collected from the hospital's central data repository (laboratory test dates and results), billing claims (hospitalizations and hospital discharge diagnoses), administrative records (patient demographics and insurance status), and directly from the electronic medical record (EMR) (problem lists, prescribed medications at the end of the intervention period, and clinic visits). In addition, we performed manual chart reviews at the intervention site and one control clinic (control clinic A) to assess changes in blood pressure and medication prescription.

Diabetes registries

We generated lists of potentially eligible patients using billing claims for nongestational diabetes (ICD-9 codes 250.00–250.90) over a 3-year period. For two clinics (the intervention clinic and control clinic A), we undertook detailed chart review using trained research nurses to create diabetes registries. Diabetes was defined based on the diagnosis listed in the problem list, diabetes-specific medicine listed in the medication list (e.g., sulfonylurea, metformin, insulin, or equipment for insulin injection or home glucose monitoring), or diabetes diagnosis discussed in a progress note. Using these registries as a "gold standard," we then developed an automated algorithm to identify patients with diabetes using billing claims, laboratory testing, and problem lists and medications from the EMR. Compared with the gold-standard chart review, the algorithm had a sensitivity of 98% and specificity of 98% for diabetes. We then used this validated algorithm to develop diabetes registries for the two additional control clinics.

Clinical sites and participants

The intervention clinical site, a community health center serving a predominantly working class community in Revere, Massachsetts, was chosen for population management because of the availability of a diabetes-trained nurse practitioner who could commit 4 hours per week to the intervention. Control sites were similarly organized primary care clinics located in the greater Boston metropolitan area. Eligible patients were diagnosed with diabetes before the intervention period, were alive at study completion, and received continuous care at their designated clinical site, with at least one visit in both the baseline and intervention time periods. All analyses were based on comparison of each clinic's diabetes patient registry.

Intervention and population management

We developed a novel clinical software application (PopMan) to rank a defined registry of patients with diabetes according to any of the following nine criteria: days since last clinic visit and either days since last measurement or the last recorded level for four diabetes-related risk factors (HbA_{1c}, systolic blood pressure, diastolic blood pressure, and LDL cholesterol) (Fig. 1). This ranking software enabled the population manager to sort the diabetes registry on a weekly basis and thereby identify the patients in the overall population with the highest or most out-of-date results at a given time.

Although individual patients were initially selected based on a single outlying result (e.g., elevated HbA_{1c}), the population manager systematically assessed all aspects of the patient's care by applying American Diabetes Association clinical practice recommendations for hyperglycemia, hypertension, and hyperlipidemia management (20). The population manager then created a brief, individualized summary of care recommendations regarding testing, referral, and medication adjustment for each patient reviewed. This summary was entered as a "population manager" note in the EMR and electronically forwarded to the patient's PCP. Some patients also received letters directly from the population manager either requesting that they make a follow-up appointment with their PCP or that they come to the clinic for laboratory testing.

Statistical methods

We examined differences between clinic cohorts in patient and provider characteristics at baseline using Student's *t* tests and χ^2 tests. We then compared changes from baseline between the intervention clinic and the three control clinics in proportion with HbA_{1c}, LDL cholesterol, and urine microalbumin testing and mean HbA_{1c} and LDL cholesterol levels. We also compared changes in medications and blood pressure management between the intervention clinic and control clinic A. We performed a longitudinal (rather than sequential cross-sectional) analysis by limiting our analysis cohorts to patients who were present in the diabetes registries during both the baseline and intervention periods. We used paired *t* tests and McNemar's tests for within-group comparisons (comparing baseline and follow-up within individual clinic cohorts) and generalized estimating equations to account for physician-clustering effects (21). Variables that were imbalanced between clinic sites were added to the generalized estimating equation models but did not significantly alter our findings.

Power calculations were based on an intraclass correlation coefficient of 0.09 to inflate sample size estimates for clustering effects, which provided for 90% power at 0.05 two-sided significance to detect a 10 vs. 3% improvement in intervention versus control populations reaching goal HbA_{1c} levels. In a "treatment received" analysis, we also compared changes among the subset of intervention patients who received an active population manager intervention to a randomly selected group of patients from the control clinics matched one for one on age, sex, and race/ethnicity. All analyses were performed using SAS (SAS version 8.0; SAS Institute,

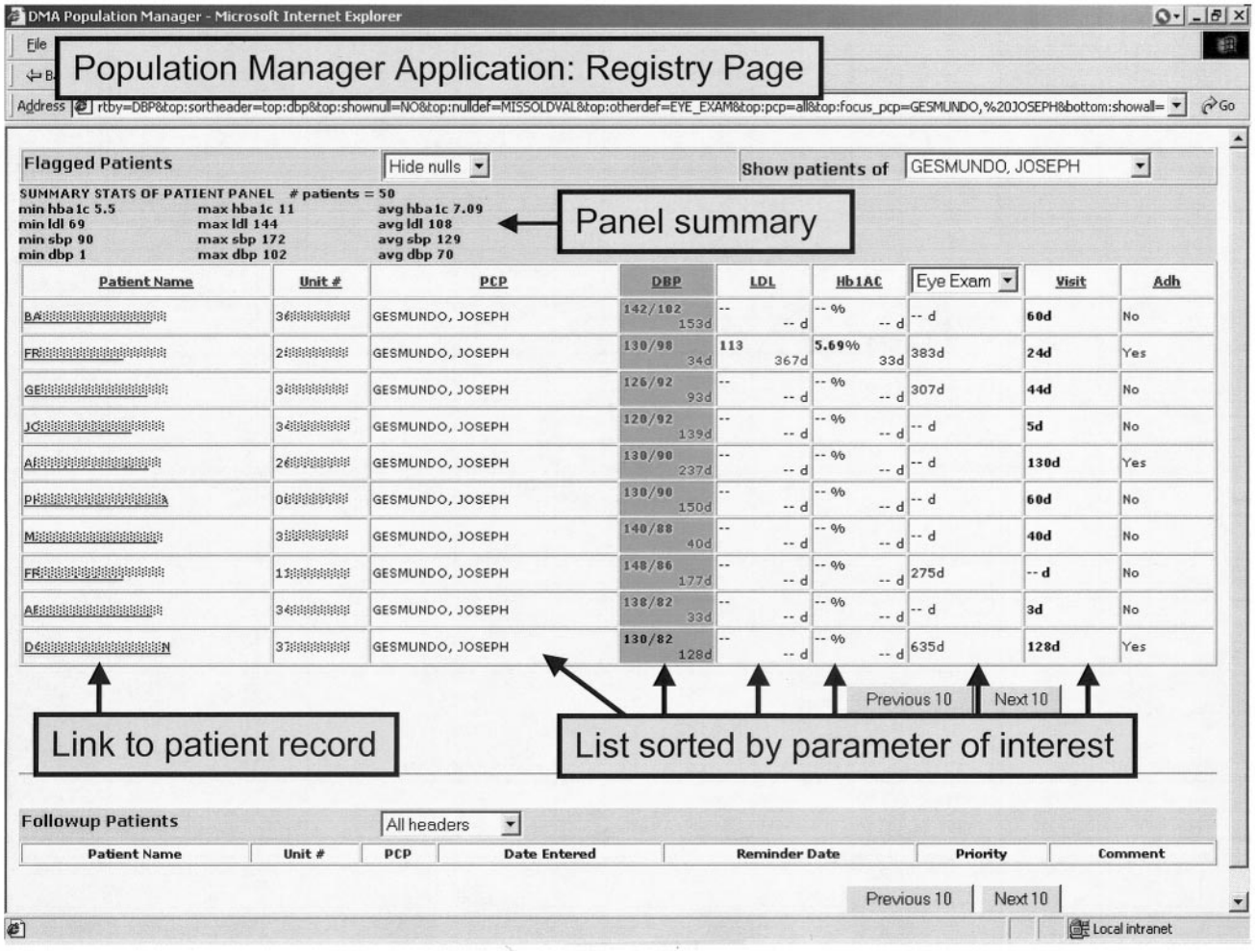

Figure 1—*PopMan software screen shot. Sorted by highest diastolic blood pressures.*

Cary, NC). *P* values <0.05 were considered statistically significant.

RESULTS — Diabetes registry characteristics for each clinic are presented in Table 1. Registries ranged in size from 352 to 1,137 patients, with the size of the intervention clinic registry ($n = 898$) similar to the overall mean size for all clinics. Patients were mostly white, with a mean age of 65 years. Nearly one-third of patients were treated with insulin. Hypertension and hyperlipidemia were highly prevalent comorbid conditions. Patients in the intervention clinic were more likely than control patients to be women, nonwhite, and insured by Medicare or Medicaid, although the absolute differences were small.

Population manager actions

Over the 20-month intervention, the population manager used the PopMan application to review 625 patients 857 times (including patients newly identified during the intervention period who were not counted in the analysis cohort). Among the subset of patients present in both the baseline and follow-up registries (analysis cohort, $n = 898$), PopMan reviewed 446 patients (54%) 542 times (1.2 reviews per patient). Commonly identified problems included lack of recent risk-factor testing, elevated test results, and lack of aspirin prescription (Table 2). Co-occurrence of problems was common: 94 patients (21%) had all three risk factors elevated and 71 (16%) were missing recent results for all three risk factors.

From this group of screened patients, the population manager delivered 414 active interventions to 343 patients (41% of registry). These interventions included detailed clinical summaries, with clinical suggestions sent directly to PCPs ($n = 297$, 72%), letters and laboratory testing requisitions mailed to 108 patients ($n = 108$, 26%), or both PCP e-mails and patient letters ($n = 9$, 2%). Interventions were not delivered for the remaining patients identified by the population manager either because of an upcoming or recent PCP appointment or significant medical or social comorbidity.

Comparison of intervention and control populations

During the baseline period, risk-factor testing rates were high and risk-factor levels were fairly well controlled. Testing rates and metabolic control improved at both the intervention and control clinics during the intervention period (Table 3). The intervention had a statistically significant impact in several important domains of diabetes care but not in others. Specifically, when compared with changes from baseline in the control clinics, the intervention population had

Table 1—*Baseline clinic and patient characteristics*

	Intervention clinic	Control clinics			
		A	B	C	Total	*P**
Clinic characteristics						
MD providers	21	49	12	18	79	—
MD FTEs	10.9	22	7.9	14.5	44.4	—
Total patients	11,404	28,451	6,106	18,494	53,051	—
Diabetic patients	1,133	2,923	500	1,200	4,623	—
Diabetic population (% of total patient population)	9.9	8.5	8.2	6.5	8.7	—
Patient characteristics, analysis cohorts						
n	898	1137	352	692	2181	
Women (%)	52.3	47.0	54.3	44.4	47.3	0.01
Age (years)	65.1 ± 12.9	65.3 ± 12.8	64.9 ± 13.9	65.9 ± 12.3	65.4 ± 12.8	0.5
Nonwhite (%)	15.9	26.0	9.8	16.1	20.3	0.01
Medicare/Medicaid (%)	68.0	61.2	67.9	52.6	59.6	<0.01
Diagnosed CAD (%)	28.8	33.0	27.8	32.4	32.0	0.09
Charlson score (ref. 36)	2.8 ± 1.6	2.6 ± 1.8	2.5 ± 1.7	3.0 ± 1.8	2.7 ± 1.8	0.11

Data are means ± SD, unless noted otherwise. **P* value compares results for the intervention clinic with totals for control clinics by *t* test or χ^2 test. CAD, coronary artery disease listed in medical record problem list; FTE, full-time equivalent (eight half-day clinic sessions per week).

greater increases in proportion of patients with HbA_{1c} and LDL cholesterol testing and a small but statistically significant decline in diastolic blood pressure. In addition, a greater overall proportion of intervention patients received urine microalbumin screening.

Detailed medication information was obtained from the intervention clinic and control clinic A (Table 3). From the end of the baseline to the end of the intervention period, the proportion of patients prescribed ACE inhibitors or angiotensin receptor blockers, statins, aspirin, insulin, and any antihypertensive medicines all increased. However, there were no significant differences comparing intervention and control populations.

Risk factor levels (HbA_{1c}, LDL cholesterol, and blood pressure) improved for all clinic cohorts from the baseline to follow-up periods, with only diastolic blood pressure significantly more improved in the intervention population (15.2 vs. 5.7%, reaching goal of <80 mmHg, $P < 0.001$) compared with the control population. Among patients tested in both time periods (regardless of intervention or control status), HbA_{1c} decreased by 0.2% (from 7.7 to 7.5%, $P < 0.001$, $n = 2,850$) and LDL cholesterol by 11 mg/dl (from 104 to 93 mg/dl, $P < 0.001$, $n = 2,103$) over the course of the study.

We repeated all of the above analyses in the subset of intervention patients who received active population manager interventions (PCP e-mail or patient letter) matched one for one by age, sex, and race/ethnicity to a randomly selected group of control patients. Results of this "on treatment" analysis did not qualitatively differ from the overall cohort analysis.

CONCLUSIONS — The results of this controlled trial of population management lead to the following conclusions. *1*) The population level "information triage" of a large registry of diabetic patients using an innovative clinical informatics application can effectively identify a dynamic group of patients with outlying testing dates and results over time. *2*) The translation of this information into action through the mechanism

Table 2—*Population management: problems identified and actions taken (542 reviews of 446 patients)*

	Risk-factor management			
Problems identified	Hyperglycemia	Hypertension	Hyperlipidemia	Total
Missing test results	107	134	240	481
Elevated levels	302	291	206	799
Inadequate treatment	60	32	54	146
Indicated chemoprophylaxis				
Missing aspirin				81
Missing ACE inhibitor/ARB				27
Patient loss to follow-up				12
Actions taken				
PCP e-mail with recommendations				297
Letter to patients				108
Both				9
None				128

Test results and elevated levels include HbA_{1c} (for hyperglycemia), blood pressure (for hypertension), and LDL cholesterol for hyperlipidemia. Chemoprophylaxis section indicates chemoprophylaxis with aspirin for patients with diagnosed coronary artery disease and with angiotensin-blocking agents if microalbuminuria was present. Loss to follow-up indicates no clinical encounter in the preceding 1 year. ARB, angiotensin receptor blocker.

Table 3—*Changes in testing, risk-factor levels, and medication prescriptions from baseline through the intervention period*

	Intervention clinic	Control clinics				*P*
		A	B	C	Total	
n	898	1,137	352	692	2,542	
Testing						
HbA_{1c}						
Tested at baseline	95.1	97.0	98.9	94.1	96.4	—
Change	1.4	−0.3	−3.2	−2.2	−1.4	0.004
LDL cholesterol						
Tested at baseline	69.9	83.3	73.0	87.1	82.9	—
Change	14.7	5.7	5.7	0.5	4.0	<0.001
Blood pressure						
Tested at baseline	94.2	96.7	—	—	96.7	—
Change	2.0	2.4	—	—	2.4	0.9
Urine albumin						
Tested at baseline	61.9	32.0	23.9	31.8	30.6	—
Change	4.6	21.5	10.8	18.8	18.9	<0.001
Risk factor levels						
HbA_{1c}						
Last baseline value	7.9	7.8	7.8	7.6	7.8	—
Change in HbA_{1c} level (%)	−0.3	−0.2	−0.2	−0.2	−0.3	0.7
Change in percentage of patients with HbA_{1c} <7.0%	10.5	5.6	5.7	3.2	4.8	0.09
LDL cholesterol						
Last baseline value (mg/dl)	106	103	110	106	105	—
Change	−11	−10	−15	−9	−10	0.5
Change in percentage of patients with LDL cholesterol level <100 mg/dl	19.3	14.5	19.3	13.7	15.1	0.9
Blood pressure						
Last baseline value (mmHg)	133/76	132/76	—	—	132/76	—
Change	−2.6/−4.4	−2.1/−1.5	—	−2.1/−1.5	—	0.7/0.06
Change in percentage of patients with blood pressure <130/80 mmHg	7.9	6.2	—	—	6.2	0.4
Medication						
ACE inhibitor/angiotensin receptor blocker						
Prescribed at baseline	61.5	60.5	—	—		—
Change	9.1	13.2	—	—		0.02
Aspirin						
Prescribed at baseline	41.8	47.3	—	—		—
Change	8.8	11.8	—	—		0.06
Statins						
Prescribed at baseline	46.4	53.3	—	—		—
Change	11.8	9.9	—	—		0.2

Data are percent, unless noted otherwise, and indicate proportions and percentage of change for that proportion (for testing and medication changes) or means and mean change when last measured from baseline (1 January 2000 to 31 August 2001) to follow-up (1 December 2001 to 31 July 2003) (for risk-factor levels). *P* values compare intervention clinic versus control clinic(s), accounting for clustering by physician. Statins, hydroxymethylglutaryl-CoA reductase inhibitors.

of informing PCPs via e-mail, even when performed within an advanced EMR by a diabetes-knowledgeable clinician well known and respected by the PCPs, has a very modest effect on outcomes. 3) The marked improvement in testing rates and risk factor control in the intervention site was to a large extent matched by similar improvements in the three control clinics, emphasizing the critical importance of rigorous, controlled studies to demonstrate the true efficacy of translational research interventions.

There were several factors that may have reduced the impact of our intervention. The low absolute levels of improvement in risk factor levels may have been a consequence of the "ceiling effect" of the generally excellent levels of control at baseline. However, even in our exploratory "on treatment" analysis of the outliers identified by the population manager, we found similar improvements in the matched group of control patients, revealing a strong temporal trend of better care among all patients in the study.

Although the PopMan application provided the capacity to easily identify outliers within a relatively large patient cohort on a regular basis, patients identified by the population manager received a mean of only 1.2 interventions/patient over the 20-month study period. Thus,

the full benefit of the intervention may not have been realized because of the underuse of iterative follow-up in individual patients. This raises the issue of how to appropriately balance more intensive interventions in fewer patients versus less intensive intervention for more patients when total available resources are constrained.

Effective population management consists of two critical steps: *1*) organization of clinical information at a population level and *2*) translation of this clinical information into changes in care. The main "translation step" in our intervention was to summarize and forward evidence-based suggestions to PCPs. The relatively weak impact of the intervention may have been a consequence of placing the onus for changing care on the PCPs, who are time constrained and not directly compensated for patient care outside of the traditional clinic visit. Our findings confirm the considerable difficulty reported by other investigators in making significant changes in disease control using physician-directed computerized management interventions (22–25). Future interventions should focus on involvement of other members of the care team other than PCPs and on direct patient outreach. Alternatively, some have called for outsourcing diabetes management to providers with the time and training to provide top-quality diabetes care (26). However, because outsourcing may not be a feasible approach in every setting, there remains a need for further research to define effective strategies for diabetes management within primary care.

Recently published trials have demonstrated that intensive, protocol-driven, nurse practitioner–run clinics organized specifically to control individual risk factors (hyperglycemia, hypertension, or hyperlipidemia) in patients with diabetes result in significant improvement in risk-factor control (27–30). In contrast to the population-level approach taken in our intervention, however, these trials were limited to static inception cohorts of consenting research subjects and required significant investment of clinical resources in order to achieve success. The challenge remains to translate these findings into resource-limited real-world clinical situations for an unselected population of patients whose individual clinical characteristics change over time.

Other research has focused on increasing patient involvement directly in their care (31–33). In one recent study, in which patients were actively encouraged to participate in the management of their diabetes and related metabolic risk factors, intervention patients maintained significantly lower mean blood pressure, lower LDL cholesterol, and lower mean HbA_{1c} than the usual care group over the course of 4 years (34). Thus, a population management approach with a greater focus on education and empowerment of identified outlying patients may have greater impact on overall diabetes care.

Garfield et al. (35) have recently enumerated the multiple barriers to translating research into real-world settings. In clinics such as ours, with well-trained PCPs and an integrated EMR with substantial decision support, the impact of directing interventions toward PCPs will likely remain modest. Our findings underscore the importance of conducting translational research with adequate controls (rather than using before-and-after designs) to provide valid assessments of novel intervention strategies. Future efforts to translate the information triage component of population management into substantial changes in care will need to more effectively integrate both an interdisciplinary team of care providers and the patients themselves.

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