Grant Final Report

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Impact of Health IT Implementation on Diabetes Process and Outcome Measures

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Structured Abstract

Purpose: This study examined the effects of a commercially-available ambulatory electronic healthcare record (EHR), and its embedded diabetes management form (DMF), on quality of diabetes care.

Scope: Diabetes is an increasingly common chronic disease that requires long-term management. Health information technology has the potential to improve compliance with recommended diabetes-related process of care and outcome measures.

Methods: In this observational study an EHR was rolled out across 34 primary care practices over a staggered 3-year schedule. Diabetes-related care data were collected via chart audit. The primary outcome was the HealthPartners' "optimal care" measure: HbA1c ≤ 8%; LDL-cholesterol <100 mg/dL; blood pressure <130/80 mmHg; not smoking; and documented aspirin use for patients ≥40 years. Compliance was compared between patients exposed and unexposed to the EHR, and, in a subset of EHR-exposed patients, between patients for whom the DMF was and was not used.

Results: After adjusting for age, sex, and insulin use, EHR-exposed patients were significantly more likely to achieve "optimal care" (P<0.001), with an estimated difference of 9.20% (95%CI[6.08%, 12.33%]) in the final year; and were more likely to be in compliance with each process and outcome measure except HbA1c and lipid control. After adjustment, DMF-exposed patients showed less improvement in attaining "optimal care" (estimated difference-in-difference [DID]: -2.06 percentage points; P<0.001), LDL-cholesterol (DID: -2.30; P=0.023), blood pressure (DID: -3.05; P<0.001) and total cholesterol (DID: -0.47; P=0.004) targets, but greater improvement in documented microalbumin tests, aspirin prescription, and eye and foot exams.

Key Words: diabetes; electronic health record; EHR; quality of care

Final Report

Purpose

The primary objective of this project was to quantify the effects of a commercially-available ambulatory electronic healthcare record (EHR) on quality of diabetes care, as measured by compliance with recommended processes of care and patient outcome measures, in a large group of primary care practices. It also quantified the effects of use of diabetes management form embedded in this EHR.

Primary Aim: To estimate the impact of an EHR on diabetes outcomes, measured by the proportion of patients meeting the Health Partners Optimal Diabetes Care measure.

We hypothesized that implementing an EHR in a group of primary care practices would change the proportion of patients who achieve "optimal diabetes care", defined as: HbA1c < 8%; LDL cholesterol < 100 mg/dL; Blood pressure < 130/80 mmHg; Aspirin use (as measured by prescription) in patients ≥40 years; and, Not smoking.

Secondary Aim 1: To estimate impact of an EHR on specific patient outcomes and compliance with recommended process of care related to diabetes.

We hypothesize that implementing an EHR in a group of primary care practices would: a) change the proportion of patients meeting the recommended levels for each of the intermediate patient outcome measures (HbA1c, total cholesterol, LDL cholesterol, triglycerides, blood pressure); and b) change the proportion of patients in compliance with the recommended delivery of diabetes related processes of care (HbA1c test, lipid panel, test for microalbuminuria, dilated retinal eye exam, complete foot exam, prescribed aspirin, influenza vaccination, smoking cessation counseling) collected in the AMA Physician Consortium Adult Diabetes Core Measure Set[1] when these measures are examined individually.

Secondary Aim 2: To estimate the prevalence of physician use of the Diabetes Management Form, and the effect of the Diabetes Management Form on patient outcomes related to diabetes as measured by the Optimal Diabetes Care measure.

We hypothesized that, among the patients treated after EHR implementation, voluntary physician use of the diabetes management form would result in a greater proportion of patients meeting the Optimal Diabetes Care measure than among those patients for whom it was not used; and that form use would be associated with a greater likelihood of meeting the Optimal Diabetes Care measure.

Scope

Background

The United States' healthcare system is geared towards responding to patients' acute needs. As the population ages and the prevalence and complexity of chronic diseases increase, substantial reorganization is needed. Electronic health records (EHRs) are one of the forms of health IT with the potential to support this reorganization by providing a mechanism to streamline communication between physicians using a universal patient record, make clinical guidelines available at the point of care and/or provide active evidence-based clinical decision support, provide registry-type functions that physicians can use to track patient compliance with disease-specific processes of care and achievement of recommended targets on relevant outcome measures, and provide a mechanism for determining physician-level compliance with evidence-based recommendations for quality monitoring and improvement purposes.[2] In the past decade, systematic reviews of studies examining the impact of EHRs and clinical decision support systems developed and customized in-house have shown improved adherence to clinical guidelines.[3-5] However, the small studies that have previously examined the implementation of commercially available EHRs did not show similarly positive results.[6,7] What was previously lacking from the evidence base were large, rigorous studies examining the impact of relatively rapid implementation of commercially available EHRs on quality of chronic disease care and patient outcomes,[5,8] – a gap in the evidence that was of considerable concern to critics of the Obama administration's 'full steam ahead' approach to national adoption of EHRs.[9]

A second area in which evidence remains sparse is that identifying the characteristics of or tools within health information technology that effectively support improved care. It has been demonstrated that the mere presence of an EHR is not associated with patients' increased attainment of recommended clinical targets,[10] but that specific functions, such as patient identification and tracking systems, problem lists, and electronic visit notes, embedded within an EHR can improve compliance with recommended processes of care.[11,12] There is less evidence that that these are associated with improved clinical outcomes.[13]

Setting

HealthTexas Provider Network (HTPN) is the ambulatory care network affiliated with the Baylor Health Care System, a not-for-profit integrated healthcare delivery system serving patients throughout North Texas. HTPN comprises >100 practices, with 450 physicians, and has >1 million patient encounters annually. Between May 2006 and December 2009, HTPN rolled out an EHR system (GE Centricity Physician Office –EMR 2005) across its practices on a staggered schedule. This study included all HTPN practices which met the following criteria: the practice includes physicians specializing in Internal Medicine or Family Medicine; the practice was part of HTPN on 1 July 2005; and, the practice had no prior experience (such as a pilot program) with the EHR. We included patient encounters with any physician specializing in IM or FM at these practices. Practices which closed after 1 July 2005 were included in analyses until their close date. All practices which merged after 1 July 2005 had the same EHR status at the time of the merger, and were retained in the analysis.

Participants

A total of 34 practices met study inclusion criteria and 29 had implemented the EHR before the first day of the last study year. For the primary aim and first secondary aim, we included all patients seen at these practices who had 2 or more diabetes visits between 1 January 2005 and 31 December 2005 (first prevalence cohort) or between 1 July 2005 and 30 June 2006 (second prevalence cohort). We excluded patients who were seen at more than one practice (n=660). We excluded all patients less than 40 years old (n=1495) because the aspirin recommendation applies only to those age 40 years and older. The final study population consisted of 14,051 diabetes patients, 6,376 of whom were eventually seen in practices using the EHR.

The secondary analysis looking at the impact of the DMF was limited to the 20 practices that implemented the EHR prior to January 1, 2007. We included all patients over the age of 40 years seen at these practices who had at least 2 diabetes-related visits during, and had 2 additional diabetes-related visits during both 2008 and 2009, with all components of the “optimal care” bundle measured at least once during each calendar year. Patients were excluded if they had any visits prior to 2007 where the DMF was accessed, or if they were seen at multiple practices during the study period were excluded (n = 106).

Methods

Study Design

This was on observational study advantage which took advantage of the staggered roll out of a commercially available EHR within a large network of ambulatory care physician practices. Starting in May 2006, HealthTexas Provider Network (HTPN) began implementing a network wide ambulatory electronic health record (EHR) system which incorporates clinical decision support (including physician reminders), computerized order entry, and a network-wide unified patient record, among other features. The EHR was implemented on a staggered schedule over several years. Starting on 1 January 2006, HTPN conducted a semi-annual universal chart review of all primary care practices, collecting data on several diabetes process of care measures and outcome measures. We used these data through 31 December 2010 to assess the impact of EHR implementation on quality of diabetes care.

The EHR implemented incorporated a diabetes-specific documentation and passive decision support tool, the Diabetes Management Form (DMF). We, therefore, also examined the impact of DMF use on diabetes-related process and outcome measures in a cohort of diabetes patients seen after EHR implementation.

Data Sources/Collection

In 2007 HTPN created a retrospective semi-annual diabetes prevalence cohort database to enable patient-, physician- and practice-level evaluation of the diabetes care provided, using the AMA Physician Consortium Adult Diabetes Performance Measure set. The cohorts were defined by the claims-based algorithm used by the Centers for Medicare and Medicaid Service (CMS).[14]

All patients with ≥2 ambulatory care visits ≥7 days apart with a diabetes-related billing code (CMS National Measurement Specifications Diabetes Quality of Care Measures [2002]: ICD-9-CM Diagnosis Codes 250.xx) during the preceding 12 months were identified from administrative data. Corresponding patient records were then reviewed to confirm the diabetes diagnosis, and process of care and clinical outcome data were collected for overlapping 12 month periods from both paper and electronic medical records by trained nurse abstractors using a standardized data collection tool created in MS Access.

Data regarding DMF use were obtained directly from the EHR. For all patients meeting the inclusion/exclusion criteria for this secondary analysis, we queried the EHR to determine occurrences of use of the DMF. Office visits during which the DMF was accessed were identified by performing a string search on a text field within the EHR for any of the following: 'Diabetes Management Assessment/Plan:', 'Diabetes Management Exam:', 'Diabetes Management History:' These strings are automatically inserted by the DMF and are expressed/formatted in ways HTPN physicians entering data ‘free hand’ seldom use. Thus, for any visit in which one of these strings was identified in the text field, the DMF was considered to have been used. We used multiple tables to develop these data into a categorical DMF Use variable (‘yes’ or ‘no’), and then matched the patients back to the HTPN diabetes prevalence cohort database using a two-step process: first, by practice and medical record number; then by practice and social security number. Any remaining patients in the chart review cohort were considered not to have been exposed to the DMF.

Interventions

HTPN implemented an EHR package that comprises GE *Centricity Physician Office –EMR 2005*, Clinical Content Consultants (CCC) advanced forms, and Kryptiq Secure Messaging and Docutrack. These components integrate clinical and demographic information, and incorporate clinical content and decision support, secure physician-physician messaging, and integrated scanning; they also provide a single patient record throughout HTPN which ensures that, no matter which HTPN physician a patient sees, all his/her current data are available at the point of care. This package incorporates tools specific to diabetes care: When a physician selects “diabetes” from the problem list on the patient assessment screen in the EHR, two automated reminders related to evidence-based recommendations appear as screen pop-ups – one stating that aspirin is recommended for patients age 40 years or older, the other providing reminders for overdue HbA1c, lipid panel, creatinine, microalbumin/creatinine ratio, and dilated retinal exam.

Selecting ‘yes’ on these prompts auto-fills the relevant fields in all related sections of the medical record (eg, adding aspirin to the medication list, and automatically creating orders for all laboratory tests or other services for which the patient is due). The EHR also incorporates the DMF, a documentation tool physicians can elect to use, which integrates diabetes-specific data review, passive clinical decision support (showing recommended targets for key diabetes measures and whether recommended processes of care were due but not prompting any particular action), order entry, and coded data capture capabilities.

The DMF provides patient-specific clinical decision support at two points: First, on the “Diabetes Self Education” tab recommendations appear directly below the relevant measure (for example, if the patient’s last recorded HbA1c level was >8%, the form suggests the physician “consider additional action”, but leaves it to the physician to determine what action might be appropriate) as well as reminders for evidence-based process of care measures in the form of due dates (shown as “now” if the recommended period has already elapsed). Second, the final screen of the DMF summarizes the set of “therapeutic recommendations” based on the information collected in the preceding screens.

Measures

Our primary analysis assessed the HealthPartners Optimal Diabetes Care measure, adopted by MN Community Measurement,[15,16] scoring a patient as 1 in a given cohort if the most recent measures reflected HbA1c ≤ 8%, LDL cholesterol <100 mg/dL, diastolic blood pressure < 80 mmHg, systolic blood pressure <130 mmHg, aspirin prescription, and non-smoking status; and scoring the patient zero otherwise. Secondary analyses assessed the effect of EHR implementation on each of the individual diabetes process and outcome measures. For the complete list of these measures see Table 3. These same process and outcome measures were used in the secondary analysis examining the impact of the DMF.

Analysis

Primary Aim and Secondary Aim 1. Patient characteristics for the study population were summarized at baseline and according to their eligibility for each subsequent data collection cohort; baseline patient characteristics were also summarized according to whether the patient was ever exposed to EHR or not, and tested for differences using chi-square tests adjusted for clustering by practice [17]. Each outcome measure was summarized over all patient-years (annual observations on a single patient) by EHR exposure group, and the difference in crude rates between the two groups was calculated. The rates of optimal care were graphed for each exposure group over the study period. The hypothesis that EHR implementation improves optimal care was tested by estimating a mixed effects logistic model with EHR exposure as the primary independent variable, adjusted for age, sex, insulin usage, and year of study. Cohorts and practices were designated as “post-EHR" if the EHR was implemented at that practice prior to the start date of the cohort. Because of the staggered implementation of the EHR, calculating a difference score for patients in the unexposed group would have been problematic. Instead, hierarchical generalized linear model (HGLM) techniques were used to account for auto correlation of outcomes within patients, and within practices. Specifically, if Y_{ijk} indicated whether the i^{th} observation of the j^{th} patient seen at the k^{th} practice met the criteria for optimal care, we estimated:

$$\text{logit}(\Pr(Y_{ijk} = 1)) = \beta_{0jk} + \beta_{EHR}{*}EHR + \beta_{C}{*}T + \beta_{Z}{*}Z \qquad (1)$$
$$\beta_{0jk} = \gamma_{000} + u_{jk} + v_k \quad ; u_{jk} \sim N(0,\sigma^2_u),\ \ v_k \sim N(0,\sigma^2_v)$$

where EHR is EHR exposure, Z is a vector of age, sex, and insulin usage indicators and T represents calendar year. The error term u_{jk} represents random effect attributed to patient, and v_k, is a random effect at the practice level. Whether exposure to EHR had any effect on the outcome independent of secular time was assessed by testing the hypothesis H_0: $\beta_{EHR} = 0$; the odds ratio, defined as OR = $\log^{-1}(\beta_{EHR})$, was reported. To improve interpretation of model coefficients, simulation was used to estimate the difference in effect and 95% confidence interval for an average patient seen in year 5 with exposure to the EHR as compared to no exposure to EHR [18]. Model fit was assessed by calculating the C-statistic.

The above analysis was replicated for each of the individual process and outcome measures, to assess whether there were differential effects on these. In addition, separate mixed effects models using only patients treated in EHR exposed practices, with the number of months since EHR implementation as the independent variable, were estimated to assess whether the rate of optimal care for diabetes or any individual process or outcome measures improved with increasing exposure to EHR:

$$\text{logit}(\Pr(Y_{ijk} = 1)) = \beta_{0jk} + \beta_{EHR}{*}\text{EHRt} + \beta_Z{*}Z \qquad (2)$$
$$\beta_{0jk} = \gamma_{000} + u_{jk};\ u_{jk} \sim N(0,\sigma^2_u)$$

Here, EHRt is the number of months between implementation and the midpoint of the cohort period; calendar year was omitted because of collinearity with this exposure variable. Simulation was used to estimate the marginal effect and 95% confidence interval of EHR exposure after 24 months compared with 12 months of implementation for the average patient seen in year 5, and report this as the year-on-year odds ratio. Finally, because the recommended threshold for HbA1c level over the study period has been inconstant, both model (1) and model (2) were estimated for the outcome HbA1c $\leq$7%, as well as an additional model analogous to (1) with linear response and dependent variable the absolute measure of HbA1c.

All analyses were performed using Stata 11.1 [StataCorp, College Station TX].

Secondary Aim 2. Characteristics for the subset of patients included in the analysis examining the impact of the DMF on diabetes care and outcome were summarized at baseline, and χ^2 tests used to test for differences between patients who were and were not later exposed to the DMF. DMF usage during 2007, and the outcome and process measures at baseline and follow up for each patient according to whether the DMF had been accessed or not during 2008, were also summarized. The relationship between DMF use and each outcome was assessed by estimating a series of logistic HGLMs. The HGLM models account for multiple observations per patient and multiple patients within practices by specifying random effects at the patient and practice level. In particular, if Y_{ijk} represents the i^{th} measurement on the j^{th} patient at the k^{th} practice, we estimated:

$$\text{logit}(\Pr(Y_{ijk} = 1)) = \beta_0 + \beta_t{*}T + \beta_{DMF}{*}(\text{DMF}) + \beta_1{*}(T \text{ x DMF}) + \text{YEAR} + u_j + v_k$$

where T indicates the time period (zero for baseline, one for follow up), DMF indicates whether the patient was exposed to the form during 2008, and u_j, v_j are normally distributed random errors at the patient and practice level, respectively. The effect of DMF exposure on the outcome measure was assessed by testing $\beta_1 = 0$. Two models were estimated for each outcome, one as specified above and one also including age, sex, insulin use, and number of visits during the baseline period. Recycled predictions to estimate the difference in pre-post differences between exposure groups were used to improve interpretation of results.[19] The main analyses were replicated using a modified exposure variable which included form use during either 2008 or 2009.

All analyses were performed using Stata 12.1 (2011. StataCorp, College Station TX).

Limitations

This study's primary limitation is that of any observational study: the possibility of unobserved differences between comparison groups cannot be eliminated. Specifically, here, early adopters of the EHR may have differed from practices that implemented the EHR later in multiple ways that could be independently associated with the quality of diabetes care provided. And, since these early adopting practices accrued more post-EHR patients during the study period, the results are weighted in their direction. At the patient level, this study was limited by the limited clinical, demographic, and treatment data that were available; such data could be used to mitigate the observational nature of the study by allowing differences between patients in the exposed and unexposed groups to be assessed and accounted for. However, such data as were available show no differences in sex or insulin usage; and, while the non-exposed group was significantly older, older patients had the highest rate of optimal care in each year (ad hoc analysis, not shown), suggesting this imbalance biased the main result towards the null.

For the process of care measures, an additional limitation is the inability to differentiate between true changes in practice and changes in documentation with EHR implementation. Documentation practices were likely influenced by the introduction of the new health record technology and some of the improvements seen in process measures probably reflect this to some degree. Documented aspirin use (included in the optimal care measure) might be particularly subject to this limitation in light of the automated prompt physicians received.

For the analyses examining the impact of the DMF on diabetes-related processes and outcomes of care, a critical limitation is that it was impossible to tell how much of the DMF was used – physicians could have used many features, or could have just used the first page (patient history). Thus, while the use of the DMF may lead to better care, it is difficult to generalize our findings to specific recommendations; for example, a more user-friendly presentation of the same passive clinical decision support, or a summary of recommendations that physicians could not bypass, may have produced different results.

Results

Principal Findings

After adjusting for patient age, sex, and insulin use, patients exposed to the EHR were significantly more likely to achieve "optimal care" when compared with unexposed patients (P < 0.001), with an estimated difference of 9.20% (95%CI[6.08%, 12.33%]) in the final year between exposed patients and patients never exposed. Components of the optimal care bundle showing positive improvement after adjustment were systolic blood pressure < 80mmHg, diastolic blood pressure < 130mmHg, aspirin prescription and smoking cessation. Among patients exposed to EHR, all process and outcome measures except HbA1c and lipid control showed significant improvement.

After adjusting for number of visits, age, sex, and insulin use, DMF-exposed patients showed less improvement in attaining "optimal care" (estimated difference-in-difference [DID]: -2.06 percentage points; P<0.001), LDL-cholesterol (DID: -2.30; P=0.023), blood pressure (DID : -3.05; P<0.001) and total cholesterol (DID: -0.47 ; P=0.004) targets. Documented microalbumin tests, aspirin prescription, and eye and foot exams increased more. Thus, DMF use was associated with smaller gains in achieving evidence-based targets, but greater improvement in documented delivery of care.

Outcomes

Primary Aim and Secondary Aim 1. Characteristics of the study population at baseline and for each follow-up study year are shown in Table 1; characteristics of patients eventually seen in practices using the EHR vs. those never seen in such a practice are shown in Table 2.

Table 1. Characteristics of 14,051 diabetes patients age 40 years or older seen in HealthTexas Provider Network primary care practices at baseline (calendar year 2005) and at subsequent years of observation

	2005	2006	2007	2008	2009
	n(%)	n(%)	n(%)	n(%)	n(%)
N	14051 (100.0)	9742 (100.0)	8086 (100.0)	6962 (100.0)	6209 (100.0)
Age 41-50	3079 (21.9)	1764 (18.1)	1230 (15.2)	884 (12.7)	637 (10.3)
Age 51-60	5084 (36.2)	3524 (36.2)	2880 (35.6)	2466 (35.4)	2119 (34.1)
Age 61-70	4431 (31.5)	3286 (33.7)	2947 (36.4)	2678 (38.5)	2506 (40.4)
Age 70+	1457 (10.4)	1168 (12.0)	1029 (12.7)	934 (13.4)	947 (15.3)
Female	7100 (50.5)	4985 (51.2)	4102 (50.7)	3478 (50.0)	3064 (49.3)
HbA1c	7.2 (1.6)	7.0 (1.4)	7.2 (1.5)	7.2 (1.4)	7.4 (1.4)
Insulin	2375 (16.9)	1784 (18.3)	1742 (21.5)	1686 (24.2)	1650 (26.6)
EHR			627 (7.8)	4288 (61.6)	5102 (82.2)

* last HbA1c measurement in the year, mean(sd)

Table 2. Baseline characteristics of 14,051 diabetes patients age 40 years or older seen in HealthTexas Provider Network primary care practices by electronic health record (EHR) exposure status

	Never Exposed to EHR	Exposed to EHR	
	n(%)	n(%)	P-value*
N	7675 (100.0)	6376 (100.0)	
Age 41-50	1682 (21.9)	1397 (21.9)	
Age 51-60	2620 (34.1)	2464 (38.6)	
Age 61-70	2198 (28.6)	2233 (35.0)	
Age 70+	1175 (15.3)	282 (4.4)	
Female	3879 (50.5)	3221 (50.5)	0.986
HbA1c	7.3 (1.7)	7.2 (1.5)	0.004
Insulin	1367 (17.8)	1008 (15.8)	0.002

* P-values based in chi-square or t-test statistic adjusted for clustering by practice.

The percentage of diabetes patients meeting the standards of “optimal care” was greater in the EHR exposed group when compared with the non-EHR group (Table 3). Similarly, individual process and outcome measures showed similar patterns of better performance with EHR exposure: there was significantly greater compliance with all process measures except measurement of HbA1c, lipids, and urinanalysis, which showed significant declines; and flu vaccine, which showed a non-significant increase. Performance on individual outcome measures was significantly improved for blood pressure control (systolic and diastolic), and smoking status ($P<0.001$); however, we saw small but significant declines for HbA1c, lipid, and triglyceride control. All individual process and outcome model C-statistics were above 0.80 except for HbA1c ≤ 8% (C-statistic = 0.51) and smoking status (C-statistic = 0.60).

When only patients exposed to the EHR were considered, time since implementation was associated with an increased rate of "optimal care" ($P< 0.001$), with an estimated 12 month improvement of 4.98 (95%CI [3.15,6.81]) percentage points (Table 4). The C-statistic for the model was 0.92. There were similar significant improvements increasing exposure for individual process and outcome measures with the exceptions of blood pressure measurement, which was unchanged over time (baseline value of 99.9%, follow-up value of 100%; P=0.965), and HbA1c≤ 8%, which declined an estimated -1.23 (95% CI[-2.40,-0.05]; P = 0.041) percentage points with each additional 12 months of exposure.

The results of the secondary analyses using different measures of HbA1c (not shown) were entirely consistent with those above, with a slight but significant decline in whether patient HbA1c was below 7% and a slight but significant increase in the absolute level of HbA1c (both P-values < 0.05).

Table 3. Impact of electronic health record exposure on process and outcome measures for diabetes care, based on data collected between 1 January 2006 and 1 January 2011 for diabetes seen in HealthTexas Provider Network primary care practices: crude change, and adjusted for baseline performance and cohort

	Crude rates				Results adjusted for baseline performance and cohort		
	Non-EHR	EHR	Improve-ment	C-statistic	OR (95% CI)	Effect in year 5[‡]	P-value[†]
N (patient years)	35,033	10,017					
Process	**patient years (%)**	**patient years (%)**					
HbA1c	32,473 (92.7)	9,775 (97.6)	4.9	0.862	0.6 (0.5, 0.6)	-0.17 (-0.24,-0.10)	0.000
Blood Pressure	34,997 (99.9)	10,015(100.0)	0.1	0.903	36.5 (6.0, 105.9)	0.00 (-0.01,0.01)	0.000
Lipids							
Cholesterol	30,618 (87.4)	9,389 (93.7)	6.3	0.894	0.9 (0.8, 1.0)	-0.10 (-0.19,-0.01)	0.027
Triglycerides	30,626 (89.7)	9,390 (94.9)	5.1	0.894	0.8 (0.7, 0.9)	-0.12 (-0.20,-0.04)	0.002
Renal function							
Microalbumin	18,705 (54.8)	7,073 (71.5)	16.7	0.847	1.2 (1.1, 1.3)	0.77 (0.33,1.20)	0.000
Urinanalysis	17,744 (50.6)	4,768 (47.6)	-3.1	0.867	0.8 (0.7, 0.8)	-2.98 (-4.26,-1.71)	0.000
Eye Exam	7,016 (20.0)	4,190 (41.8)	21.8	0.870	1.5 (1.4, 1.7)	8.11 (6.07,10.16)	0.000
Foot Exam	3,778 (10.8)	5,670 (56.6)	45.8	0.911	2.8 (2.6, 3.0)	8.06 (4.27,11.85)	0.000
Influenza vaccine	17,709 (50.5)	6,169 (61.6)	11.0	0.893	1.1 (1.0, 1.1)	0.44 (-0.24,1.11)	0.197
Aspirin	18,001 (51.4)	8,232 (82.2)	30.8	0.965	4.8 (4.4, 5.3)	0.44 (0.21,0.67)	0.000

Smoking Assessment	33,025 (94.3)	9,877 (98.6)	4.3	0.829	2.6 (2.2, 3.1)	0.25 (0.10,0.41)	0.000
Outcomes							
HbA1c ≤ 8%	26,200 (80.7)	7,708 (78.9)	-1.8	0.511	0.9 (0.8, 1.0)	-0.13 (-0.25,-0.01)	0.025
SBP<130mmHg	16,123 (46.1)	5,230 (52.2)	6.2	0.883	1.2 (1.1, 1.3)	2.18 (1.01,3.35)	0.000
DBP< 80mmHg	18,556 (53.0)	6,366 (63.6)	10.5	0.881	1.3 (1.2, 1.3)	2.07 (1.20,2.93)	0.000
LDL<100 mg/dL	19,093 (65.5)	6,448 (71.3)	5.9	0.943	0.7 (0.6, 0.8)	-0.60 (-0.81,-0.39)	0.000
Triglycerides<150 mg/dL	15,911 (52.0)	5,149 (54.8)	2.9	0.955	0.9 (0.8, 1.0)	-0.37 (-0.73,-0.02)	0.037
Not Smoking	28,893 (82.5)	8,707 (86.9)	4.4	0.597	1.1 (1.0, 1.2)	1.07 (0.10,2.05)	0.027
Optimal Care[§]	2,963 (11.0)	1,792 (20.2)	9.3	0.936	1.5 (1.3, 1.6)	9.20 (6.08,12.33)	0.000

** Each patient year represents an annual observation on a single patient.*
[†] *P-value for test of EHR exposure*
[‡] *Estimated from model using simulation for year 5*
[§]HbA1c ≤ 8%; LDL cholesterol <100 mg/dL; blood pressure <130/80 mmHg; not smoking; and documented aspirin use

Table 4. Change over time associated with increased electronic health record exposure, based on data collected between 1 January 2006 and 1 January 2011 for diabetes patients age 40 years or older seen in HealthTexas Provider Network primary care practices: annualized odds ratio (OR) and estimated annual effect, adjusted for age, sex, insulin usage

	year-on-year OR (95% CI)	**Annual Effect[‡]**	**P-value[†]**	**C-statistic**
N (patient years)				
Process				
HbA1c	1.55 (1.25, 1.90)	0.72 (0.18,1.25)	0.001	0.6714
Blood Pressure	2.34 (0.13, 7.96)	-0.03 (-2.70,2.65)	0.965	0.5
Lipids				
Cholesterol	1.37 (1.18, 1.57)	1.00 (0.30,1.70)	0.000	0.6412
Triglycerides	1.33 (1.14, 1.54)	0.75 (0.14,1.36)	0.003	0.6324
Renal function				
Microalbumin	1.28 (1.19, 1.38)	2.97 (1.58,4.35)	0.000	0.6303
Urinanalysis	1.13 (1.05, 1.22)	2.61 (0.75,4.48)	0.004	0.7367
Eye Exam	1.12 (1.05, 1.20)	2.86 (0.86,4.85)	0.004	0.5966
Foot Exam	2.62 (2.43, 2.82)	15.65 (10.29,21.01)	0.000	0.7325
Influenza vaccine	0.86 (0.81, 0.92)	-3.08 (-4.77,-1.39)	0.000	0.6236
Aspirin	1.77 (1.61, 1.94)	4.90 (3.10,6.71)	0.000	0.6826
Smoking Assessment	3.62 (2.22, 5.43)	0.23 (-0.11,0.56)	0.000	0.84
Outcomes				
HbA1c ≤8%	0.90 (0.82, 0.98)	-1.23 (-2.40,-0.05)	0.041	0.7409
SBP<130mmHg	1.26 (1.18, 1.34)	5.64 (3.72,7.57)	0.000	0.5763
DBP<80mmHg	1.18 (1.10, 1.26)	3.41 (1.61,5.21)	0.000	0.6503
LDL<100 mg/dL	1.07 (0.98, 1.16)	0.17 (-1.40,1.74)	0.838	0.6126
Triglycerides<150 mg/dL	1.08 (1.01, 1.15)	1.81 (-0.13,3.76)	0.069	0.5739

	year-on-year OR (95% CI)	Annual Effect‡	P-value†	C-statistic
Not Smoking	1.14 (1.03, 1.25)	1.20 (0.06,2.35)	0.030	0.6196
Optimal Care§	1.32 (1.21, 1.43)	4.98 (3.15,6.81)	0.000	0.6188

* Odds ratios based on average year-to-year odds.
†P-value for test of EHR exposure
‡Estimated difference in rates in year 5 from model using simulation
§ HbA1c ≤ 8%; LDL cholesterol <100 mg/dL; blood pressure <130/80 mmHg; not smoking; and documented aspirin use (for patients ≥ 40 years)

Secondary Aim 2. There were 2108 diabetes patients who met the inclusion criteria for Secondary Aim 2; patient characteristics are shown in Table 5. There were no significant differences in age, sex, number of visits, insulin use or likelihood of meeting the criteria for optimal care at baseline.

Table 5. Baseline characteristics of 2108 diabetes patients age 40 years or older seen in 20 HealthTexas Provider Network primary care practices that had implemented an electronic health record (EHR), and who were not exposed to the Diabetes Management Form (DMF) embedded in the EHR prior to 2008

	All Patients	Control	Exposed to DMF in 2008	P-value
	n(%)	n(%)	n(%)	
N	2108 (100.0)	1005 (100.0)	1103 (100.0)	
Age Category				0.109
40-49	337 (16.0)	158 (15.7)	179 (16.2)	
50-59	709 (33.6)	314 (31.2)	395 (35.8)	
60-69	825 (39.1)	415 (41.3)	410 (37.2)	
70+	237 (11.2)	118 (11.7)	119 (10.8)	
Sex				0.110
Male	1025 (48.6)	507 (50.4)	518 (47.0)	
Female	1083 (51.4)	498 (49.6)	585 (53.0)	
Insulin use				0.194
No	1764 (83.7)	852 (84.8)	912 (82.7)	
Yes	344 (16.3)	153 (15.2)	191 (17.3)	
Visits in 2007				0.831
1	32 (1.5)	14 (1.4)	18 (1.6)	
2	385 (18.3)	194 (19.3)	191 (17.3)	
3	544 (25.8)	248 (24.7)	296 (26.8)	
4	453 (21.5)	211 (21.0)	242 (21.9)	
5	271 (12.9)	131 (13.0)	140 (12.7)	
6-10	380 (18.0)	186 (18.5)	194 (17.6)	
11+	43 (2.0)	21 (2.1)	22 (2.0)	
HbA1c<=8%				0.410
No	181 (8.6)	81 (8.1)	100 (9.1)	

	All Patients	Control	Exposed to DMF in 2008	P-value
Yes	1927 (91.4)	924 (91.9)	1003 (90.9)	
Optimal Care				0.356
No	1848 (87.7)	888 (88.4)	960 (87.0)	
Yes	260 (12.3)	117 (11.6)	143 (13.0)	

Rates for each outcome and process measure at baseline and follow up according to whether the DMF was accessed for the patient during 2008, as well as the P-values based on the HGLM models assessing the effect of DMF exposure on outcomes are shown in Table 6. In this unadjusted analysis, the use of the DMF was associated with a significantly smaller gain in attainment of "optimal care" status, blood pressure control, and cholesterol control, and with a significantly greater unadjusted decline in HbA1c control. All unadjusted gains in documented process measures were significantly greater in the DMF-exposed group, except for HbA1c measurement, lipid measurement, smoking assessment, and influenza vaccination.

Table 6. Unadjusted results for changes from baseline (2007) to follow-up (2009) in performance on evidence-based diabetes-related process and outcomes of care measures for 2108 diabetes patients age 40 years or older seen in 20 HealthTexas Provider Network primary care practices that had implemented an electronic health record, according to whether patients were exposed to the Diabetes Management Form (DMF) in 2008

Table 6a. Not Exposed to the DMF in 2008

	Baseline n/N (%)	Follow-up n/N (%)	Change (% pts)
Optimal Care	**117/1005 (11.6)**	**242/1005 (24.1)**	**12.4**
Outcomes			
HbA1c ≤8%	861/1005 (85.7)	850/1005 (84.6)	-1.1
LDL<100 mg/dL	691/1005 (68.8)	721/1005 (71.7)	3
BP<130/80 mmHg	359/1005 (35.7)	492/1005 (49.0)	13.2
Triglycerides<150 mg/dL	585/1004 (58.3)	625/1004 (62.3)	4
Cholesterol <200 mg/dL	841/1005 (83.7)	867/1005 (86.3)	2.6
Smoking status	122/1005 (12.1)	125/1005 (12.4)	0.3
Process			
Aspirin Prescribed	567/1005 (56.4)	821/1005 (81.7)	25.3
HbA1c checked	1005/1005 (100.0)	1005/1005 (100.0)	0
Lipids checked	1004/1005 (99.9)	1004/1005 (99.9)	0
Microalbumin	640/1005 (63.7)	727/1005 (72.3)	8.7
Eye Exam	311/1005 (30.9)	457/1005 (45.5)	14.5
Foot Exam	87/1005 (8.7)	569/1005 (56.6)	48
Flu vaccine	566/1005 (56.3)	622/1005 (61.9)	5.6
Smoking Assessed	1005/1005 (100.0)	1005/1005 (100.0)	0

	Baseline n/N (%)	Follow-up n/N (%)	Change (% pts)
Smoking Cessation Counseling	93/122 (76.2)	111/125 (88.8)	12.6

Table 6b. Exposed to DMF in 2008

	Baseline n/N (%)	Follow-up n/N (%)	Change (% pts)	P-value*
Optimal Care	**143/1103 (13.0)**	**260/1103 (23.6)**	**10.6**	**<0.001**
Outcomes				
HbA1c ≤8%	916/1103 (83.0)	890/1103 (80.7)	-2.4	0.021
LDL<100 mg/dL	791/1103 (71.7)	802/1103 (72.7)	1	0.050
BP<130/80 mmHg	390/1103 (35.4)	507/1103 (46.0)	10.6	<0.001
Triglycerides<150 mg/dL	633/1102 (57.4)	661/1103 (59.9)	2.5	0.188
Cholesterol <200 mg/dL	941/1103 (85.3)	966/1103 (87.6)	2.3	0.018
Smoking status	130/1103 (11.8)	114/1103 (10.3)	-1.5	0.213
Process				
Aspirin Prescribed	651/1103 (59.0)	960/1103 (87.0)	28	<0.001
HbA1c checked	1103/1103 (100.0)	1103/1103 (100.0)	0	NA
Lipids checked	1102/1103 (99.9)	1103/1103 (100.0)	0.1	NA
Microalbumin	633/1103 (57.4)	834/1103 (75.6)	18.2	<0.001
Eye Exam	276/1103 (25.0)	543/1103 (49.2)	24.2	<0.001
Foot Exam	144/1103 (13.1)	795/1103 (72.1)	59	<0.001
Flu vaccine	640/1103 (58.0)	651/1103 (59.0)	1	0.005
Smoking Assessed	1103/1103 (100.0)	1103/1103 (100.0)	0	NA
Smoking Cessation Counseling	93/130 (71.5)	95/114 (83.3)	11.8	0.127

* P-value based on random effects model with form ever used as exposure, adjusted for # visits
BP =blood pressure; DMF = diabetes management form; LDL = low density lipoprotein cholesterol

Following adjustment for age, sex, insulin usage, number of visits, and year, DMF use was still associated with a significantly smaller gain in “optimal care (see Table 7). Impact on individual process and outcome measures were also similar to the unadjusted results. Differences in gains/losses in the percentages of patients meeting the triglyceride and HbA1c targets were not statistically significant, but were still unfavorable for DMF exposure.

Table 7. Changes from baseline (2007) to follow-up (2009) in performance on evidence-based diabetes-related process and outcomes of care measures for 2108 diabetes patients age 40 years or older seen in 20 HealthTexas Provider Network primary care practices that had implemented an electronic health record, according to whether patients were exposed to the Diabetes Management Form (DMF) in 2008 and adjusted for age, sex, insulin use, and number of visits.

	No DMF Use in 2008 (n=995) absolute change (%)	DMF Use in 2008 (n=1092) absolute change (%)	Difference	P-value
Optimal Care	13.65	11.59	-2.06	<0.001
Outcomes				
HbA1c ≤8%	-1.42	-2.77	-1.35	0.166
LDL<100 mg/dL	3.39	1.09	-2.30	0.023
BP<130/80 mmHg	14.89	11.84	-3.05	<0.001
Triglycerides<150 mg/dL	4.76	3.00	-1.76	0.264
Cholesterol <200 mg/dL	2.70	2.23	-0.47	0.004
Smoking	0.00	-0.01	-0.01	0.22
Process				
Aspirin Prescribed	29.81	31.66	1.85	<0.001
HbA1c checked				NA
Lipids checked				NA
Microalbumin	10.11	19.63	9.53	<0.001
Eye Exam	16.10	26.43	10.33	<0.001
Foot Exam	51.32	60.40	9.08	<0.001
Flu vaccine	6.43	1.13	-5.30	0.005
Smoking Assessed				NA
Smoking Cessation Counseling	12.91	12.06	-0.85	0.087

* “optimal care” is defined as: HbA1c ≤ 8%; LDL cholesterol < 100 mg/dl; blood pressure < 130/80 mmHg; not smoking; and documented aspirin use.

BP =blood pressure; DMF = diabetes management form; LDL = low density lipoprotein cholesterol

Discussion

This study showed that implementation of a commercially-available EHR had a meaningful effect on the documented care and outcomes of patients with diabetes. EHR exposure was associated with significant improvement in the documented rates of patients achieving “optimal care,” as well as in many individual process and outcome measures. In addition, a pattern of improvement in optimal care was seen with increasing exposure to the EHR, supporting the hypothesis that the improvements seen at least partly resulted from use of the EHR. Effects on the individual process measures were mixed, with rates of HbA1c testing, lipid measurement, and urinanalysis declining while compliance with other recommended processes increased; similarly for the outcome measures, HbA1c and lipid control declined, while the other measures improved with EHR exposure.

These results are consistent with previous findings on the effect of EHR implementation on chronic disease care and management. Analyses of National Ambulatory Medical Care Survey and Ambulatory Medical Care Survey data found no consistent association between either a complete EHR or any specific EHR components and receipt of appropriate therapy for chronic conditions [13], and found use of an EHR was generally associated with no difference in quality.[20] For diabetes, performance on process and outcome indicators was generally worse for physicians using an EHR in one study [6] and worsened during the first 2 years following implementation of a commercially-available EHR in another.[7]

A recent randomized controlled trial showed significant improvements in HbA1c and systolic blood pressure control, but only borderline improvement on diastolic blood pressure control, and no improvement on LDL cholesterol levels.[21] In contrast, a group of 38 practices that used an electronic registry derived from an EHR to monitor and provide feedback to physicians on a 'bundle' of 9 'best practices' for diabetes care showed an increase in the number of patients receiving all 9 measures from 2.4% to 6.5% in 12 months; [22] and a recent study in 46 primary care practices found that, after adjusting for covariates such as insurance type and patient demographics and socioeconomic factors, compliance with the composite measure for diabetes processes of care was 35.1% higher at practices with an EHR (incorporating clinical decision support targeting regionally endorsed standards of care) than paper-based practices, and performance on the intermediate outcomes composite measure was 15.2% higher at EHR practices. [23]

Looking at the impact of the DMF on quality of diabetes care, patients for whom the DMF was used had a smaller increase in likelihood of meeting the standards of "optimal care" during a follow-up year. After risk adjustment, there was an estimated absolute increase of 11.6 percentage points in the proportion of patients achieving "optimal care" among patients with at least one visit during 2008 in which the DMF was accessed, compared with an estimated increase of 13.7 percentage points among patients not exposed to the form.

Possible explanations for DMF-use having failed to achieve greater improvement in patient outcomes include the lack of active clinical decision support and other key features of clinical decision support systems known to be associated with improvement [24], and the fact that it was physician-focused, while the changes required to alter a patient's diabetes-related outcome measures are in the patient's lifestyle, making tools that assist patients in self-management more likely to achieve improvement. [25]

Greater increases in the rates of aspirin prescription, eye exam, foot exam, and microalbumin testing were seen with DMF use, although it is likely that large shares of these improvements are due to improved documentation with use of the structured form. [26] Greater improvement in these process measures with DMF use is consistent with the observations reported for similar documentation-based decision support tools for chronic disease management.[27,28]

In contrast, studies examining more intensive, active clinical decision support for chronic disease management have shown disappointing results in improving compliance with evidence-based guidelines,[29,30] leading the authors to conclude that the "physicians rebelled against the notion of the computer telling them how to manage their patients"[29] or that the active clinical decision support provided recommendations with which the physicians did not agree or that it did not fit well with the clinical workflow.[30]

Conclusions

The implementation of commercially-available electronic health records in primary care practice may lead to significant improvements in the both processes of care and intermediate outcomes for chronic conditions such as diabetes, but did not appear to affect the most important measure of diabetes care, HbA1c control. The incremental effect of the DMF was negative or mixed. Its use was associated with smaller gains in achieving evidence-based targets, but greater improvement in documented delivery of care.

As room for further improvement exists, future efforts should examine the possibilities of enhancing or expanding the decision-support capabilities within EHRs to focus more directly on improving outcomes, and of using the EHR data to create disease-based registries that can support care coordination and population management initiatives.

Significance and Implications

Diabetes is an increasingly common chronic disease that requires long-term management. Historically, the care provided to diabetes patients has fallen short of the best care practices established in evidence-based clinical guidelines. A decade ago, there was some perception that health information technology would be the "magic bullet" that cured the ills of chronic disease management – ensuring all the patients received all the appropriate evidence-based processes of care and improving clinical outcomes.

This study, and the similar results of other studies evaluating the impact of health information technology in the intervening years, demonstrates that health information technology can indeed help improve the quality of chronic disease care – particularly in increasing compliance with delivery of evidence-based processes of care – but that it cannot provide great improvements in and of itself. This is particularly true of goals to improve performance on clinical outcomes. Given that today the adoption of at least basic health information technology (such as an EHR) is generally viewed as inevitable, research needs to move on from the question of "Does implementation of health information technology improve care?" to that of "How can we use health information technology to improve quality of care?"

The results presented here suggest some answers to this question. First, the success seen in improving guideline compliance for diabetes-related processes of care, both with the EHR as a whole and when looking for incremental benefit of the DMF, suggest that structuring EHR screens to ensure physicians are presented with all the relevant information for the patient's particular condition in a single place, while leaving decisions about the appropriate response to the physician's clinical judgment and the patient's expressed preferences, may be a more successful strategy for increasing the use of evidence-based practices in chronic disease management than more active clinical decision support. Second, the lack of improvement observed in some of the important diabetes-related clinical outcomes – most notably in glucose and lipid control – suggests that efforts to improve these should not focus on physician-centric health information technology interventions such as the EHR and embedded DMF examined here. As these are factors substantially influenced by patients' health behaviors and environment, future initiatives should perhaps focus on tools that educate patients and support their daily efforts at disease management.

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List of Publications and Products

1. Herrin J, da Graca B, Nicewander D, Fullerton C, Aponte P, Stanek G, Cowling T, Collinsworth A, Fleming NS, Ballard DJ. The Effectiveness of Implementing an Electronic Health Record on Diabetes Care and Outcomes. *Health Serv Res*. Health Serv Res. 2012 Aug;47(4):1522-40. Winner of the John Eisenberg Award for the best paper published in 2012 in HSR.

2. Herrin J. Impact of an EHR-based Diabetes Management Form on Quality and Outcomes of Diabetes Care in Primary Care Practices. AHRQ Annual Conference, Bethesda, MD, Sept 9-11, 2012.

3. Herrin J, Aponte P, da Graca B, Stanek G, Cowling T, Fullerton C, Hollander P, Ballard DJ. Impact of an EHR-based Diabetes Management Form on Quality and Outcomes of Diabetes Care in Primary Care Practices. International Society for Quality in Health Care Annual Meeting, Geneva, Oct 21-24, 2013.

4. Herrin J, da Graca B, Aponte P, Stanek HG, Cowling T, Fullerton C, Hollander P, Ballard DJ. Impact of an EHR-based Diabetes Management Form on Quality and Outcomes of Diabetes Care in Primary Care Practices. *Am J Med Qual* (in press).