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ORIGINAL ARTICLE

The Impact of Planned Care and a Diabetes Electronic Management System on Community-Based Diabetes Care

The Mayo Health System Diabetes Translation Project

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OBJECTIVE — The Mayo Health System Diabetes Translation Project sought to assess models of community-based diabetes care and use of a diabetes electronic management system (DEMS). Planned care is a redesigned model of chronic disease care that involves guideline implementation, support of self-management, and use of clinical information systems.

RESEARCH DESIGN AND METHODS — We studied adult diabetic patients attending three primary care practice sites in Wisconsin and Minnesota. We implemented planned care at all sites and DEMS in the practice of 16 primary care providers. We assessed quality of diabetes care using standard indicators for 200 patients randomly selected from each site at baseline and at 24 months of implementation. We used multivariable analyses to estimate the association between planned care and DEMS and each quality indicator.

RESULTS — Planned care was associated with improvements in measurement of HbA_{1c} (odds ratio 7.0 [95% CI 4.2–11.6]), HDL cholesterol (5.6 [4.1–7.5]), and microalbuminuria (5.3 [3.5–8.0]), as well as the provision of tobacco advice (6.9 [4.7–10.1]), among other performance measures. DEMS use was associated with improvements in all indicators, including microalbuminuria (3.2 [1.9–5.2]), retinal examination (2.4 [1.5–3.9]), foot examinations (2.3 [1.2–4.4]), and self-management support (2.6 [1.7–3.8]). Although planned care was associated with improvements in metabolic control, we observed no additional metabolic benefit when providers used DEMS.

CONCLUSIONS — Planned care was associated with improved performance and metabolic outcomes in primary care. DEMS use augmented the impact of planned care on performance outcomes but not on metabolic outcomes. Optimal identification of the best translation of evidence to diabetes practice will require longer follow-up or new care-delivery models.

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I mprovement of the quality of diabetes care is a national priority. Practice redesign to support patients with diabetes and to ensure the delivery of evidence-based interventions is likely to improve the quality of diabetes care in the community setting, where most people with diabetes receive medical attention (1).

The Mayo Health System Diabetes Translation Project was a practice development, demonstration, and continuous quality improvement project. Its goal was to identify methods to enhance the delivery of evidence-based diabetes care (2,3). We studied whether practice redesign to prospectively plan the provision of diabetes care could improve adherence to national standards in a community setting. It further studied whether this planned care combined with the use of the diabetes electronic management system (DEMS) led to greater adherence to national standards than planned care alone.

RESEARCH DESIGN AND METHODS — The Institutional Review Boards and Ethics Committees of the Mayo Clinic Rochester and Mayo Health System practice sites approved the study protocol, and all participants (patients and physicians) gave informed consent. We have previously described the study design and population of the Translation Project (3). A brief description follows.

Practice sites and patients

We chose to implement the Translation Project in Mayo Health System practice sites that cared for >300 patients with diabetes, had appropriate level of information technology support, were committed to improve their diabetes care, and were willing to offer on-site endocrinology and diabetes education consultations. Three of the 11 sites fulfilled all of these criteria and were included in the project. Of the three sites, we randomly selected two sites and asked the clinical leadership at each site to nominate, without input

from the research team or consideration of project-specific attributes, 16 primary care providers that could be representative of the 56 family medicine and internal medicine providers who cared for people with diabetes. We implemented DEMS in the practice of these 16 providers.

We identified patients ≥18 years of age with diagnoses of type 1 or type 2 diabetes (ICD-9 250.00–250.930) using each site's administrative data. We used a modification of the strategy recommended by the Provider Recognition Program (PRP) of the American Diabetes Association (ADA) and the National Committee for Quality Assurance (4) to designate patients attending the practice regularly as attending patients. An attending patient had 1) diagnosis of diabetes for at least 1 year, 2) at least one visit in the last quarter of 1996 (baseline index visit) or in the last quarter of 1999 (follow-up index visit), and 3) at least one additional visit 12 months before the index visit. We reviewed the medical record to confirm the diagnosis of diabetes and each patient's attending status. During the baseline year, 6,646 patients (30% of which were attending patients) visited the practice sites in the last quarter of 1996 compared with 6,336 patients (27% attending patients) in the last quarter of 1999.

Interventions

During the first quarter of 1997, we implemented a planned care program at each practice site. This involved the implementation of practice guidelines, support for self-management, and clinical information systems. At each site, a diabetes nurse educator, a local physician leader, and local key personnel involved in diabetes care constituted a guideline implementation team. Each team determined goals and designed site-specific strategies to implement the Institute for Clinical Systems Improvement practice guidelines for management of type 2 diabetes (5). Clinical information systems included practice audit with feedback to the providers, patient lists, referral forms to diabetes self-management support sessions, and chronic disease management flow sheets (6).

We began to implement DEMS during the first quarter of 1998. We have described DEMS in detail elsewhere (7). Designated physicians (DEMS providers) used DEMS in the clinical care of patients, entering information at the point of care

and incrementally adding their patients to its database. Because many of the DEMS providers and their team (primary care nurse, clinical assistants, and diabetes educator) were computer naïve, each received ~4 h of general computer and DEMS training. While delivering care, DEMS providers received further on-the-spot training addressing their individual needs. After training of local personnel and implementation of DEMS, the research team met monthly with DEMS users to troubleshoot implementation issues. After 24 months of implementation, physicians were using DEMS at different levels: some used it as a clinical registry to review laboratory and vital statistics and others used it to its full potential as an electronic medical management system.

In addition to their traditional role, the diabetes educators were key facilitators for the Translation Project, the guideline team, and the clinical use of DEMS as a diabetes registry and a medical record, serving as an on-site superuser of DEMS (6). To fulfill these roles, the diabetes educators received formal training in continuous quality improvement and in the use of DEMS.

Outcome measures

To assess the quality of care provided before initiation of the project, we measured standard performance measures (consistent with those of the PRP) during the 12 months before each of the two index visits. These indicators included clinical process measures (e.g., frequency of examination of the feet and retina), laboratory measures (e.g., frequency of measurement of lipids), and counseling (e.g., self-management support). We used the PRP-weighted criterion score to control for multiple clinical testing (4).

We also measured metabolic outcomes, including all HbA_{1c}, lipid, and blood pressure values (up to four) obtained during the 12 months before the index visits. We used the most recent clinical and laboratory parameters before each index visit to calculate each patient's 10-year coronary risk using the Framingham coronary risk prediction score (8). To quantify health care use, we measured number of physician, emergency room, and hospital visits.

Data collection

We collected performance and metabolic outcomes and health care use data during the 12 months before each index visit by auditing the medical records of 200 randomly selected attending patients from each site, assuring equal representation of patients from DEMS providers and from providers not using DEMS. The initial audit was carried out by one of the diabetes educators. In addition, professional auditors conducted an independent audit of 10% of the randomly selected medical records. Agreement between audits was >90%. To assess patient health status, we mailed a generic functional health status questionnaire (the Medical Outcomes Study Short Form-36 [9]) to each patient followed by repeat mailing to nonresponders a month later. After these two mailings, the response rate was 67%. Survey responders and nonresponders had similar demographic characteristics, including similar glycemic control, diabetes treatments, and diabetes complications.

The information contained in DEMS was either automatically copied into DEMS from other electronic databases (i.e., laboratory test results) or entered by any member of the primary care team while providing care to a patient. As described above, we completed audits of the medical record to collect several patient data items. During these audits, we noted for each patient how many of these items had also been accurately entered into DEMS (in addition to having been entered into the medical record) by members of the primary care team. We used this item count as a metric of the intensity of DEMS use by the health care team (DEMS intensity score).

Before DEMS implementation and again 2 years after implementation, we measured the time the patient spent with the primary care nurse and with the provider in a convenience sample of patients of providers using DEMS.

Statistical analyses

The primary outcome of interest was the magnitude of improvement in performance measures from baseline. When appropriate, we used the Wilcoxon's rank-sum test or Fisher's exact test to test the hypothesis of no difference at baseline between DEMS providers and providers not using DEMS (and their patients). We assessed the impact of planned care on performance measures by comparing the

Table 1—Patient and provider characteristics at baseline

	DEMS providers	Providers not using DEMS	P
Patients			
Age (years)	68.9 (25.6–92.4)	71.8 (22.1–99.2)	0.002
Male sex (%)	44.2	40.1	0.43
SF-36 physical composite score	37.66 (12.85–63.97)	37.8 (12.1–59.7)	0.98
SF-36 mental composite score	53.44 (12.17–68.66)	54.2 (17.7–70.5)	0.61
Treatment of diabetes			0.70
Diet only	64 (16)	32 (15)	
Oral agent only	182 (46)	87 (42)	
Oral agent and insulin	16 (4)	11 (5)	
Insulin only	137 (34)	78 (38)	
Providers			
Male sex (%)	78.6	88.6	0.37
Family medicine/Internal medicine (%)	57.1/42.9	61.4/38.6	1.00
Years in practice	11.5 (3–40)	17 (6–41)	0.07
Number of patients with diabetes per provider	126.5 (33–265)	82.5 (1–241)	0.91

Data are median (range) or n (%), unless otherwise indicated. SF-36, Medical Outcomes Study Short Form-36.

baseline to 2-year audit data from patients whose providers did not use DEMS but who received planned care. We used logistic regression to determine the magnitude of change on the performance measures after adjusting for site differences. We used the 2-year audit data and logistic regression to assess the impact of DEMS (and of the DEMS intensity score in providers using DEMS) on the performance measures after accounting for site differences. We compared performance measures between low-intensity use of DEMS (the bottom third of the distribution of DEMS intensity scores) and high-intensity use (those in the top third of the distribution). Using linear regression for continuous variables, we assessed the significance of DEMS use on metabolic outcomes. None of these comparisons represent within-patient changes, but they do represent changes in the health system assessed using cross-sectional random samples. We used the Wilcoxon's rank-sum test to test the hypothesis that time measurements were not longer for providers when using DEMS.

RESULTS — At baseline, DEMS providers and their patients were similar to providers not using DEMS and their patients (Table 1). Planned care had a differential impact on performance measures after 2 years of implementation (Table 2). Planned care was associated with im- provements in measurement of HbA_{1c} (odds ratio [OR] 7.0 [95% CI 4.2–11.6]), HDL cholesterol (5.6 [4.1–7.5]), and microalbuminuria (5.3 [3.5–8.0]), as well as the provision of tobacco advice (6.9 [4.7–10.1]), among other performance measures. On the other hand, planned care was associated with significant deterioration in documentation of self-management support. Planned care resulted in improved performance in the ADA PRP-weighted criterion score (P = 0.0001).

DEMS use had positive impact on all performance measurements and was associated with a greater improvement than that seen with planned care (Table 3). DEMS use was associated with significantly improved frequency of measurement of microalbuminuria (OR 3.2 [95% CI 1.9–5.2]) and documentation of retina examination (2.4 [1.5–3.9]), foot examinations (2.3 [1.2–4.4]), self-management support (2.6 [1.7–3.8]), diet (1.9 [1.2–3.0]), and exercise advice (2.7 [1.6–

Table 2—The impact of planned care on performance measures

Performance measures	Baseline (%)	Planned care 2 years post-implementation (%)	OR (95% CI)
Tobacco advice	59	87	6.9 (4.7–10.1)
HbA_{1c}	75	94	7.0 (4.2–11.6)
HDL cholesterol	35	75	5.6 (4.1–7.5)
Microalbuminuria	8	27	5.3 (3.5–8.0)
Retina examination	31	36	1.6 (1.2–2.1)
Triglycerides	62	75	1.6 (1.1–2.1)
Total cholesterol	75	79	1.3 (0.9–1.7)
Foot examination	67	66	1.2 (0.9–1.6)
Immunizations	61	64	1.2 (0.9–1.6)
Exercise advice	57	52	0.9 (0.7–1.2)
Diet advice	65	60	0.9 (0.6–1.1)
Self-management support	57	38	0.5 (0.3–0.6)

The table lists performance measures in decreasing order of favorable impact of planned care (using the lower limit of the CI) when comparing prevalence of performance measures at baseline and 2 years after planned care implementation.

Table 3—*The impact of the DEMS on performance measures*

Performance measures	Impact of DEMS use		
	No DEMS (%)	DEMS (%)	OR (95% CI)
Microalbuminuria	27	55	3.2 (1.9–5.2)
Exercise advice	52	80	2.7 (1.6–4.5)
Self-management support	38	61	2.6 (1.7–3.8)
Retina examination	36	69	2.4 (1.5–3.9)
Foot examination	66	88	2.3 (1.2–4.4)
Diet advice	60	70	1.9 (1.2–3.0)
Immunizations	64	80	1.7 (1.1–2.7)
HbA$_{1c}$	94	99	4.5 (1.0–19.5)
HDL cholesterol	75	83	1.6 (1.0–2.7)
Triglycerides	75	82	5.0 (0.9–2.4)
Tobacco advice	87	94	2.0 (0.9–4.3)
Total cholesterol	79	84	1.4 (0.8–2.3)

The table lists performance measures in decreasing order of favorable impact of DEMS (using the lower limit of the CI) when comparing prevalence of performance measures after 2 years of planned care in providers using and not using DEMS.

4.5]). DEMS use was also associated with improved compliance with the measurement of HbA$_{1c}$ (4.5 [1.0–19.5]) and total cholesterol (1.4 [0.8–2.3]); however, the latter did not reach statistical significance. The effect of DEMS was similar across practice sites (data not shown). Compared with low-intensity use of DEMS, high-intensity use was associated with significantly greater compliance with the measurement of microalbuminuria (40 vs. 60%, $P < 0.001$), total and HDL cholesterol and triglycerides (65 vs. 100%, $P < 0.001$), and documentation of self-management support (44 vs. 81%, $P < 0.001$). Low- and high-intensity DEMS use did not differ in compliance with measurement of HbA$_{1c}$ (96 vs. 100%, $P = 0.1$) and documentation of retina examination (65 vs. 77%, $P = 0.06$), foot examination (81 vs. 96%, $P = 0.02$), and immunizations (69 vs. 89%, $P = 0.02$).

Planned care was associated with improved metabolic outcomes and a significant reduction in the calculated 10-year coronary risk score (Table 4). Metabolic outcomes (Table 4) and health care use (number of emergency room visits, frequency of hospitalization, and provider visits) did not differ between patients whose providers used DEMS and patients whose providers did not use DEMS. Sim-

ilarly, there were no differences in metabolic outcomes between low- and high-intensity use of DEMS (data not shown).

At baseline, patients of providers using DEMS spent a median (range) of 5 min (0–30) with the primary care nurse and 15 min (4–45) with the provider. Two years after DEMS implementation, time with nurse increased to 9.5 min (0–34) ($P < 0.001$) and with provider to 18 min (10–55) ($P = 0.012$), respectively.

CONCLUSIONS — The Mayo Health System Translation Project demonstrated that the delivery of planned care either alone or in conjunction with an electronic management system in a primary care setting improved metabolic outcomes. Planned care, as originally advocated by Wagner et al. (1), involves redesigning the health care delivery system to support patient self-management by using clinical information and decision support systems (10). Consistent with others, we found that implementation of planned care in a primary care setting was associated with improved performance measures (11–14) and improved metabolic outcomes (13). Few models of care, including planned care, can consistently improve performance measures when more than five preventive measures (as with diabetes) are targeted (12). We have shown that the addition of DEMS (an electronic information management system) to planned care led to improvement in all performance measures (Table 3). In

Table 4—*The impact of planned care and the DEMS on metabolic outcomes*

Metabolic outcomes	Mean change (95% CI)		
	Baseline	Difference between index years (effect of planned care)	Difference at index year 2 between users and nonusers of DEMS (effect of DEMS)
Glycemic control			
Last HbA$_{1c}$	7.3 (4.2–16)	−0.5 (−0.8 to −0.3)	0.01 (−0.3 to 0.4)
Lipids (mmol/l)			
Total cholesterol	5.3 (2.3–8.5)	−0.3 (−5.0 to 1.7)	−0.1 (−3.5 to 1.8)
LDL cholesterol	3.2 (0.9–6.5)	−0.4 (−0.6 to −0.3)	−0.1 (−3.0 to 1.8)
Triglycerides	2.1 (0.4–19)	−0.2 (−0.5 to −0.01)	0.1 (−1.7 to 3.5)
Blood pressure (mmHg)			
Systolic blood pressure	140 (92–220)	−0.1 (−3 to 2.6)	−0.8 (−5.0 to 3.4)
Diastolic blood pressure	75 (40–110)	0.2 (−1.2 to 1.7)	−0.6 (−2.4 to 1.1)
Calculated coronary disease risk			
Framingham coronary risk score	12 (−8 to 21)	−1.0 (−2.0 to 0.0)	−0.3 (−1.4 to 0.9)
10-year coronary risk (%)	23.3 (0.4–75.6)	−4.8 (−7.9 to −1.8)	−2.1 (−1.1 to 5.3)

Data are median (range), unless otherwise indicated.

particular, DEMS use improved documentation of self-management support, diet and exercise counseling, and immunizations—performance measures that did not improve (instead they deteriorated) with the implementation of planned care alone. Finally, the impact of practice redesign is better assessed at the population level. For instance, a 10% increase in immunizations (similar to the change from 64 to 80% associated with DEMS use in this study) could mean, in a population of 1,000 patients with diabetes followed for 1 year, two fewer deaths and one fewer hospitalization due to pneumonia (15).

The expanded role of the diabetes nurse educator in this project provides an example of the role played by members of the health care team in quality improvement activities (3,11–13). All members of the team actively participated in the adoption of guidelines and assisted in the planning of multifaceted interventions. The diabetes nurse educator also served as liaison between specialty and primary care providers (3,16). Because of present limitations of information systems, reorganization of the practice was necessary for successful implementation of DEMS. In the present study, training of a primary care nurse in DEMS use at each practice site proved to be an effective means of collecting data at the point of care before each patient encounter with a DEMS provider (7,17).

The present data indicate that effective clinical information systems can be integrated into the clinical process in a primary care setting. Quality improvement requires attention not only to processes but also to outcomes. While use of DEMS was associated with global improvements in all measures of performance, DEMS use was not associated with clinically significant improvements in metabolic outcomes. Long-term improvements in patient outcomes remain elusive (13,18–21). Unfortunately, many "final" reports of health services evaluations lack power to demonstrate improvements in patient outcomes. Largely, this is due to funding limitations and changes in funding priority (13). Our study was large enough to detect the incremental impact of DEMS over that of planned care on performance measures. The ability to detect an impact on metabolic outcomes, however, may require a longer study period. Also, DEMS was not designed to provide

detailed advice about changes in medications and other management decisions that could intuitively lead to improvement in metabolic outcomes. We have conducted and described pilot implementations of an alternative model of generalist-specialist interaction and decision support using telemedicine and DEMS (3,6). In this model, specialists advised generalists about medication changes and other management strategies that, when followed, appeared to impact glycemic control. Thus, facilitated generalist-specialist communication and decision support systems may be effective in improving patient outcomes.

The before-after study design and the lack of control practice sites (which impair our ability to account for secular trends and regression to the mean) weaken the inferences we can draw about the true association between planned care and improved diabetes care. We chose this study design because it was the only one acceptable to the participants at eligible practice sites and to the research team, all of whom were committed to optimal delivery of diabetes care. The sites that were not eligible could not serve as control sites because they did not have effective strategies to collect data during the study period. Lack of randomized allocation, which limits our ability to account for imbalances in known and unknown prognostic factors between patients from providers using and not using DEMS, weakens our inferences about the true association between use of DEMS and improved diabetes care. However, the inference that DEMS use improves diabetes care is strengthened by the positive association between greater intensity of use of DEMS and improved performance measures.

In summary, the Mayo Health System Translation Project results indicate that the way in which health care services are organized and delivered can improve documentation of clinical activity, adherence to performance measures, and metabolic outcomes. Further studies will be required to determine whether such services can decrease the cost of care and improve the long-term quality of life of diabetic individuals by preventing or delaying the complications of diabetes.

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