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Beyond Health Information Technology: Critical Factors Necessary for Effective Diabetes Disease Management

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Abstract

Background:

Electronic health records (EHRs) have been implemented throughout the United States with varying degrees of success. Past EHR implementation experiences can inform health systems planning to initiate new or expand existing EHR systems. Key "critical success factors," e.g., use of disease registries, workflow integration, and real-time clinical guideline support, have been identified but not fully tested in practice.

Methods:

A pre/postintervention cohort analysis was conducted on 495 adult patients selected randomly from a diabetes registry and followed for 6 years. Two intervention phases were evaluated: a "low-dose" period targeting primary care provider (PCP) and patient education followed by a "high-dose" EHR diabetes management implementation period, including a diabetes disease registry and office workflow changes, e.g., diabetes patient preidentification to facilitate real-time diabetes preventive care, disease management, and patient education.

Results:

Across baseline, "low-dose," and "high-dose" postintervention periods, a significantly greater proportion of patients (a) achieved American Diabetes Association (ADA) guidelines for control of blood pressure (26.9 to 33.1 to 43.9%), glycosylated hemoglobin (48.5 to 57.5 to 66.8%), and low-density lipoprotein cholesterol (33.1 to 44.4 to 56.6%) and (b) received recommended preventive eye (26.2 to 36.4 to 58%), foot (23.4 to 40.3 to 66.9%), and renal (38.5 to 53.9 to 71%) examinations or screens.

Conclusions:

Implementation of a fully functional, specialized EHR combined with tailored office workflow process changes was associated with increased adherence to ADA guidelines, including risk factor control, by PCPs and their patients with diabetes. Incorporation of previously identified "critical success factors" potentially contributed to the success of the program, as did use of a two-phase approach.

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Abbreviations: (ADA) American Diabetes Association, (BC) Billings Clinic, (CI) confidence interval, (EHR) electronic health record, (HbA1c) glycosylated hemoglobin, (LDL) low-density lipoprotein, (NCQA) National Committee for Quality Assurance, (OR) odds ratio

Keywords: chronic disease management, diabetes, EHR, health information technology

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Introduction

The prevalence of diabetes in the United States has reached epic proportions. The number of persons with diagnosed diabetes in the United States quadrupled from 1980 to 2007, and the numbers continue to rise, with 23.6 million people affected, or nearly 8% of the population.[1] Diabetes continues as the sixth leading cause of death in the United States and is the leading cause of adult blindness, lower-limb amputation, kidney disease, and nerve damage,[1] with substantial economic impact estimated at $174 billion in 2007.[2] The prevalence of diabetes is projected to rise substantially, with estimated projections of 48.3 million people with diagnosed diabetes in the United States in 2050.[3]

While consistent improvements in morbidity and mortality for adult diabetes patients who achieve evidence-based levels of vascular risk factors, i.e., blood pressure, glycosylated hemoglobin (HbA1c) , and low-density lipoprotein (LDL) cholesterol, have been well established in the literature,[4–10] routine clinical practice settings continue to struggle to achieve these American Diabetes Association (ADA) established clinical goals.[5,11,12] Numerous quality improvement interventions have been developed and implemented with mixed results, including those utilizing health information technology.[13–18] Many studies that evaluated the impact of implementation of an electronic health record (EHR) concluded that technology alone was not sufficient to effect real change.[14–19]

Several direct and indirect facilitators, or "critical success factors,"[16] for achieving these goals have been identified. These include system-level factors, such as provider-targeted education initiatives, use of disease registries, and financial/professional incentives. Provider-targeted education initiatives focus on efficient and effective transmission of educational information from provider to patient. Disease registries facilitate previsit identification of disease-specific patient groups for targeted services. Financial and professional incentives include provider bonuses linked to clinical/process patient outcomes, e.g., proportion of patients with controlled diabetes risk factors, e.g., blood pressure <130/80.[14–17,19]

Office-level critical success factors include office workflow process change, enhanced information for patients, real-time clinical guideline support, and institution of care improvement methods pre-EHR implementation.[14–17,19] Integration of office workflow process change into clinic-based interventions is critical to success, i.e., improvement of efficiencies without clinic flow disruption. Real-time guideline support aids providers in efficient patient management. The early introduction of care improvement methods supports an incremental approach to process change.

This study fills an important gap in the literature by directly addressing specific problems identified in previous studies of EHR implementation for chronic disease management and integrating them into program development and implementation. Specific problems included (1) disease management improvement methods instituted simultaneous to EHR implementation (versus a phased-in approach); (2) EHR implementation without tailored disease management modules; (3) lack of office workflow process integration; (4) lack of explicit explanation of EHR purpose to staff; (5) absence of diabetes patient registry; (6) no physician/staff financial incentives; (7) lack of provider performance monitoring; (8) no information support to patients, e.g., use of diabetes report card; and (9) lack of real-time clinical guideline support for providers. These problems have been identified as key "critical success factors" for successful EHR implementation for chronic disease management. The objective of this study was to examine a specialized intervention strategy that incorporates several key "critical success factors" identified in the literature to improve physicians' adherence to diabetes care guidelines and control of patient risk factors.

Methods

The study design was a 6-year pre/postintervention (July 2001–June 2007). A 2-year baseline period was followed by two consecutive 2-year intervention periods. The two intervention phases were designated "low dose" and "high dose" and are described in detail. **Table 1** lists the "critical success factors" present during each intervention period.

Non-EHR Diabetes Management Improvement: "Low-Dose" Intervention Period

In July 2003, in conjunction with a targeted diabetes outreach initiative, an interdisciplinary team of physicians, nurses, and managers began to develop a targeted education program for primary care clinic staff

to improve point-of-care management of diabetes patients. The team instituted several system-level critical success factors, including explicit explanation of the purpose and importance of the EHR as it relates to diabetes care management and system-wide provider education on the ADA guidelines. Development of a diabetes patient registry was initiated during this period, although formal reporting structures were not added until the subsequent "high-dose" intervention period.

The "low-dose" intervention period was also characterized by several office-level critical success factors, including implementation of four educational modules designed to cue nurses and physicians to provide appropriate diabetes care and follow established clinical guidelines. Paper-based education modules were implemented in three primary care clinics and included a focus on foot, eye, and renal screening examinations, as well as self-management of vascular risk factors, i.e., blood pressure, blood glucose, and lipids. Clinic staff was provided training on each education module, its components, and materials. Examination and waiting room posters on each topic were rotated every quarter, and take-home educational materials were provided to patients. These improvements in patient care were accompanied by a cultural shift, as care providers moved from a one-on-one clinician–patient model to a team diabetes care approach in the office setting. The "low-dose" intervention period, therefore, included several critical success factors at the office and system levels (see **Table 1**).

Electronic Health Record-Based Diabetes Management Program Initiative: "High-Dose" Intervention Period

At the systems level, the "high-dose" intervention period, initiated in 2005, was characterized by implementation of a new "fully functional" integrated EHR system, transforming the organization's approach to managing patients with complex chronic medical conditions. The EHR system was customized to generate electronically the following components for diabetes disease management: (1) disease registry to identify patients with diabetes; (2) diabetes management module for point-of-care provider alerting; (3) electronic forms for documentation of foot and eye examinations; (4) patient report cards with individualized patient results based on a clinic encounter; and (5) provider patient panel reports, enabling providers to track their performance compared with the aggregate performance of other organization primary care physicians and with national benchmarks. **Figures 1–5** provide example EHR screen shots corresponding to the aforementioned components.

System-level financial incentives, e.g., merit increases tied to performance, and professional recognition, i.e., National Committee for Quality Assurance (NCQA) Diabetes Physician Recognition Program, were also offered to physicians and their staff who reached

Table 1.
Critical Success Factors by "Low-Dose" and "High-Dose" Study Intervention Periods

	Critical success factors
Low-dose intervention period	System level: • Provider/staff explicit explanation of EHR purpose and importance • ADA guideline education • Diabetes patient disease registry development • Office level—point of care: • Institution of diabetes care improvement methods ° Information support for patients—paper-based diabetes education modules (foot, eye, and renal screening and vascular risk factor control) ° Clinical guideline support for providers—paper-based • Office workflow process changes development
High-dose intervention period	System level: • Diabetes patient EHR-based disease registry • Patient panel comparisons for providers • Financial and professional incentives for physicians/staff • Reinforcement of provider/staff explicit explanation of EHR purpose and importance Office level—point of care: • Office workflow process changes implementation • Information support for patients—EHR-based diabetes patient report card (included individualized test results and goals for preventive screenings and risk factor control) • EHR-based real-time clinical guideline support for providers

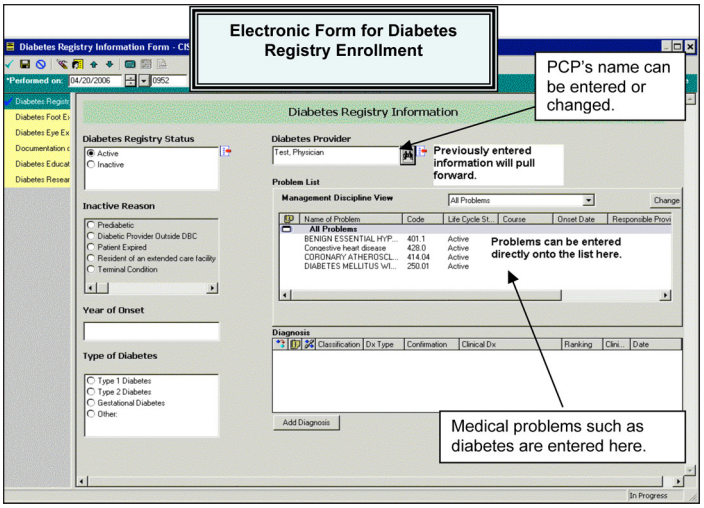

Figure 1. Diabetes registry electronic form—EHR screen shot. PCP, primary care provider

specified goals in diabetes patient care. The importance and purpose of the EHR were explicitly explained to all staff in the organization.

At the office level, critical success factors included crucial office workflow process changes designed to improve the integration of services for diabetes patients. Utilizing critical input from clinic staff, the EHR was integrated into office workflow processes. Through a diabetes disease registry link, patients were identified prior to their office visit to enable staff to preprint patient diabetes care summary sheets for providers and patient report cards for patients. Staff was trained to initiate patient education during the rooming process, and nurses were empowered to provide protocol-driven immunizations. EHR-based real-time clinical guideline support for providers at the office level was important to this process. The "high-dose" intervention period, therefore, included several critical success factors at the system and office levels (see **Table 1**).

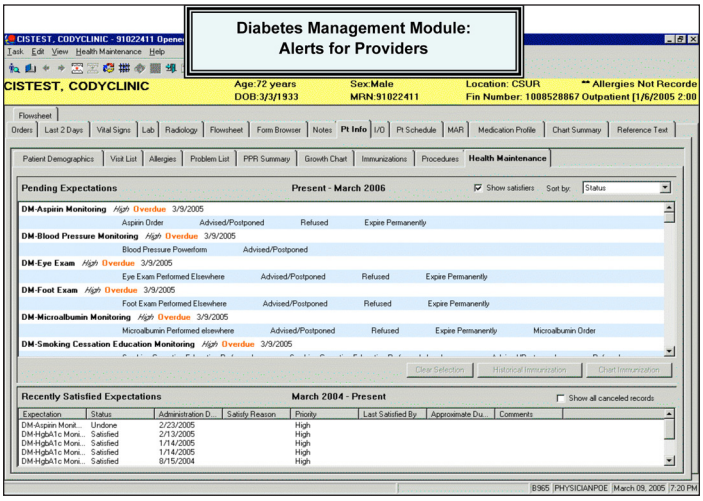

Figure 2. Point-of-care diabetes management module—EHR screen shot.

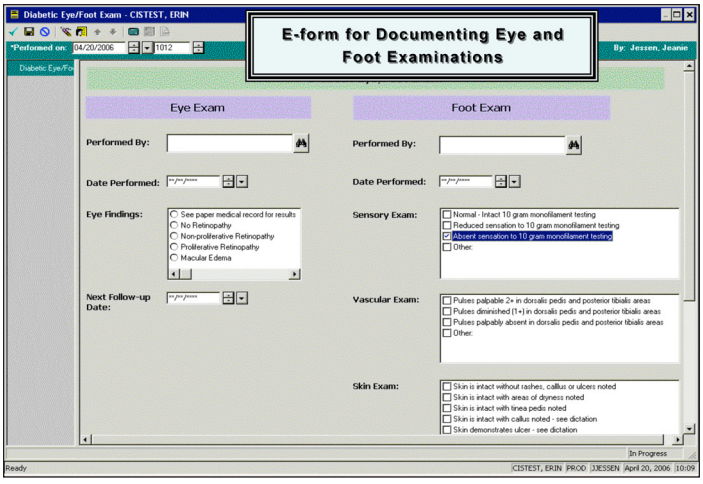

Figure 3. Point-of-care e-forms for imputing eye and foot examinations—EHR screen shot.

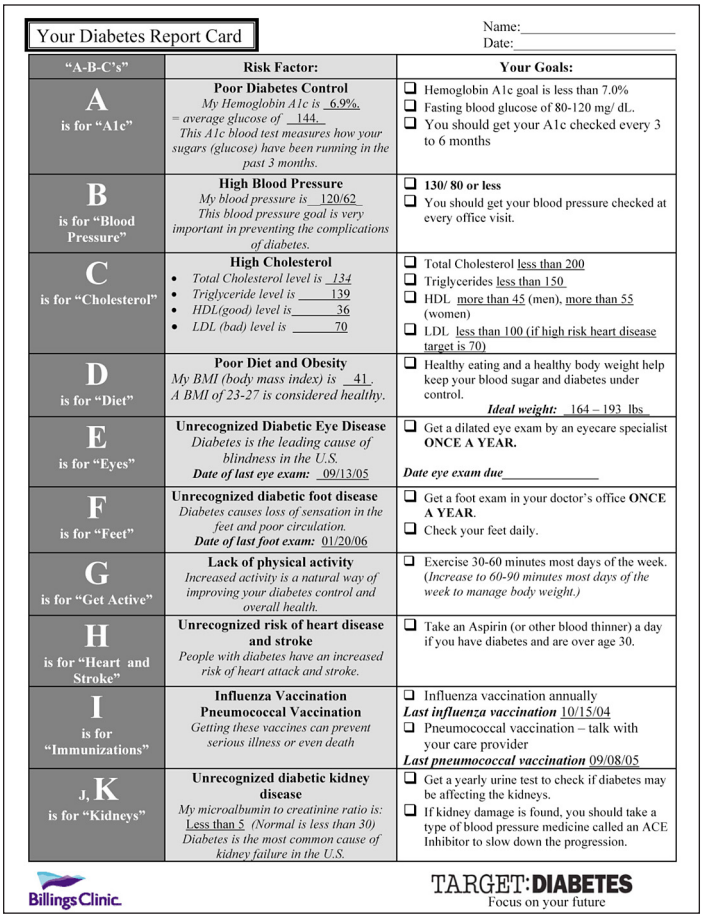

Figure 4. Point-of-care printed patient report card for diabetes.

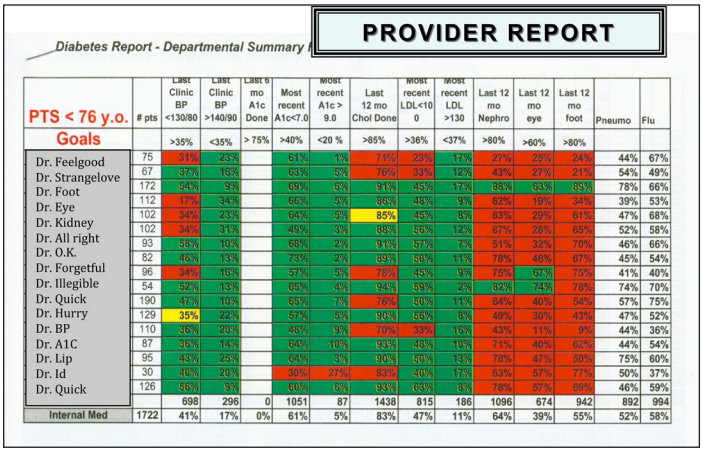

Figure 5. Diabetes patient panel report card for providers—aggregate data pulled from electronic health record.

Study Sites

The Billings Clinic (BC) Health Care System is a community-owned, not-for-profit medical foundation, with a 272-bed hospital and a 225-physician multispecialty group practice. Billings Clinic is the region's largest multispecialty health system, with 14,324 hospital admissions, 34,279 emergency department visits, and 888,942 outpatient clinic visits in fiscal year 2008. The health care system includes the Billings Clinic, the BC hospital, one local nursing home, two local satellite clinics, and four organization-owned regional branch clinics serving the rural population of central/eastern Montana and northern Wyoming.

All 28 primary care providers at the three study clinics participated in this study, which was part of an organizational quality improvement initiative. Two local satellite and the main outpatient clinic were represented.

Study Subjects

Included in this study were 495 eligible patients selected randomly from a diabetes registry (n = 3056; International Classification of Diseases, 9th Revision = 250.00–250.99) in study year 3. Study patient demographic and clinical characteristics were similar to those of the entire registry. To evaluate the interventions' effects by age and Medicare status, the study sample included equal proportions of patients representing three age groups obtained through a stratified random sampling: (1) <65 years, (2) 65–75 years, and (3) >75 years. Power calculations indicated greater than 90% power to detect a 20% point improvement in study outcome measures from baseline to study year 4, taking into account an annual attrition rate of 20% over a 5-year period.

Figure 6 displays the study patient selection method. A random selection of 165 patients from each age group was included if they had been seen for diabetes by a BC provider in the past year. Exclusion criteria comprised gestational diabetes, steroid-induced diabetes, nursing home residents, prednisone use >2 months, non-BC provider diabetes management, or seen more than once by an endocrinologist for diabetes within a data collection year or had >50% tests ordered by an endocrinologist. In each of the 6 data collection years, a patient had to be seen at least once by a BC primary care provider for diabetes, or in the first 6 months of the data collection year for new patients, to be included in that year's cohort. Therefore, patients were not dropped from the study due to nonparticipation in a given study year; this prevented selection bias of limiting the cohort to patients with visits in all 6 years.

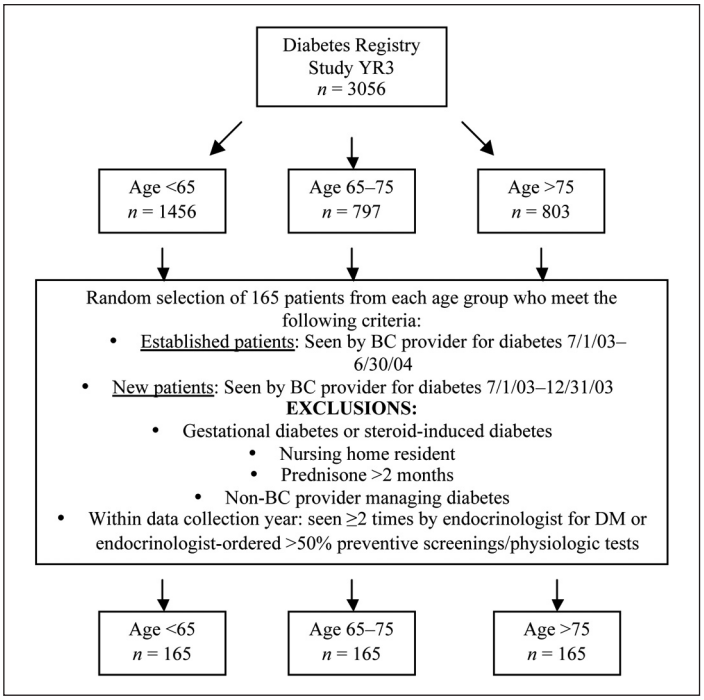

Figure 6. Accrual of study patients (n = 495). DM, diabetes management.

Outcome Measures

Intermediate clinical outcome measures included the proportion of patients with risk factors at target: blood pressure <130/80 mm Hg, HbA1c <7%, and LDL cholesterol <100 mg/dl using the last patient measurement in each 2-year study period. Process outcome measures included the proportion of patients who received preventive screening tests, i.e., documented dilated eye examination, documented foot screen (monofilament testing), or measured renal screen (microalbumin/creatinine ratio) in each study year. Receipt of biannual HbA1c and annual lipid panel tests were documented. Data were collected through chart audits and abstracted directly from the EHR.

Control Measures

Several additional independent variables were tested for being potential covariates in the subsequent regression models predicting the outcome measures, including (1) clinic site; (2) provider specialty—family practice or internal medicine; (3) provider type—physician, physician assistant, or nurse practitioner; (4) comorbid conditions—depression, hypertension, or dyslipidemia; (5) patient gender; and (6) patient age. Measures were chosen for inclusion based on univariable analyses results or a priori knowledge of independent associations with the selected dependent variables.

Statistical Methods

The proportion of patients meeting recommended levels of risk factor control was calculated for each study period, e.g., baseline and intervention period rates of blood pressure <130/80. The proportion of patients for whom each clinical process guideline was followed was calculated, e.g., baseline and intervention period rates of receipt of a foot examination.

Risk factor control and clinical process guideline adherence were compared across the three study periods using the generalized estimating equations approach, which accounts for within-subject correlations and missing patient data in a given time period.[20] The two intervention periods were compared with the baseline period; the "high-dose" intervention was also compared with the "low-dose" period. Potentially confounding independent variables were tested in the regression models. There were no significant covariates, but some basic demographic characteristics were included in the models. Because of the large number of providers represented and the low patient-to-provider ratio (data not shown), no substantial clustering effects by provider were determined to be present.

This study was approved by the Institutional Review Board of Billings.

Results

There were 495 patients included in the study sample. At the end of study year 3, the year of sample selection, the mean age was 64 years and 55% were female. Most patients were seen by a physician; more than three-quarters were seen by an internist. Eighty-three and 70% of patients had a diagnosis of hypertension and dyslipidemia, respectively. These results are consistent with characteristics of the larger diabetes registry population.

Longitudinal comparisons of diabetes risk factor control are displayed in **Table 2**. Baseline, low-dose, and high-dose intervention period rates for blood pressure control were 26.9, 33.1, and 43.9%; glycemic control rates were 48.5, 57.5, and 66.8%; and lipid control rates were 33.1, 44.4, and 56.6%, respectively. The proportion of patients with each risk factor in control increased significantly between the baseline and the postintervention periods by 63% among participants with controlled blood pressure [odds ratio (OR) =2.0, 95% confidence interval (CI): 1.6–2.5], 38% among participants with controlled HbA1c levels (OR = 2.2, 95% CI: 1.8–2.7), and 71% among participants with controlled lipids (OR = 2.5, 95% CI: 2.0–3.0). In addition, the proportion of patients with at least two controlled risk factors following the intervention nearly doubled from 31 to 58.4% (OR = 3.0, 95% CI: 2.4–3.7).

Table 2.
Control of Diabetes Risk Factors (RF) and Adherence to Guidelines Pre/Postintervention by Dose over Time (n = 495)[a]

Risk factor	Baseline period (%)	Low-dose intervention period (%)	High-dose intervention period (%)	Odds ratio low vs baseline	Odds ratio high vs baseline
Blood pressure	26.9	33.1	43.9	1.3*	2.0†
Glycemic control	48.5	57.5	66.8	1.5†	2.2†
LDL cholesterol control	33.1	44.4	56.6	1.5†	2.5†
Two or more RF in control	31.0	42.5	58.4	1.6†	3.0†
Clinical process guideline					
Annual lipid profile	71.4	78.6	87.0	1.4*	2.6†
Biannual HbA1c test	99.9	100	100	1.0	1.0
Annual eye exam	26.2	36.4	58.0	1.4†	3.0†
Annual foot screen	23.4	40.3	66.9	2.1†	5.8†
Annual renal screen (microalbumin/creatinine test)	38.5	53.9	71.0	1.8†	3.5†
Received all three preventive screening exams	4.3	15.0	39.2	3.4†	11.2†

[a] All measures controlled for age, gender, clinic, and physician specialty.
* $p < 0.01$.
† $p < 0.0001$.

Regression models were controlled for age and gender of patient, clinic site, and clinician type and specialty—none of which emerged as independent predictors of risk factor control. Stratifying the analysis by age group or clinic site did not identify a subgroup with noticeably different improvements.

Longitudinal comparisons of receipt and documentation of preventive screening examinations also demonstrated significant improvements. Baseline, low-dose, and high-dose intervention period rates for receipt of an annual lipid profile were 71.4, 78.6, and 87%; eye examination rates were 26.2, 36.4, and 58%; foot examination rates were 23.4, 40.3, and 66.9%; and renal screen rates were 38.5, 53.9, and 71%, respectively. Patients' receipt of an annual lipid profile increased by 22% ($p < 0.0001$) between baseline and high-dose periods. The proportion of study patients receiving the recommended semiannual HbA1c tests did not demonstrate significant improvements due to baseline rates of nearly 100%.

The proportion of patients who received recommended preventive examinations increased significantly from baseline to the high-dose period by 121, 186, and 84% for eye, foot, and renal examinations, respectively. The proportion of patients who received all three preventive examinations increased by 812% ($p < 0.0001$).

Discussion

Study findings indicate that there have been significant improvements in diabetes control and documentation of preventive services since implementation of an initial nonelectronic health record-based diabetes management initiative followed by the implementation of an EHR-based diabetes management program. At study's end, subjects were 3.5 to 6 times more likely to receive a preventive screening examination and 11 times more likely to receive all three recommended tests than they were at baseline. They were also two to three times more likely to have controlled clinical risk factors, i.e., blood pressure, blood glucose, and lipids, at levels recommended by the ADA.[5,21] Evidence suggests that these are valid intermediate measures of adverse vascular clinical events.[22]

These findings reinforce previous studies that have concluded that implementation of an EHR is necessary, but not sufficient, for a successful chronic disease management program. Following recommendations stated in numerous published studies,[14–17,19] this program incorporated several critical components into its design. During the "low-dose" intervention period, full EHR implementation was preceded by a paper-based education component, a diabetes patient registry, and office workflow process changes in anticipation of the impending implementation of a fully functional EHR.

During the "high-dose" intervention period, the technology component of the diabetes disease management program was developed and implemented to fit into tailored office workflow process changes that reflected the realities of individual primary care practices. The EHR-integrated diabetes-specific components were point of care focused; administrative components enhanced patient care and galvanized providers, including a diabetes patient report card, diabetes patient disease registry, real-time clinical guideline support, and comparative patient panel reports for providers. Additional financial and professional incentives were available to providers meeting specified goals in diabetes patient care.

The inclusion of specific critical success factors identified in the literature enabled us to surpass diabetes-related successes associated with EHR implementation reported in the literature. O'Connor and colleagues found that EHR use led to an increased number of HbA1c and LDL tests, but not to better metabolic control.[17] Another study found better diabetes care among medical practices without an EHR in terms of following diabetes care guidelines for process, treatment, and intermediate outcomes.[14] Orzano and associates demonstrated significant improvements in attainment of clinical targets associated with the use of identification/tracking systems for blood pressure and LDL, but not for HbA1c.[18] These authors did not find the presence of an EHR to be associated with attainment of clinical targets. All of these studies identified the lack of one or more critical success factors as causal in their suboptimal study findings. We incorporated many of these same critical success factors into our program and demonstrated improved clinical and process outcomes.

This study's primary limitation was the lack of a direct comparison population. Logistical, ethical, and financial barriers prevented study patient randomization. However, a comparison of findings to nationally established benchmarks during similar time periods [23,24] enabled us to rule out a type I error, which would have occurred if we falsely attributed study findings solely to national trends. Comparisons to national trends enabled us to demonstrate degrees of improvement that far exceeded those demonstrated at state and national levels (see **Table 3**).

Table 3.
Guideline Adherence and Risk Factor Control Outcomes Compared with State and National Outcomes (% Change over Time)

Process outcomes	Billings Clinic intervention 2001–2007	Billings Clinic intervention 2001–2005	Montana BRFSS[a] 2001–2005[b]
Annual eye exam	145.9%	107.0%	–2.0%
Annual comprehensive foot exam	277.9%	197.0%	–5.7%
Clinical outcomes		Billings Clinic intervention 2001–2007	NHANES[d] 2001–2004
Blood pressure control[c]		63.2%	0.6%
Glycemic control (HbA1c <7%)		39.4%	15.0%
Glycemic out of control (HbA1c >9%)		–42.4%	–30.3%
Lipids control[†]		71.0%	51.4%

[a] Behavioral Risk Factor Surveillance System.
[b] Age-adjusted percent change.
[c] Blood pressure and lipids control data from NHANES 1990–2000.[26]
[d] National Health and Nutrition Examination Survey.

Another procedural limitation may have resulted in less than expected improvements in study outcome measures. Provider panel report card benchmarks, based on the NCQA national guidelines, were low relative to improvements in this patient population. For example, the national benchmark goal for patient blood pressure control rate was 35%. If a provider met this goal, it was indicated on his/her panel report for that measure that the goal had been met. This approach provided little further incentive for improvement. Similarly, benchmark goals for patient glycemic and lipid control rates were low at 40 and 36%, respectively.

This observation suggests a need to develop more appropriate provider incentives, such as composite all-or-none measures that sum performance across several indicators for an individual patient, as have been implemented by the Minnesota health care community.[25] Composite measures have demonstrated success in incentivizing physicians to take action, but are not yet widely utilized in the ambulatory setting.

Although we demonstrated marked improvements in preventive screenings, we cannot necessarily distinguish between the receipt and the documentation of preventive screening tests. It is possible that documentation improved but that the number of tests conducted remained static. Finally, due to the multifaceted nature of the intervention, we were unable to determine which attribute, or combination of attributes, was most responsible for the observed results.

Conclusions

This study demonstrated a clear shift in the proportion of patients both with controlled risk factors and with documented receipt of recommended preventive screening tests. Implementation of an intervention that included key critical success factors, i.e., EHR implementation preceded by institution of diabetes care improvement processes, tailored clinic workflow process changes and technology implementation to fit directly into new workflow, use of a diabetes patient registry, real-time clinical guideline support, comparative patient panel reports for providers, a diabetes patient report card, and provider financial incentives, appears to have had a beneficial effect on diabetes care in the organization. Since the conduct of this study, the diabetes management program has been expanded to rural clinic sites, which are arguably even more in need of this type of intervention. Preliminary reports are promising and efforts are under way to rigorously evaluate this expansion to the rural community.

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Disclosure:

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