Trial of Decision Support to Improve Diabetes Outcomes

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ABSTRACT

Purpose: To estimate the effects of EMR-centered diabetes decision support (CDS-DM^2) on 1) quality and 2) utilization. Secondary analyses examine adoption of CDS.
Scope: 200 physicians in 24 practices of two health systems
Methods: Parallel 2-year trials with a common feature (DM^2) across the systems were used. System A compared DM^2 with EMR alone; DM^2 included real-time clinical decision support for physicians. System B's groups included patient portal access to their records (EMR-PA); EMR-PA enhanced by diabetes-specific features (PA-E); and PA-E plus DM^2 (Both). Quality was measured by changes in 1) A1c levels and 2) an eight-item ADA score, subdivided into patient-centered (5) and MD-centered (3) components.
Results: There were no significant cross-group changes in A1c levels associated with DM^2; borderline improvements in the ADA-8 score; and a significant 25% relative improvement in the three-item, MD-centered subscore ($p<0.001$). DM^2 was associated with a 20% reduction in hospitalizations ($p=0.01$) but no significant reductions in ED or primary care visits. There was more web portal adoption among patients in the PA-E and "both" groups than in the group with PA alone.
Conclusions: CDS substantially improved physician-centered, but not patient-centered, quality measures, and it appears to have improved hospitalization rates. Disease-enhanced features may increase patient web portal use.

Key Words: Diabetes, Heath Information Technology, Decision Support

PURPOSE

Diabetes is epidemic in the United States and is the most common cause of adult blindness, amputations, kidney failure, and cardiovascular disease. The disease and its complications are more prevalent among African Americans and Hispanics than among White Americans. The CDC estimates that 90% of these complications could be eliminated if we closed the gap between what is possible and what is actually done in the care of patients with diabetes. Much of this care depends on physician decision making in clinical settings, but a growing body of work also highlights the key roles of patient-centered self-management and contextual variables, such as the adequacy of health insurance.

Whether electronic medical record (EMR)-catalyzed clinical decision support (CDS) can help close the gap is unclear. Approaches that are now possible include sophisticated CDS focused on helping physicians and their practices undertake disease management for diabetes (DM^2) as well as patient-centered web-portal access (PA) CDS setups that can be enhanced by disease-specific features (PA-E). Whether disease-specific enhancements to PA coupled with physician-centered CDS (PA-E plus DM^2) could be synergistic for improving patient outcomes is untested.

In the current investigation, we examine the quality and utilization-related effects of CDS on patients with diabetes in 24 practice sites of two large healthcare systems. Parallel, 2-year cluster trials were undertaken that included a common feature (DM^2). Specific aims include:

Primary Aim 1. To estimate the incremental effects of DM^2 on patient quality measures, including changes in hemoglobin A1c levels and a composite eight-item ADA score, then divided into subscores related to patient-centered standards (ADA-5) and physician-centered standards (ADA-3)
Secondary Aim 1a. To estimate the effects of insurance on baseline glycemia, adjusting for patient demographics, clinical comorbidities and adherence-related measures, census-derived contextual measures, and site of care
Secondary Aim 1b. To estimate the incremental effects of DM^2 on patient quality measures in specific subgroups, including race/ethnicity and insurance status (Medicare, commercial, Medicaid, uninsured)
Primary Aim 2. To estimate the incremental effects of DM^2 on health services utilization overall and in categories divided according to desirability
Secondary Aim 2a. To estimate the incremental effects of DM^2 on health services utilization in specific subgroups, including race/ethnicity and insurance status, as above
Secondary Aim 3. To examine adoption of our CDS interventions, including physician adoption of and satisfaction with DM^2 and patient adoption of PA, PA-E, and PA-E plus DM^2 (Both)
Secondary Aim 4. To describe general and intervention-specific unintended consequences of our interventions, including consequences related to patient safety and care for comorbid illnesses

SCOPE

BACKGROUND AND SIGNIFICANCE

Epidemiology of Diabetes: Burden of Suffering and Cost

Diabetes is a chronic and costly disease associated with multiple comorbid illnesses (1). Affecting more than 18 million Americans (1), it is an independent risk factor for cardiac disease and stroke, two of the three major causes of death in the United States, and it is the most common cause of end-stage kidney disease and blindness among adults (2). In addition to $132

billion in direct medical costs each year, diabetes is estimated to cost society another $40 billion in indirect costs due to lost productivity (1).

Type 1 diabetes is a disease largely of children and young adults, but type 2 diabetes is a disease mostly of adults that has been linked to obesity and insulin resistance (3). Type 2 diabetes accounts for 90-95% of prevalent cases. The prevalence of diagnosed diabetes has increased 61% since 1991, to 6.9%, and it is projected to more than double by 2050 (4-6). Hispanics and non-Hispanic Black people have both a greater prevalence of diabetes (7,8) and an anticipated greater increase in diabetes incidence during this time (4). Using data from the National Health Interview Survey, Narayan and colleagues (9) estimated the lifetime risk of developing diabetes for individuals born in the year 2000 as an astonishing 32.8% for men and 38.5% for women, with the greatest lifetime risk among Hispanics (men, 45.4% and women, 52.5%).

Clinical Epidemiology of Diabetes: Care and Outcomes

The complex relationships of diabetes care to outcomes can be summarized by describing the influence of glycemic control on outcomes and by evidence about the preventability of diabetes' major complications. Glycemic control, as reflected by hemoglobin A1c (A1c) values, is felt to be fundamental to prognosis and management. The average A1c value among nondiabetic adults is 5.2%; among Americans with type 2 diabetes, it is 7.8% (10). Analyses of the UK Prospective Diabetes Study (UKPDS), a randomized controlled trial of intensive versus standard treatment of type 2 diabetes (11,12), estimated a 14% reduction in all-cause mortality and myocardial infarction for every 1% absolute reduction in A1c (13); this relationship appears to be linear, with no threshold or lower limit of A1c at which additional lowering has no benefit (2,13). Cardiovascular disease (CVD) is the cause of death in about 65% of people with diabetes (2) and is accelerated by the frequently coexisting conditions of hypertension and dyslipidemias (14). In addition to direct evidence from the UKPDS trial favoring aggressive glycemic control, expert consensus has targeted specific blood pressure levels and low-density lipoprotein (LDL) cholesterol values that should be achieved in people with diabetes to favorably affect CVD risk (2). End-stage renal disease (ESRD) affects about 43,000 people with diabetes annually and is presaged by the occurrence of microalbuminuria (2). Importantly, progression to ESRD can be retarded by treatment with specific classes of medicines (ACE inhibitors and ARBs) (15-18) and by aggressive glycemic and blood pressure control (2,11,12). Diabetic eye disease affects about 13,000 diabetics in the US each year and is presaged by vascular changes that can be identified on retinal examination. After neovascular changes have been identified, the incidence of blindness can be substantially reduced by treatment with panretinal photocoagulation surgery (19-23), resulting in recommendations for annual dilated eye examinations in diabetics (2). The CDC estimates that attention to these measures could reduce the incidence of diabetes-related CVD mortality by about 30%, ESRD by about 50%, and blindness by 90% (1).

Health Services Research in Diabetes: Quality and Safety in Diabetes Care

The data above imply a major gap between what is possible to achieve and our current performance in diabetes care. These data also highlight the multitude of care processes that are required to achieve optimal diabetes outcomes, including screening, monitoring, specialist referrals, and medical and non-medical treatment of diabetes, its complications, and its co-existing conditions. A variety of interventions to improve diabetes care and outcomes have been investigated, including patient empowerment and self-management (24,25), disease and case management (26-29), and approaches that use health information technology (HIT) to provide decision support for providers or their patients with diabetes (30-35). Self-management programs are motivated by evidence of significant deficits in knowledge and skill in an many as 80% of people with diabetes (24,36). The effectiveness of patient training in self-management has been summarized in a systematic review of studies that have collectively demonstrated

positive effects on knowledge and self-reported behaviors (e.g., blood glucose monitoring) and short-term improvements in glycemic control but variable effects on other measures (24,25). The literature highlights the importance of patient education and engaging the patient with diabetes in his or her own care. This research is amplified by the work of Peterson and colleagues (37), which demonstrated a strong linear relationship between a patient's "readiness to change" and changes in A1c values after a diabetes educational program. Disease management and case management approaches for diabetes care have been used singly and in combination (24). Diabetes disease management programs focus healthcare on systems (e.g., guidelines, information systems) to monitor care and outcomes for all patients/enrollees with diabetes, whereas case management programs typically develop individual care plans that are "managed" by an individual who typically is not a provider of direct medical care. In a systematic review by Norris et al. (28), both approaches have been shown to have significant, albeit modest and mostly short-term, effects on glycemic control (28). Collectively, disease/case management interventions have demonstrated their ability to effect moderate improvements in process of care measures (24,28). They have been less effective in demonstrating significant changes in A1c levels – with experimental versus control group differences typically being on the order of 0.3-1.0% – and have rarely reported favorable effects on other important intermediate outcome variables, such as weight control, lipid levels, and blood pressure. Notable for their absence in these studies are investigations of the appropriate use of statins for management of dyslipidemias and the use of ACE inhibitors or ARBs for treatment of proteinuria.

Use of Health Information Technology to Improve Care

Though many argue that HIT has the potential to improve patients' health and quality of life (38), there has been considerable disagreement about which technologies to use, how much is enough or too much, and whether the technologies are providing value for the money spent (39,40). Decision support systems have shown a great deal of promise in reducing errors (41-44). Computer-based decision support interventions have also been shown to improve physicians' compliance with outpatient preventive care (45,46), inpatient preventive care (47) and inpatient drug-monitoring guidelines (43,48). However, few studies of computer-based decision support have assessed patient outcomes, and only a small proportion of them have found benefits. Hunt and colleagues (49) conducted a systematic review of 68 studies of the effects of clinical decision support systems on physician performance and patient outcomes. Only 14 studies assessed patient outcomes, and only six documented benefit (49). In a more recent review, Kaplan (50) found that studies examining the effects of decision support systems on patient outcomes showed little improvement and raised concern about clinician adoption.

To date, research on clinical decision support systems has not convincingly demonstrated its effectiveness in the management of chronic diseases (50,51). For example, Meigs and colleagues (30) tested the effectiveness of a web-based decision support tool to improve evidence-based management of type 2 diabetes. Although they found modest but significant increases in rates of testing for levels of A1c and LDL cholesterol, there were no significant improvements in glycemic and lipid control. Tierney and colleagues (52) tested the effect of an intensive, computer-based intervention to reduce errors of omission among patients with heart disease. Although opportunities to improve care were frequent, the intervention had no positive effect on either adherence to the guidelines or any patient outcomes, principally because physicians lacked enthusiasm and thought the guidelines were oversimplified "cookbook" medicine. A similar study of patients who had asthma or angina found that the median number of times physicians accessed the decision support system was zero, despite substantial work to make it user friendly (32).

It would seem that systems that merely provide additional information to the physician fail to improve effectiveness of care for chronic medical conditions. Older systems may be more

effective for triggering "one-time" events than for ongoing management of a chronic medical condition, underscoring the need for HIT solutions that incorporate the key principles of delivering effective chronic illness care, particularly improved care coordination and patient self-management support that activates patients to participate in their own care (51). For example, Zrebiec and Jacobson (53) describe a web-based system used by diabetics or their family members to exchange ideas and experiences in a mediated forum. Topics that the website covered included motivation, emotion, blood glucose levels, and complications. The website logged over 45,000 visits over a 21-month period, although no information about outcomes was provided. In summary, there are several examples of promising web-based support systems for chronic disease management. Although the promise of the systems are immense, results to date have been mixed, and clear evidence of improved patient outcomes is largely lacking.

Unintended Consequences

The implementation of any technology including HIT is not without the risk of unintended consequences. Becher and Chassin (54) identify two ways that physicians make errors: through lack of knowledge or skill (error of omission) and through slips and attention lapses (error of commission). The authors acknowledge the benefit of information and technology but recognize that increasing complexity increases the probability of the two types of error. In the management context, Schultze and Vandenbosch (55) found that the overabundance of information provided by an information system results in an increasingly complex work environment. This in turn leads to a greater reliance on information and increased information intensity, increasing the likelihood of errors due to information overload. The authors suggest the need for additional processing of information in order to provide the right information to the right person at the right moment.

Information overload can lead professionals to trust the course suggested by the computer more than is actually called for (56). Studies have also shown that HIT can impose additional work tasks on healthcare professionals (57). In an extensive review of qualitative studies, Ash et al. (58) reported many instances in which HIT applications seem to foster errors rather than reduce their likelihood. They have stressed the need of multidisciplinary research to ensure better understanding of work flow, systems design, and IT implementation in healthcare.

Cost and Financial Benefits of Health Information Technology

ALthough published evidence on the value of health information technology is scarce, for the most part, it points toward positive financial benefits. In a cost-benefit analysis of electronic medical records in primary care, Wang et al. (59) estimated a net benefit of $86,400 per provider over a 5-year period. Benefits occurred primarily from savings in drug expenditures, appropriate utilization of radiology tests, better capture of charges, and decreased billing errors. In early work, Tierney and colleagues (60) found that automated order entry resulted in a 12.7 percent decrease in total charges and a 0.9-day decrease in length of stay. LDS Hospital demonstrated that a program that assisted with antibiotic management resulted in a fivefold decrease in the frequency of excess drug dosages, with substantially lower total costs and lengths of stay (41). In light of the growing body of evidence suggesting that physician order entry and decision support systems may decrease error rates, thereby improving outcomes and decreasing hospital length of stay, they probably reduce costs indirectly. Unfortunately, there is also little evidence about the long-term cost effectiveness of patient-centered decision support systems and patient monitoring.

METHODS

Setting: Study sites included 24 primary care (Internal Medicine or Family Practice) practices at the MetroHealth System (MHS-10) and Cleveland Clinic (CCF-14) in Northeast Ohio.

Participants: Approximately 20,000 patients with diabetes (older than age 18) from the practices' approximately 200 PCPs were included in the study. Diabetes was defined by its listing on the patient's problem list and at least one encounter identifying diabetes as the reason for the patient's visit. Participants were excluded if they are unable to speak English, were blind, were pregnant, or (at CCF) stated they were physically incapable of using a computer. No prisoners or institutionalized patients were included. The study was approved by the Institutional Review Boards at both the MetroHealth System (MHS) and Cleveland Clinic (CCF).

Study Design: Two-year, parallel, cluster-randomized trials (CRT) at the two healthcare systems, with sites randomly assigned EMR-based disease management (DM^2) in one cluster of five practices at MHS and, at CCF, a web portal-based patient access (PA) to one cluster of four practices, PA enhanced by diabetes-specific functions for patient entry and feedback to a cluster of six practices (PA-E), and PA-E supplemented by DM^2 (Both) to one cluster of four practices. Assignment of sites to study groups and random assignment of study groups to interventions have been described in detail (61).

Data sources and Collection: There were two broad categories of data collected in this investigation: 1) administrative and clinical data, including EMR-related data from the healthcare systems; and 2) survey data from patients and their PCPs. Roster-related data (for each PCP's patient registry) were updated continuously (e.g., a new adult with diabetes seen for patient care by a practice site PCP was linked automatically to that PCP's roster). Practice profile data for the DM^2 intervention was updated monthly at CCF; data pertaining to ED visits and in-hospital care at a CCF-owned hospital were retrospectively obtained by CCF. These data were transferred to the Data Management and Analysis Group at MHS.

Survey data from PCPs and patients were obtained at the time of enrollment in the CRT; a second round of survey data from both patients and PCPs was collected during CRT months 23-24. Paper surveys were distributed for a potentially eligible participant at the time of his/her first visit with the PCP during the trial period. Patients in the PA-E and Both study groups were offered the opportunity to consent to the PA-E intervention, to complete the survey, or both. Patients declining to participate in the PA-E intervention still provide survey data, enabling a comparison of attributes between adopters and non-adopters of this intervention.

Intervention:
Electronic Medical Record-Disease Management for Diabetes Mellitus (DM^2)
The EMR-DM^2 intervention consisted of EMR components and Disease Management components. The EMR components consisted of EMR functionalities represented by the acronym ALLPEP, for Alerts, Links, Letters, tailored Patient Education, and Profiles. Furthermore, the EMR components consist of Encounter-Centered functionalities, available at the time of a patient visit to his/her PCP, and Practice-Centered functionalities, available to the PCP at any time in his/her examination room, office, or home. The disease management component of the EMR-DM^2 intervention was a combination of disease management and case management, linking a nurse coordinator to both patients and their PCPs. These have been described elsewhere (62).

Encounter-centered alerts actively informed the PCP of overdue recommended interventions or test results that were beyond ADA thresholds. Alerts appeared automatically within the patient's Epic encounter workspace and were linked to order sets to facilitate specific referrals (Ophthalmology, Nephrology, Podiatry, Diabetes Self-Management Program), tests (A1c; lipid profile, including LDL; urine microalbumin; blood chemistries that include kidney function tests); and immunizations (pneumococcal and influenza) or treatment changes (ACE inhibitors or

ARBs for microalbuminuria; statins for elevated LDL levels, changes in anti-hypertension medications). Each of these messages facilitated, but did not mandate, actions: the language used was of the "*consideration should be given to* "X" action" variety, but links to specific order sets were provided that enabled the suggested orders to be executed easily. These links were also associated with opportunities for the PCP to print tailored patient education materials.

Practice-centered functionalities consisted of two distinct parts: (1) using the Epic Roster function, the PCP could view and act upon a list of all of his/her patients with diabetes and the status of their diabetic measures, as well as their medical record and telephone numbers; (2) using a hyperlink to an external database, the PCP could view a profile of his/her performance, as reflected in bar charts and pie charts of his/her diabetic panel's measures, compared against ADA standards and compared with practice-wide and healthcare system-wide peers. Diabetes measures in Epic rosters included the most recent A1c level and the interval (in months) since last obtained; most recent LDL level and the interval since last obtained; most recent urine microalbumin level, and, if abnormal, whether the patient is on an ACE inhibitor or ARB; interval since last dilated eye examination; and date of most recent pneumococcal vaccination and most recent influenza vaccination. For each patient on the list, all measures were color coded, with red indicating an abnormal measure (result or interval) and green indicating a normal measure. By highlighting a particular column (e.g., A1c levels), the PCP was able to sort all of his/her patients by that measure, identifying all of his/her patients needing a pneumococcal vaccination. Importantly, the PCP could act on upon these findings in one of two ways: (1) contacting the patient directly or (2) linking to the disease management nurse coordinator.

Electronic Medical Record-Patient Access (PA)
The PA intervention engaged the patient in his/her own care and decision making through web-portal access to his/her own health-and diabetes-related data and the healthcare system. *MyChart* was accessed securely by the patient from any web browser.

General health-related services enable the patient to:

1. Renew Prescriptions. Patients could choose to renew their diabetes medicines by selecting them from their active medication list, including the duration of the prescription up to 90 days.
2. Schedule Appointments. Patients could choose from a list of physicians and clinical departments in which they have been seen in the past 2 years and request an appointment, including preference for day of week and time of day.
3. Message the Institution. The patient could send a message to the system that he/she has changed telephone numbers or is experiencing technical difficulties with MyChart.
4. View Personal Health Information. Patients may view diagnoses, results, messages, and letters that their PCP's have released to them. The patient with diabetes could choose to review the Health Maintenance Module and request an appointment to obtain a recommended pneumococcal vaccination.

Diabetes-specific services, in the PA-E study group, enable the patient to:

1. Enter and view glucometer results. A diabetic patient could log onto the system to enter his/her glucometer reading and view a graph of recent results.
2. Learn about his/her diabetes. In reviewing his/her diagnoses, the patient could select a hyperlink that discusses the disease; or, in reviewing test results, he/she may select a hyperlink to learn about A1c tests.
3. Identify emergent situations. If the patient attempted to enter a glucometer reading that was less than 20 or greater than 699, he/she received a message requesting re-entry. Values entered that were less than 65 or greater than 299 resulted in a message informing the patient to immediately contact his/her physician, go to an emergency room, or call 911. All such readings and alerts transmitted to the patient were simultaneously transmitted to the patient's

PCP through the EMR. In addition, the alert and values were transmitted to clinical nurse pools for immediate response.

Electronic Medical Record Control Group (EMR only)

The ambulatory EMR at both sites implements similar Epic applications of passive (e.g., Health Maintenance module) and active (e.g. Alerts) functions. At both MHS and CCF, flags linked to patients with diabetes highlight a HM schedule that recommended a yearly full lipid profile, ophthalmology examination, and urine microalbumin; twice-yearly A1c determinations; and a one-time pneumococcal vaccination.

Measures:

Dependent Variables: Our primary dependent variables addressed issues of patient quality/safety of care (Aim 1 and secondary Aim 1a) and healthcare utilization (Aim 2 and secondary Aim 2a), the latter categorized as "desirable" and "undesirable." Our secondary dependent variables are subject to adoption of our EMR-centered interventions (Aim 3) and selected unintended consequences of our interventions (Aim 4).

For Aim 1, the dependent variables examined for quality/safety of care were A) A1c levels; B) a composite score of eight standards of the American Diabetes Association (**ADA-8**), including 1) hemoglobin A1c<7%; 2) LDL cholesterol value<100 mg/dL; 3) blood pressure<130/80 mmHg; 4) body mass index (BMI)<30 kg/m2, 5) documented status as a non-smoker; 6) urine testing for microalbuminuria within the past year or on treatment with an ACE inhibitor or ARB medication; 7) receipt of an eye examination by an ophthalmologist within the past year; and 8) documented receipt of a pneumococcal vaccination. The ADA-8 was subdivided *a priori* into subscores consisting of gfive patient-centered standards of intermediate outcomes (**ADA-5**) or standards #1-5, above, and three provider-centered process-oriented standards (**ADA-3**), or standards #6-8 above. For Aim 2, our dependent variables for utilization were categorized as “desirable” utilization and “undesirable” utilization. Desirable utilization is defined as patient visits to his/her PCP and visits to designated appropriate specialty physicians or services, including Ophthalmology; Nephrology, for patients with serum creatinine values of 2.0 or higher; and Endocrinology or Diabetes, for patients with A1c values of 9.0% or higher. Undesirable utilization is defined as Emergency Department visits or hospitalizations for any cause.
For secondary Aim 3, there were several measures of subject adoption of our CDS. We focus here on PCP actions taken in relation to alerts generated in the DM^2 intervention and several specific uses of the web portal by patients in the PA, PA-E, and Both intervention groups.
For secondary Aim 4, we measured selected general and intervention-specific unintended consequences. We focus here on the occurrence of outpatient-documented episodes of hypoglycemia; the performance of Pap smears and mammograms in relevant patient groups; and ED visits for asthma and CHF for relevant patient groups.

Survey Measures: The patient survey domains measured in the pre-CRT phase were attitude toward technology, subjective norms, perceived behavioral control, behavioral intention, and readiness to change. Patient surveys included 69 items on the five dimensions.

Analyses for Aim 1 (cross-group changes in quality). We describe comparisons of patients in intervention and control sites for four key outcomes: hemoglobin A1c level (%) and three composite measures described above, the ADA-8 and its patient and physician-centered subscores, the ADA-5 and ADA-3, respectively. We begin with descriptive graphical and numerical summaries of unadjusted results and then present models to predict values of each of the four main outcomes at the end of the patient’s enrollment in the study. Predictors for each model include an indicator for intervention group and covariate information. All models account for clustering of practice sites using robust standard errors. For each outcome, Model 1 incorporates as predictors the baseline value of the outcome of interest, number of weeks of the study, age, gender, and ethnicity. Model 2 for each outcome adds insurance payor (commercial, Medicare, Medicaid or uninsured), comorbidities (operationalized as 0, 1, 2, and 3 or more of

nine conditions), and baseline smoking status. Model 3 adds census block estimates of neighborhood median income, educational attainment, and % of households with female heads and children. For A1c, we also present Model 3 results for two subsets of interest – patients with baseline A1c values below 7 and above 9.

Analyses for Aim 1a (insurance effects on baseline glycemic control). We examined the effect of insurance type on hemoglobin A1c values using sequential logit models that sequentially added 1) age, sex, and ethnicity; 2) clinical and adherence-related variables (smoking status, "no-show" rates); 3) income and other census-derived socioeconomic variables; and 4) site of care. Commercially insured patients were used as the referent.

Analyses for Aim 2 (cross-group changes in utilization). Difference-in-differences analysis, employing negative binomial regressions models, was used. A difference-in-difference strategy was adopted to adjust for pre-existing differences (i.e., prior to intervention) in the utilization by patients in different sites. Site-level differences in utilization of ED visits and hospitalizations prior to initiation of the intervention were found to substantial, likely reflecting a larger amount of unmeasured utilization at sites more distant to the main hospital. The negative binomial model is employed to most appropriately accommodate the distribution of outcomes, which are in the form of counts with substantial dispersion in the right tail. We utilize a general form of the negative binomial model, which allows the level of dispersion to be a function of the included covariates. Standard errors in all models are corrected for residual clustering at the site level.

RESULTS

Principal Findings:

Aim 1. Intervention Effects on Quality Measures and Standards

Changes in A1c. We begin in Table 1 by considering hemoglobin A1c for the 5881 patients with distinct A1c values at baseline and their last visit during the study.

Table 1. A1c starting and ending values for DM^2 and control patients

	# Patients	Starting A1c Mean (SD)	Ending A1c Mean (SD)	Difference (95% CI)
DM^2	3568	7.57 (2.08)	7.41 (1.86)	0.16 (0.09, 0.22)
Control	2313	7.52 (2.08)	7.38 (1.87)	0.14 (0.07, 0.23)

In this unadjusted comparison, there was almost no incremental effect on A1c in the intervention group beyond the secular trend observed in the control sites. Although mean A1c improved over the trial for both intervention and control patients, the incremental intervention effect was not significant (effect size = 0.02 percentage points of A1c; 95% CI: [-0.10, 0.11]; p = .89.) Subgroup analyses by baseline A1c values (good, average, poor), and results of multivariate models above, were no different.

Changes in ADA-8 and its Subscores. We turn now to our three ADA composite summary measures, for which we describe results for a sample of 6510 patients. For each patient, we calculate all three ADA composites at baseline and study exit. Figure 1 displays the percentage of patients in each trial arm who either improved from baseline to study exit or maintained a perfect composite score at both baseline and study exit.

The results clearly indicate that our intervention had a significant beneficial effect on the physician-centered, process-oriented standards in the ADA-8 (attention to nephropathy, eye examinations, and pneumococcal vaccinations) but not on the patient-centered ones.

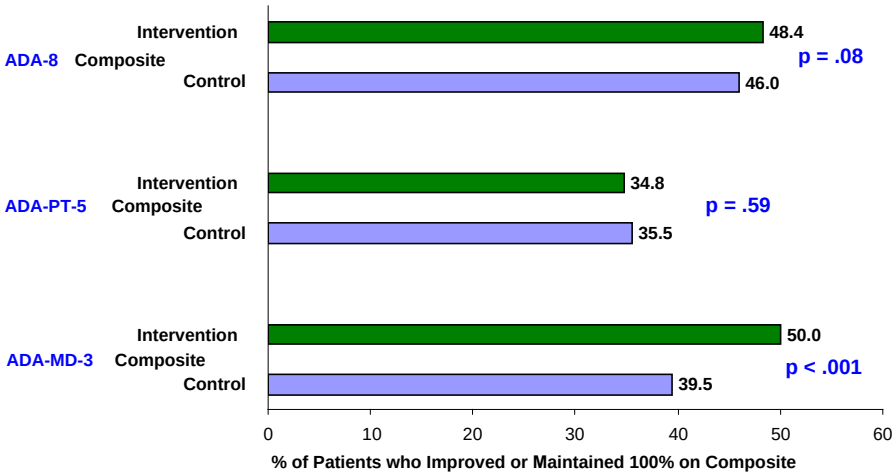

Figure 1. Percentage of Patients Improving or Maintaining Perfect Scores on ADA Composites, by Trial Arm

To examine whether differences in the baseline distribution of composite scores across the two arms of the trial could affect the results, we examined the ADA composite scores at study exit across the two trial arms within strata of starting value of the composite, and our results displayed similar findings across strata. We then examined changes in the ADA-3 using sequentially additive regression models (Table 2), with similar results.

Table 2. Results of Three Models for Ending **ADA-3** Composite Score

Model	Description [n = 6510]	Intervention Effect (95% CI)	p
1	Intervention group, baseline A1c, age, sex, race, weeks in trial	5.66 (2.85, 8.46)	.002
2	Add insurance, comorbidities, and smoking status to Model 1	5.82 (3.15, 8.48)	.001
3	Add census-based neighborhood SES estimates to Model 2	5.59 (2.77, 8.42)	.002

Aim 1a. Effect of Insurance on Baseline Glycemic Control. Among the 6987 patients with complete baseline data, 34% were insured by Medicare; 26%, by commercial insurers; and 27%, by Medicaid. Another 20% were uninsured. Using conventional criteria for "poor glycemic control" from performance incentive systems (A1c>9%), poor values were observed in 11.6% of Medicare, 19.5% of commercial, 24.7% of Medicaid, and 28.6% of uninsured patients. Insurance effects were robust to the addition of potential confounders: in the final model (see Analysis section above), patients on Medicare were 19% less likely (P<0.05), and uninsured patients were 44% more likely (p<0.01), to have poor glycemic values than commercially insured patients were.

Aim 2. Intervention Effects on Utilization. The table below reports the count of patients and mean measures of utilization by site and cohort. We highlight three principal findings from this table: 1) For PCP visits, there was no difference in means across intervention and control sites in the pre-analytic cohort. 2) For ED visits and hospitalizations, there are large pre-existing differences in utilization by patients in different sites. Patients in intervention sites had, on average, 0.56 more ED visits and 0.43 more hospitalizations. 3) The difference in mean ED visits and hospitalizations across intervention and control sites is substantially smaller in the analytic cohort, suggesting that exposure to the intervention (DM^2) reduced these forms of utilization.

Table 3: Mean Utilization by Site and Cohort

	N (patients)		# PCP Visits		# ED Visits		# Hospitalizations	
	PAC	AC	PAC	AC	PAC	AC	PAC	AC
Intervention Sites	3422	4514	7.70	8.41	1.48	1.39	0.90	0.61
site 1	499	853	7.51	8.37	0.83	1.22	0.46	0.45
site 2	845	1389	8.34	9.56	1.97	1.54	1.07	0.70
site 3	1577	1756	7.04	7.79	1.64	1.51	1.09	0.72
site 4	501	516	8.87	7.53	0.71	0.84	0.49	0.31
Control Sites	1918	1995	7.70	8.75	0.92	1.00	0.48	0.39
site 1	365	466	7.18	7.51	1.09	1.37	0.58	0.53
site 2	103	148	6.71	8.76	0.72	0.80	0.51	0.14
site 3	581	489	8.22	10.39	1.33	1.37	0.55	0.47
site 4	372	431	7.95	8.78	0.39	0.31	0.37	0.22
site 5	497	461	7.50	8.23	0.75	0.92	0.38	0.43
Mean Difference (Int-Control sites)			0.00 (0.14)	-0.34* (0.15)	0.56** (0.08)	0.39** (0.07)	0.43** (0.05)	0.22** (0.04)

Table notes: "PAC" refers to pre-analytic cohort; "AC" refers to analytic cohort. "Mean Difference" reports Intervention Sites mean minus Control Site mean (standard error in parentheses).

Estimates from the negative binomial models appear to confirm these suggestive findings. Treatment is associated with a 5% reduction in PCP visits (IRR=.95; 95% CI=[.89,1.01]; p=.08), a 10% reduction in ED visits (IRR=.90; 95% CI=[.78,1.04]; p=.13), and a 20% reduction in hospitalizations (IRR=.80; 95% CI=[.67,.95]; p=.01), although only the hospitalization estimate is statistically significant. If confirmed by additional analyses, these results support the hypothesis that exposure to the EMR-DM^2 intervention substantial reduced patients' rate of hospitalizations, a primary driver in the medical costs associated with diabetes. **Secondary Aim 3 (Adoption and satisfaction with CDS).** In the DM^2 arms of the trials, eight alerts were accompanied by linked order sets as actions that might be appropriate for the PCPs to take. The Adoption Rate was calculated as the proportion of alerts that were accompanied by these actions across 62 experimental group PCPs in the MetroHealth trial. Figure 2 summarizes our findings. The adoption rate was 28% overall; that is, more than one in four opportunities for action were taken, with the highest rate for recommendations that an A1c test be ordered (48.6%) and lowest for consideration to refer to Nurse Case Management (NCM, 9.1%). PCP satisfaction with the CDS was determined by survey questions pertaining to whether various computer-centered components of DM^2 should be kept (yes-no) after trial completion. Figure 3 summaries our results, highlighting a high degree of satisfaction with our alerts and related order sets (97% "keep" after trial) and lesser but still impressive keep rates for our more complex registry and performance reports (77%) and Nurse Case Management prompts (81%).

For the web portal access arms of the trial at CCF, we measured this web-based patient portal activity for all 851 consented patients within our three study arms at our site. Activities that were "measured" included the number of sessions that the patient logged into the portal; the number of sessions that the patient reviewed their health maintenance activities; the number of sessions that the patient reviewed laboratory tests; the number of messages exchanged between the healthcare system and patient; and the number of self-monitoring blood glucose (SMBG) submissions made to the patient's provider. This activity was limited only to those in the **PA-E** or **Both** groups.

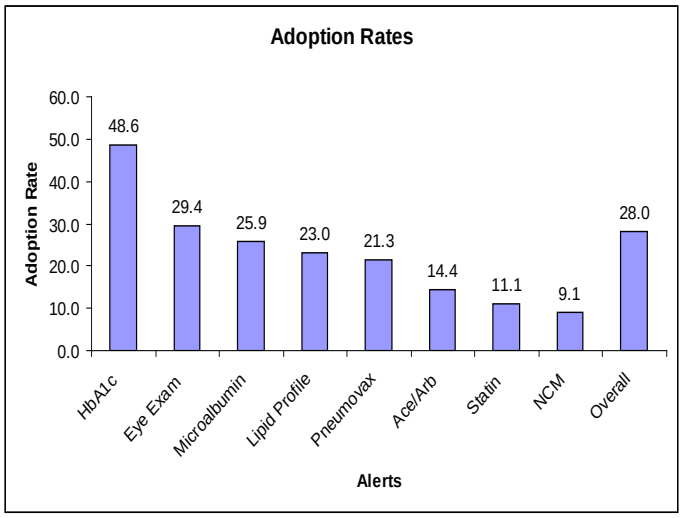

Figure 2. Adoption of Alerts by PCPs

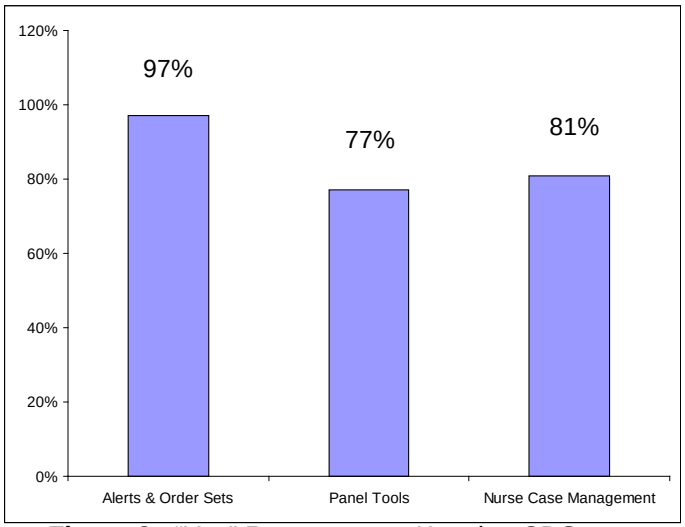

Figure 3. "Yes" Responses to Keeping CDS Components After Trial Completion.

Use of the web-based portal activities varied across groups among the 851 patients participating in the study (Figure 4). In the **PA** group, 163 of 313 (52.1%) used the web-based patient portal compared with 166/270, or 61.5%, in the **PA-E** group and 188/268, or 70.1%, in the **Both** group. The values are normalized to the amount of activity per patient to compensate for differences in the number of patients in each arm of the study. There is an increase in the number of login sessions that patients have in the enhanced portal groups (**PA-E** and **Both**) compared with the **PA** group. Moreover, there are also more messages exchanged within these **PA-E** groups. However, there are also differences between the **PA-E** and **Both** groups. Despite similar activity around messaging, reviewing laboratory results, and health maintenance and despite fewer logins in the **Both** group, there was an increase in the amount of SMBG activity. These results suggest that disease-based enhancements to web-based patient portals lead to more use of these systems. Moreover, there may a patient activation effect of having "diabetes" specific enhancements within the EHR targeted to providers. For example, patients may be more inclined to utilize the web-based portal for blood sugar submissions from home if, when they present to their physician, the diabetes-specific enhancements in the EHR direct the provider to focus on the diabetic care of the patient.

Secondary Aim 4 (unintended consequences). Analyses used a difference-in-difference approach, as with our utilization analyses more generally, because of substantial baseline differences across sites in baseline utilization. We examined whether there were more episodes of documented hypoglycemia among experimental-group patients (2.8% in both groups with one or more episodes, p=0.96) as well as fewer mammograms ordered among women age 50-75 (51.9% vs. 56.4% in the control groups, p=0.01), Pap smears (45.9% vs. 44.9%, p=0.55), and ED visits for asthma (p=0.17).

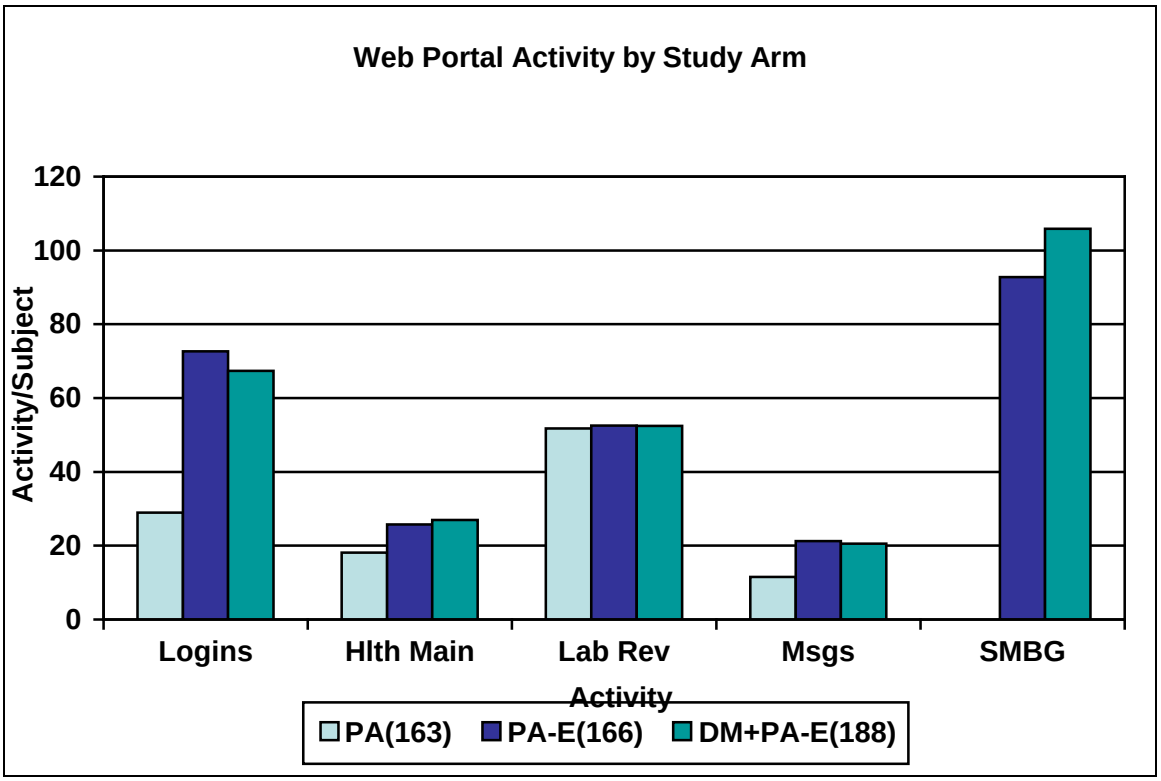

Figure 4. Web-based patient portal activity/patient subject by study arm among patients with at least one login

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